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Rules and Regulations

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 61

[Docket No.: FAA–2018–1050; Amdt. No. 61–149]

RIN 2120–AL23

Removal of Training Requirements for an Airline Transport Pilot Certificate Issued Concurrently With a Single-Engine Airplane Type Rating

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

ACTION: Final rule.

SUMMARY: This final rule removes a multiengine training requirement for pilots seeking to obtain an initial airline transport pilot (ATP) certificate concurrently with a single-engine airplane type rating. The final rule also removes a 2014 compliance date because it is no longer necessary.

DATES: This final rule is effective on December 9, 2021.

ADDRESSES: For information on where to obtain copies of rulemaking documents and other information related to this final rule, see ''How to Obtain Additional Information'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Barbara Adams, Air Transportation Division, Training and Simulation Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone (202) 267–8166; email: *Barbara.Adams@faa.gov.*

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The Federal Aviation Administration (FAA) is responsible for the safety of flight in the U.S. and for the safety of U.S. civil operators, U.S. registered civil aircraft, and U.S. certificated airmen. Sections 106(f) and (g) of title 49, U.S. Code, subtitle I establish the FAA Administrator's authority to issue rules on aviation safety. Subtitle VII of title 49, Aviation Programs, describes in more detail the scope of the agency's authority.

The FAA is promulgating this rulemaking under the authority described in 49 U.S.C. 106(f), which establishes the authority of the Administrator to promulgate regulations and rules; 49 U.S.C. 44701(a)(5), which requires the Administrator to promulgate regulations and minimum standards for other practices, methods, and procedures necessary for safety in air commerce and national security; and 49 U.S.C. 44703(a), which requires the Administrator to prescribe regulations for the issuance of airman certificates when the Administrator finds, after investigation, that an individual is qualified for, and physically able to perform the duties related to, the position authorized by the certificate. This rulemaking is within the scope of the FAA's authority because it amends the eligibility requirements for the issuance of a single-engine airplane ATP certificate.

List of Abbreviations and Acronyms Frequently Used in This Document

ATP Airline Transport Pilot
ATP CTP Airline Transport Pilot Certification Training Program
FSTD Flight Simulation Training Device
NPRM Notice of proposed rulemaking
PIC Pilot in Command
SOE Supervised operating experience

Table of Contents

I. Overview of Final Rule

This rule removes an unnecessary multiengine training requirement for pilots seeking to obtain an initial ATP certificate concurrently with a single-engine airplane type rating. It also revises several provisions of the pilot certification regulations by removing from the text the July 31, 2014, date, which served as the compliance date for the multiengine ATP training requirements, because the date is no longer necessary.

II. Background

A. Statement of the Problem

Current regulations require a pilot seeking an ATP certificate concurrently with an airplane type rating to complete training in an FAA approved course from an authorized training provider. This training is commonly referred to as the ATP Certification Training Program (ATP CTP) and includes both ground training and flight simulation training device (FSTD) training in a device that represents a multiengine airplane.[1] The FAA intended this training requirement to apply to pilots seeking an ATP certificate in a multiengine airplane. However, because the regulations do not specify ''multiengine'' type rating, the requirement applies to single-engine airplanes for which a type rating is required.

When the training requirement became effective in 2014, there were no single-engine airplanes that required the pilot to obtain a type rating prior to serving as pilot in command (PIC). With the certification of the Cirrus Vision Jet in 2016, there is now a single-engine airplane that requires the pilot to obtain a type rating prior to serving as PIC. Under the current regulations, if a pilot seeks a type rating in the Cirrus Vision Jet concurrently with the initial issuance of the ATP certificate in the airplane category with a single-engine class rating, that pilot would be required to complete the ATP CTP to be eligible for the practical test. This final rule removes the ATP CTP requirement for pilots seeking an ATP certificate concurrently with a single-engine type rating.

[1] 14 CFR 61.156.

B. History

The Airline Safety and Federal Aviation Administration Extension Act of 2010 (Pub. L. 111–216) (the Act) was signed into law in August 2010 and included provisions to improve airline safety and pilot certification and training. In response to the Act, the FAA modified the eligibility requirements for an ATP certificate with an airplane category multiengine class rating in the *Pilot Certification and Qualification Requirements for Air Carrier Operations* Final Rule (2013 Final Rule).[2] Section 216 of the Act specifically required all pilots of 14 Code of Federal Regulations (CFR) part 121 operations to have an ATP certificate and an appropriate amount of multiengine time. Section 217 of the Act established minimum qualifications for an ATP certificate that were focused on air carrier pilots and multiengine airplane experience. The statute did not address single-engine airplanes. Additionally, part 121 prohibits the use of single-engine airplanes.[3]

To address the ATP requirements set forth in the Act, the FAA established a requirement for a pilot to complete an FAA approved ATP CTP. The ATP CTP includes ground training and flight training in a multiengine FSTD. Pilots must complete the ATP CTP and present the graduation certificate to be eligible for the ATP multiengine knowledge test.[4] Applicants for an ATP certificate with an airplane category multiengine class rating or ATP certificate obtained concurrently with an airplane type rating must then present the graduation certificate for the ATP CTP and the passing knowledge test results when applying for the practical test.[5]

Upon review of the regulatory requirements for an ATP certificate, the FAA found that some of the requirements do not distinguish between a pilot seeking a single-engine airplane rating and a multiengine airplane rating. For example, as noted, pilots seeking an ''airline transport pilot certificate obtained concurrently with an airplane type rating'' are required to complete the ATP CTP specified in § 61.156 and receive a graduation certificate from an authorized training provider. With that express language, pilots seeking an ATP certificate concurrently with a single-engine airplane type rating must complete multiengine airplane training to obtain an ATP certificate in a single-engine airplane.

At the time the 2013 Final Rule published, there were no single-engine airplanes that required a type rating to serve as PIC. However, since the 2013 Final Rule published, Cirrus Aircraft received type certification for its single-engine Vision Jet (SF50),[6] and a pilot is required to hold a type rating for that airplane to serve as PIC. Because the 2013 Final Rule did not specify that the ATP CTP was required only when a pilot was seeking an ATP certificate concurrently with a multiengine type rating, a pilot cannot complete a practical test for an initial ATP certificate with the SF50 type rating unless the pilot completes the ATP CTP. Alternatively, to avoid the training requirement, a pilot could use a different single-engine airplane (*i.e.,* one that does not require a type rating) to obtain the initial ATP certificate and then complete a second practical test in the SF50 to add the type rating to the ATP certificate.[7] Or, a pilot could add the type rating to his or her commercial pilot certificate first and then complete an ATP practical test in a different single-engine airplane and the SF50 type rating would be carried forward to the ATP certificate. In either case, the pilot would be taking an additional practical test to avoid completing the multiengine training in the ATP CTP.

Several sections in part 61 apply to a pilot seeking an ATP certificate with a multiengine airplane rating or an ATP certificate concurrently with an ''airplane type rating.'' Prior to certification of the SF50, there was no need for regulatory requirements to delineate the class rating because all type-rated airplanes were multiengine. In the current environment, without the delineation of a class rating, the type rating training requirements that were intended to apply to pilots seeking an ATP certificate concurrently with a multiengine airplane type rating are being applied to pilots seeking an ATP certificate concurrently with a single-engine type rating. As a consequence, under the previous regulations, pilots seeking an ATP certificate concurrently with a single-engine type rating were subject to unnecessary and burdensome training requirements.

C. Summary of the Notice of Proposed Rulemaking

On December 20, 2018, the FAA published a notice of proposed rulemaking (NPRM) titled *Removal of Training Requirements for an Airline Transport Pilot Certificate Issued Concurrently With a Single-Engine Airplane Type Rating.*[8] In the NPRM, the FAA proposed to revise §§ 61.39(d), 61.153(e), 61.156, and 61.165(f) to reflect that the ground training and FSTD training in a multiengine airplane, which is specified in § 61.156, applies to pilots seeking an ATP certificate with a multiengine airplane rating or an ATP certificate obtained concurrently with a multiengine airplane type rating. Additionally, because §§ 61.39(b), 61.155(c)(14), and 61.160 contain the same problematic language that fails to specify ''multiengine'' airplane type rating, the FAA proposed to make similar revisions to §§ 61.39(b), 61.155(c)(14),[9] and 61.160 to reflect the FAA's original intent. The FAA explained that these amendments are necessary to ensure a pilot seeking an ATP certificate concurrently with a single-engine airplane type rating will not be required to comply with training requirements that were intended for applicants seeking an ATP certificate in a multiengine airplane. Consistent with the Act's direction to enhance multiengine experience requirements, the NPRM did not propose any changes for what is currently required for a pilot seeking a multiengine airplane ATP certificate.

The FAA noted that, while the multiengine training requirement of § 61.156 would be removed for a pilot seeking an ATP certificate concurrently with a single-engine airplane type rating, there would be no reduction in safety because a pilot is still required to obtain specific training and testing that is appropriate to the single-engine airplane type rating the pilot is seeking.[10]

In addition to the amendments previously discussed, the FAA proposed to amend several sections in part 61 by removing the July 31, 2014 date, which served as the compliance date for the multiengine training requirement. This date is no longer necessary in the following regulations: §§ 61.35(a)(2) and (a)(3)(iii)(C); 61.153(e); 61.155(c)(14); the introductory text of 61.156; and

[2] 78 FR 42324 (July 15, 2013).

[3] 14 CFR 121.159.

[4] 14 CFR 61.35, 61.153, 61.159.

[5] 14 CFR 61.39 and 61.156.

[6] Cirrus Aircraft received type certification of the SF50 Vision Jet in October 2016.

[7] 14 CFR 61.157(b).

[8] 83 FR 65316.

[9] The proposed language of § 61.155(c)(14) has been revised in the final rule for consistency with the language in the other sections. This change results in no substantive change.

[10] To add a single-engine airplane type rating to an ATP certificate or obtain a single-engine type rating concurrently with an ATP certificate, a pilot must: (1) Receive and log ground and flight training from an authorized instructor; (2) receive an endorsement from an authorized instructor that the training was completed; and (3) perform a practical test in accordance with the requirements in § 61.157(b).

61.165(c)(2) and (f)(2). The FAA also proposed to remove § 61.35(a)(3)(iii)(B) because it contained a prerequisite for applicants seeking issuance of an ATP certificate prior to August 1, 2014, which is now unnecessary. As a result, the FAA proposed to redesignate § 61.35(a)(3)(iii)(C) as § 61.35(a)(3)(iii)(B).

Furthermore, the FAA concluded that § 61.155(d) is no longer necessary. This section required an applicant who successfully completed the ATP knowledge test prior to August 1, 2014, to successfully complete the practical test within 24 months from the month in which the knowledge test was successfully completed. Because more than 24 months has elapsed since August 1, 2014, it is impossible for an applicant to successfully complete an ATP practical test within 24 months of taking a knowledge test prior to that date. The FAA proposed to remove § 61.155(d) from part 61. For the same reasons, the FAA proposed to remove language from § 61.165(f)(2) that allows a pilot to present valid ATP knowledge test results from a test taken prior to August 1, 2014.

The NPRM provided for a 60-day comment period, which ended on February 19, 2019.

III. Discussion of Public Comments and Final Rule

The FAA received three comments to the NPRM, two from individuals and one from a training center. One individual recommended an amendment to the supervised operating experience (SOE) limitations defined in § 61.64(f)(2). The individual recommended that an airman who holds an unrestricted multiengine turbojet airplane type rating be eligible for an unrestricted single-engine type rating upon successful completion of a single-engine type rating practical test conducted in a flight simulator. The individual suggested this allowance would be based on the airman's existing operational experience in turbojet aircraft.

The FAA has considered the recommendation and determined it is outside the scope of this rulemaking. The commenter sought to allow multiengine turbine-powered airplane experience to count towards single-engine turbine-powered airplane experience. In accordance with the definition in 14 CFR part 1, a class as used with respect to the certification, ratings, privileges, and limitations of airmen, is established within a category of aircraft for aircraft having similar operating characteristics. Examples include ''single engine'' and ''multiengine'' for the airplane category. This distinction is necessary because the differences in operating characteristics between the two classes of airplane are significant, particularly with regard to handling an engine failure. Section 61.64 allows a Level C or higher full flight simulator to be used for a practical test for the issuance of an airman certificate or rating provided that simulator represents the category, class, and type for the rating sought. Because the practical test is administered in a simulator and not the airplane, a pilot is issued a SOE limitation unless the pilot meets prescribed experience requirements. Requiring 25 hours of supervised experience in the airplane following a successful practical test in a simulator is an important safety mitigation when the pilot does not otherwise have the requisite experience in an aircraft.

To allow experience in one class of airplane to count for another class of airplane to avoid an SOE requirement would require a more comprehensive review of the existing requirements in § 61.64 and the safety implications for making such a change, followed by a subsequent notice and comment period. In addition, because there is only one single-engine airplane that requires a type rating, there is a small number of pilots that could potentially benefit from such a change; therefore, the FAA will not pursue a review at this time.

The same individual noted that the § 61.159(a)(3) requirement of 50 hours of time in class for an ATP certificate is burdensome. The FAA has determined the comment is outside the scope of this rulemaking because the NPRM did not propose a change to § 61.159(a)(3). The FAA notes that it conducted a rulemaking proposing this requirement in 2012 in response to Public Law 111–216. It addressed the comments in the 2013 final rule and determined 50 hours of time in class for an ATP certificate was appropriate for all airplane classes, not just the airplane multiengine land class rating, and permitted up to 25 hours to be completed in a simulator if part of an approved training program.[11] No changes to the final rule will be made as a result of this comment.

An additional individual commenter requested an update to § 61.159(d)(2) to allow flight time credit towards an ATP certificate for navigators in the U.S. Armed Forces similar to the credit permitted for flight engineers. The FAA has determined the comment is outside the scope of this rulemaking because the NPRM did not propose a change to § 61.159(d)(2).[12]

The final comment came from CAE, Inc. (CAE). CAE contends that there are training tasks and learning objectives identified in the training course required in § 61.156 that are applicable to single-engine type rating candidates. CAE recommended the FAA task a committee to ''carefully study the requirements and make recommendations as to which tasks and elements should be applied to ATP single-engine type rating candidates.''

The FAA has considered CAE's recommendation and determined that it is not necessary to task a committee to review and recommend tasks that should be applied to ATP single-engine type rating candidates. The FAA established these multiengine ATP certification requirements in response to Public Law 111–216. The statute was specific to modifying the multiengine ATP certificate requirements to incorporate the content now codified in § 61.156. The FAA recognizes some of the subject matter would be applicable to candidates for a single-engine type rating. However, there is no statutory or regulatory requirement for single-engine ATP applicants to receive such training. Training providers can review the existing guidance in Advisory Circular 61–138, Airline Transport Pilot Certification Program, and determine which topic areas are applicable should they want to offer such training voluntarily. In addition, the FAA published the ATP-Airplane Airman Certification Standards in June 2019, which further captures what a pilot of a single-engine airplane needs to know at the ATP level, and what a pilot of a single-engine airplane type rating needs to know, pursuant to FAA regulatory requirements. The FAA encourages training providers to use the available information and incorporate the applicable content in their single-engine type rating training programs.

The FAA received no other comments on the proposal. Accordingly, for the reasons stated in the NPRM and reiterated in section II.C of this document, the FAA is finalizing the proposed amendments without change. The FAA notes that, with the corrections to § 61.160(a) through (d),

[11] 78 FR 42332.

[12] The FAA has denied several petitions for exemption from individuals seeking to credit time as a military-trained navigator toward requirements for an ATP certificate. The FAA concluded that the training, proficiency, and decision-making skills are significantly different from those of a pilot-in-command and that such an exemption would not provide an equivalent level of safety to that provided in the regulation. See Exemption No. 17785 (FAA–2017–0160); Exemption No. 17866 (FAA–2017–1198).

the FAA is also amending paragraph (f) to achieve parallel construction of the multiengine airplane phrasing. The FAA is also making a clarifying amendment to § 61.160(e) by adding a cross-reference that was inadvertently omitted in the *Pilot Certification and Qualification Requirements for Air Carrier Operations* final rule.[13] As evident from the preamble to that final rule, § 61.160(e) was intended to ''reduce the cross-country flight time required for all applicants for an R–ATP [airline transport pilot certificate with restricted privileges] certificate to 200 hours.'' [14] However, the express language of the rule provided relief only to those categories of applicants listed in paragraphs (a), (b), and (c). Because the relief in § 61.160(e) was intended for all eligible applicants,[15] including persons eligible under § 61.160(d), the FAA is amending § 61.160 by adding a cross-reference to paragraph (d).

IV. Regulatory Notices and Analyses

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

In conducting these analyses, the FAA has determined that this final rule: (1) Has cost savings with no additional costs; (2) is not a significant regulatory action as defined by Executive Order 12866; (3) does not require an analysis under the Regulatory Flexibility Act; (4) will not create unnecessary obstacles to the foreign commerce of the United States; and (5) will not impose an unfunded mandate on State, local, or tribal governments, or on the private sector by exceeding the threshold identified above. These analyses are summarized below.

A. Regulatory Evaluation

This final rule does not make any changes to the requirements for a pilot seeking a multiengine airplane ATP certificate. Rather, this final rule simply removes an unintended and unnecessary training requirement in multiengine airplanes for a pilot seeking a single-engine airplane ATP certificate concurrently with a single-engine airplane type rating, with no reduction in safety because a pilot will still be required to obtain specific training and be tested to receive the single-engine airplane type rating.

This final rule will relieve costs for a pilot seeking an ATP certificate concurrently with a single-engine airplane type rating. Current regulations require a person seeking both an ATP and a single-engine type rating concurrently to complete the ATP CTP.

In order to estimate cost savings of this final rule, the FAA based its regulatory evaluation on the following assumptions, factors, and data. These are similar to those used for the regulatory evaluation of the proposed rule. The FAA received no comments on the regulatory evaluation of the proposed rule.

- The FAA uses a five-year period of analysis based on the most current data available at the time.
- The FAA uses a seven and three percent discount rate for estimating present values of cost savings as prescribed by the Office of Management and Budget (OMB) in Circular A–4.
- Monetized estimates for the final rule are in 2020 dollars by adjusting proposed rule values with the GDP deflator for 2020. OMB Circular A–4 recommends using the GDP deflator to adjust monetized effects to a constant dollar year.
- The FAA estimates costs of an ATP CTP to an applicant to be $5,105.
- The FAA estimates that the cost of renting a newer, all glass display, single-engine airplane to be approximately $179 per hour wet (rounded from $178.60). An airplane rented wet includes maintenance, insurance, fuel, airport fees, any other duties, and taxes.
- The FAA estimates that for an ATP practical test, a single-engine airplane has to be rented for three hours to practice for the test and two hours for the test.
- In addition to renting an airplane, a designee is required. The FAA estimates that the designee will cost the applicant $511.
- Based on data from Airlines for America (A4A), the FAA estimates that the average domestic round-trip fare and fees will be about $347.[16]
- Based on data from the General Services Administration website, for 2017, the average cost of a hotel in the continental U.S. is $93 per day and the average cost of the per diem, including meals and incidental expenses, is $51 per day.[17]

As previously discussed, there were no single-engine airplanes that required a type rating until the certification of the Cirrus Vision Jet (SF50) in 2016. From October 2016 through June 2021, 493 pilots received SF50 type ratings. Of these 493 pilots, the FAA estimates that 40 percent could have upgraded their certificate if they had completed the ATP CTP, but opted to just add the SF50 type rating to their commercial certificate to avoid the ATP CTP training costs. Since there are 57 months from October 2016 through June 2021, the FAA estimates that there will be an average of about 9 pilots per month that will receive a single-engine type certificate (493 pilots divided by 57 months), or about 108 pilots per year (9 pilots multiplied by 12 months). The FAA then estimates that 40 percent of 108 pilots per year, or 43 pilots (0.4 multiplied by 108) per year, will receive savings by avoiding the costs of the ATP CTP.

In order to estimate the savings for an applicant, the FAA estimated the avoided costs of the ATP CTP based on two options for an applicant. For the first option, the applicant has to complete a five to seven day ATP CTP provided by an FAA-authorized training provider. The FAA estimates the course takes an average of six days ((5 + 7)/2). The applicant also incurs the expense to travel to the training provider to take the course, get a hotel for six days, and pay a per diem for meals. In the case above, an ATP CTP costs $5,105, round trip airfare costs about $347, a hotel costs $93 a day, and meals and incidental expenses cost $51 a day. Using these costs, the FAA estimates the relief provided in this final rule saves an

[13] 78 FR 42324.

[14] 78 FR 42348–49.

[15] This point was also summarized in the differences between the NPRM and the final rule stating ''[m]inimum cross country time for all eligible pilots is 200 hours''. 78 FR 42330.

[16] *https://airlines.org/dataset/annual-round-trip-fares-and-fees-domestic/* Accessed October 2018.

[17] *https://www.gsa.gov/travel/plan-book/per-diem-rates/per-diem-files-archived.*

applicant about $6,651 under this option. The following table shows the cost savings estimates of the first option over the five-year period of analysis.

OPTION 1—POTENTIAL COST SAVINGS

Year	Class	Fare	Hotel	Per diem	Avg days	#Pilots	Total cost savings	Present value	
	A	B	C	D	E	F	(A + B + ((C + D) × E)) × F	7%	3%
1	$5,105	$347	$93	$51	6	43	$271,588	$253,821	$263,678
2	5,105	347	93	51	6	43	271,588	237,215	255,998
3	5,105	347	93	51	6	43	271,588	221,697	248,541
4	5,105	347	93	51	6	43	271,588	207,193	241,302
5	5,105	347	93	51	6	43	271,588	193,638	234,274
Total (Adjusted with 2020 GDP deflator 2020:2017 = 5.3%)							1,429,911	1,172,583	1,309,715
Savings per pilot (2020 dollars)							6,651	5,454	6,092

Note: Numbers may not add due to rounding.

For the second option, the applicant has to rent a single-engine airplane and hire a designee (check pilot) for the practical test. The FAA estimates that for an ATP practical test, the applicant will rent a single-engine airplane for five hours (three hours to practice for the test and two hours for the test). Using the assumptions above, the rent of a single-engine airplane costs approximately $178.6 per hour. The FAA estimates the airplane rental costs a total of approximately $893 to rent ($178.6 multiplied by 5 total hours). The applicant also incurs expenses to travel to a private plane rental company, hire a designee, get a hotel for one day, and pay a per diem for meals. In the assumptions above, round trip airfare costs about $347, a designee would cost $511, a hotel would cost $93 a day, and meals and incidental expenses would cost $51 a day. Using these costs, the FAA estimates that in this situation the relief provided in this final rule will save an applicant about $1,895 under this option. The following table shows the cost savings estimates of the second option over the five-year period of analysis.

OPTION 2—POTENTIAL COST SAVINGS

Year	Fare	A/C rental	Designee	Hotel	Per diem	#Pilots	Total cost	Present value	
	A	B	C	D	E	F	(A + B + ((C + D) × E)) × F	7%	3%
1	$347	$893	$511	$93	$51	43	$81,485	$76,154	$79,112
2	347	893	511	93	51	43	81,485	71,172	76,807
3	347	893	511	93	51	43	81,485	66,516	74,570
4	347	893	511	93	51	43	81,485	62,165	72,398
5	347	893	511	93	51	43	81,485	58,098	70,290
Total (Adjusted with 2020 GDP deflator 2020:2017 = 5.3%)							407,425	334,105	373,177
Savings per pilot (2020 dollars)							1,895	1,554	1,736

Note: Numbers may not add due to rounding.

Using the analysis from both options, the FAA estimates that this final rule has present value cost savings from $334 thousand to $1.2 million at a seven percent discount rate over the five-year period of analysis. At a three percent discount rate, this final rule has present value cost savings from $373 thousand to $1.3 million over the five-year period of analysis. While this final rule results in small total cost savings with no additional costs, it will provide substantial cost savings to affected pilots ranging from $1,895 to $6,651 per pilot.

B. Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (Pub. L. 96–354) (RFA) establishes ''as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation.'' To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration. The RFA covers a wide-range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a rulemaking would have a significant economic impact on a substantial number of small entities. If the agency determines that it will, the agency must prepare a regulatory flexibility analysis as described in the RFA. However, if an agency determines that a rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the RFA provides that the head of the agency may so certify, and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

This final rule does not make any changes to the requirements for a pilot seeking a multiengine airplane ATP certificate. Rather, this final rule will simply remove an unintended and unnecessary training requirement in multiengine airplanes for a pilot seeking a single-engine airplane ATP certificate concurrently with a single-engine airplane type rating, with no reduction in safety because a pilot will still be required to obtain specific training and be tested to receive the single-engine airplane type rating. This final rule relieves costs for a pilot seeking an ATP certificate concurrently with a single-engine airplane type rating. This rule directly affects individual pilots and not small entities.

Therefore, as provided in section 605(b), the head of the FAA certifies that this final rule does not result in a significant economic impact on a substantial number of small entities.

C. International Trade Impact Assessment

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

The FAA has assessed the potential effect of this final rule and determined that it has only a domestic impact and therefore no effect on international trade.

D. Unfunded Mandates Assessment

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a final agency rule that may result in an expenditure of $100 million or more (in 1995 dollars) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a ''significant regulatory action.'' The FAA currently uses an inflation-adjusted value of $155.0 million in lieu of $100 million. This final rule does not contain such a mandate; therefore, the requirements of Title II of the Act do not apply.

E. Paperwork Reduction Act

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

The FAA has determined that there will be no new requirement for information collection associated with this final rule. The FAA has also determined it is not necessary to amend any existing collection. The current paperwork filing that established the ATP CTP imposes a requirement for a training provider to submit a training program to the FAA for approval. In the original filing, it was determined there was no paperwork burden on a person taking the ATP CTP; therefore, this final rule will have no impact on that filing. The FAA also evaluated the paperwork filing for the Airman Certificate and/or Rating Application. If an applicant is seeking a multiengine airplane ATP certificate, submitting the ATP CTP graduation certificate is required as part of that collection. This final rule does not change that requirement; therefore, no amendment is needed.

F. International Compatibility

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

G. Environmental Analysis

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

V. Executive Order Determinations

A. Executive Order 13132, Federalism

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

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

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

C. Executive Order 13609, Promoting International Regulatory Cooperation

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

VI. How To Obtain Additional Information

A. Electronic Access and Filing

A copy of the notice of proposed rulemaking, all comments received, this final rule, and all background material may be viewed online at *https://www.regulations.gov* using the docket number listed above. A copy of this rule will be placed in the docket. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year. An electronic copy of this document may also be downloaded from the Office of the Federal Register's website at *https://www.federalregister.gov* and the Government Publishing Office's website at *https://www.govinfo.gov.* A copy may also be found at the FAA's Regulations and Policies website at *https://www.faa.gov/regulations_policies.*

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

All documents the FAA considered in developing this rule, including economic analyses and technical reports, may be accessed in the electronic docket for this rulemaking.

B. Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires the FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. A small entity with questions regarding

this document, may contact its local FAA official, or the person listed under the **FOR FURTHER INFORMATION CONTACT** heading at the beginning of the preamble. To find out more about SBREFA on the internet, visit *https://www.faa.gov/regulations_policies/rulemaking/sbre_act/.*

List of Subjects in 14 CFR Part 61

Aircraft, Airmen, Aviation safety.

The Amendment

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

PART 61—CERTIFICATION: PILOTS, FLIGHT INSTRUCTORS, AND GROUND INSTRUCTORS

■ 1. The authority citation for part 61 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40113, 44701–44703, 44707, 44709–44711, 44729, 44903, 45102–45103, 45301–45302, Sec. 2307 Pub. L. 114–190, 130 Stat. 615 (49 U.S.C. 44703 note).

■ 2. Amend § 61.35 by:
■ a. Revising paragraphs (a)(2) and (a)(3)(iii)(A);
■ b. Removing paragraph (a)(3)(iii)(B);
■ c. Redesignating paragraph (a)(3)(iii)(C) as paragraph (a)(3)(iii)(B); and
■ d. Revising newly-redesignated paragraph (a)(3)(iii)(B).

The revisions read as follows:

§ 61.35 Knowledge test: Prerequisites and passing grades.

(a) * * *

(2) For the knowledge test for an airline transport pilot certificate with an airplane category multiengine class rating, a graduation certificate for the airline transport pilot certification training program specified in § 61.156; and

(3) * * *

(iii) * * *

(A) For issuance of certificates other than the ATP certificate with an airplane category multiengine class rating, the applicant meets or will meet the age requirements of this part for the certificate sought before the expiration date of the airman knowledge test report; and

(B) For issuance of an ATP certificate with an airplane category multiengine class rating obtained under the aeronautical experience requirements of § 61.159 or § 61.160, the applicant is at least 18 years of age at the time of the knowledge test;

* * * * *

■ 3. Amend § 61.39 by revising paragraph (b) introductory text and paragraph (d) introductory text to read as follows:

§ 61.39 Prerequisites for practical tests.

* * * * *

(b) An applicant for an airline transport pilot certificate with an airplane category multiengine class rating or an airline transport pilot certificate obtained concurrently with a multiengine airplane type rating may take the practical test with an expired knowledge test only if the applicant passed the knowledge test after July 31, 2014, and is employed:

* * * * *

(d) In addition to the requirements in paragraph (a) of this section, to be eligible for a practical test for an airline transport pilot certificate with an airplane category multiengine class rating or airline transport pilot certificate obtained concurrently with a multiengine airplane type rating, an applicant must:

* * * * *

■ 4. Amend § 61.153 by revising paragraph (e) to read as follows:

§ 61.153 Eligibility requirements: General.

* * * * *

(e) For an airline transport pilot certificate with an airplane category multiengine class rating or an airline transport pilot certificate obtained concurrently with a multiengine airplane type rating, receive a graduation certificate from an authorized training provider certifying completion of the airline transport pilot certification training program specified in § 61.156 before applying for the knowledge test required by paragraph (g) of this section;

* * * * *

■ 5. Amend § 61.155 by revising paragraph (c)(14) and removing paragraph (d).

The revision reads as follows:

§ 61.155 Aeronautical knowledge.

* * * * *

(c) * * *

(14) For an airline transport pilot certificate with an airplane category multiengine class rating or an airline transport pilot certificate obtained concurrently with a multiengine airplane type rating, the content of the airline transport pilot certification training program in § 61.156.

■ 6. Amend § 61.156 by revising the section heading and introductory text to read as follows:

§ 61.156 Training requirements: Airplane category—multiengine class or multiengine airplane type rating concurrently with an airline transport pilot certificate.

A person who applies for the knowledge test for an airline transport pilot certificate with an airplane category multiengine class rating must present a graduation certificate from an authorized training provider under part 121, 135, 141, or 142 of this chapter certifying the applicant has completed the following training in a course approved by the Administrator.

* * * * *

■ 7. Amend § 61.160 by revising paragraphs (a) introductory text, (b) introductory text, (c) introductory text, and paragraphs (d), (e), and (f) to read as follows:

§ 61.160 Aeronautical experience—airplane category restricted privileges.

(a) Except for a person who has been removed from flying status for lack of proficiency or because of a disciplinary action involving aircraft operations, a U.S. military pilot or former U.S. military pilot may apply for an airline transport pilot certificate with an airplane category multiengine class rating or an airline transport pilot certificate concurrently with a multiengine airplane type rating with a minimum of 750 hours of total time as a pilot if the pilot presents:

* * * * *

(b) A person may apply for an airline transport pilot certificate with an airplane category multiengine class rating or an airline transport pilot certificate concurrently with a multiengine airplane type rating with a minimum of 1,000 hours of total time as a pilot if the person:

* * * * *

(c) A person may apply for an airline transport pilot certificate with an airplane category multiengine class rating or an airline transport pilot certificate concurrently with a multiengine airplane type rating with a minimum of 1,250 hours of total time as a pilot if the person:

* * * * *

(d) A graduate of an institution of higher education who completes fewer than 60 semester credit hours but at least 30 credit hours and otherwise satisfies the requirements of paragraph (b) of this section may apply for an airline transport pilot certificate with an airplane category multiengine class rating or an airline transport pilot certificate concurrently with a multiengine airplane type rating with a minimum of 1,250 hours of total time as a pilot.

(e) A person who applies for an airline transport pilot certificate under the total flight times listed in paragraphs (a), (b), (c), and (d) of this section must otherwise meet the aeronautical experience requirements of § 61.159, except that the person may apply for an airline transport pilot certificate with 200 hours of cross-country flight time.

(f) A person may apply for an airline transport pilot certificate with an airplane category multiengine class rating or an airline transport pilot certificate concurrently with a multiengine airplane type rating if the person has 1,500 hours total time as a pilot, 200 hours of cross-country flight time, and otherwise meets the aeronautical experience requirements of § 61.159.

* * * * *

■ 8. Amend § 61.165 by revising paragraphs (c)(2), (f) introductory text, and (f)(2) to read as follows:

§ 61.165 Additional aircraft category and class ratings.

* * * * *

(c) * * *

(2) Successfully complete the airline transport pilot certification training program specified in § 61.156;

* * * * *

(f) *Adding a multiengine class rating to an airline transport pilot certificate with a single engine class rating.* A person applying to add a multiengine class rating, or a multiengine class rating concurrently with a multiengine airplane type rating, to an airline transport pilot certificate with an airplane category single engine class rating must—

* * * * *

(2) Pass a required knowledge test on the aeronautical knowledge areas of § 61.155(c), as applicable to multiengine airplanes;

* * * * *

Issued under authority provided by 49 U.S.C. 106(f), 44701(a), and 44703 in Washington, DC, on or about November 3, 2021.

Steve Dickson,

Administrator.

[FR Doc. 2021–24411 Filed 11–8–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 95

[Docket No. 31399; Amdt. No. 562]

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 2, 2021.

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 October 29, 2021.

Thomas J. Nichols,

Aviation Safety, Flight Standards Service, Manager, Standards Section, Flight Procedures & Airspace Group, Flight Technologies and Procedures Division.

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 2, 2021.

PART 95—[AMENDED]

■ 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 562, Effective Date December 2, 2021]

FROM	TO	MEA
§ 95.1001 Direct Routes—U.S. Color Routes		
§ 95.20 Red Federal Airway R4 Is Amended To Delete		
CHENA, AK NDB	BEAR CREEK, AK NDB	5000

FROM	TO	MEA	MAA
§ 95.3000 Low Altitude RNAV Routes			
§ 95.3407 RNAV Route T407 Is Added To Read			
SIOUX FALLS, SD VORTAC	FFORT, SD WP	3600	17500
FFORT, SD WP	FARGO, ND VOR/DME	*4500	17500
*3800—MOCA			
FARGO, ND VOR/DME	GRAND FORKS, ND VOR/DME	2700	17500
GRAND FORKS, ND VOR/DME	WUBED, MN WP	2600	17500
WUBED, MN WP	U.S. CANADIAN BORDER	2500	17500

FROM	TO	MEA
§ 95.6001 Victor Routes—U.S		
§ 95.6015 VOR Federal Airway V15 Is Amended To Read in Part		
ABERDEEN, SD VOR/DME	BISMARCK, ND VOR/DME	*5000
*3700—MOCA		
§ 95.6044 VOR Federal Airway V44 Is Amended To Read in Part		
FORISTELL, MO VORTAC	MOODS, IL FIX	2700
SPEAK, MD FIX	SEA ISLE, NJ VORTAC	*7000
*2000—GNSS MEA		
§ 95.6045 VOR Federal Airway V45 Is Amended To Read in Part		
BLUEFIELD, WV VOR/DME	CHARLESTON, WV VOR/DME	6000
§ 95.6059 VOR Federal Airway V59 Is Amended To Read in Part		
PULASKI, VA VORTAC	SOFTY, WV FIX	6400
SOFTY, WV FIX	BECKLEY, WV VOR/DME	#6000
#BECKLEY R–161 UNUSABLE		
BECKLEY, WV VOR/DME	WARDO, WV FIX	5100
§ 95.6136 VOR Federal Airway V136 Is Amended To Read in Part		
SWELL, TN FIX	*VOLUNTEER, TN VORTAC	3000
*5000—MCA VOLUNTEER, TN VORTAC, E BND		
VOLUNTEER, TN VORTAC	AUBRY, TN FIX.	
	W BND	5000
	E BND	6000
AUBRY, TN FIX	*PITTE, TN FIX	6000
*8000—MCA PITTE, TN FIX, E BND		
PITTE, TN FIX	SNOWBIRD, TN VORTAC	8000
§ 95.6173 VOR Federal Airway V173 Is Amended To Read in Part		
SPINNER, IL VORTAC	PEOTONE, IL VORTAC	4500
§ 95.6181 VOR Federal Airway V181 Is Amended To Delete		
GRAND FORKS, ND VOR/DME	HUMBOLDT, MN VORTAC	2600
HUMBOLDT, MN VORTAC	ZOMTA, MN WP	2800
ZOMTA, MN WP	U.S. CANADIAN BORDER	2800
§ 95.6206 VOR Federal Airway V206 Is Amended To Read in Part		
KIRKSVILLE, MO VORTAC	OTTUMWA, IA VOR/DME	3100
§ 95.6258 VOR Federal Airway V258 Is Amended To Read in Part		
BECKLEY, WV VOR/DME	ZOOMS, WV FIX	UNUSABLE

FROM	TO	MEA
§ 95.6266 VOR Federal Airway V266 Is Amended To Read in Part		
SOUTH BOSTON, VA VORTAC	LAWRENCEVILLE, VA VORTAC	#*3000
*2000—MOCA *2300—GNSS MEA #LAWRENCEVILLE R–269 UNUSABLE, USE SOUTH BOSTON R–086		
LAWRENCEVILLE, VA VORTAC	FRANKLIN, VA VORTAC	UNUSABLE
FRANKLIN, VA VORTAC	*SUNNS, NC FIX	UNUSABLE
*5000—MCA SUNNS, NC FIX, SE BND		
§ 95.6270 VOR Federal Airway V270 Is Amended To Read in Part		
BINGHAMTON, NY VOR/DME	DELANCEY, NY VOR/DME.	
	W BND	4500
	E BND	4800
DELANCEY, NY VOR/DME	*ACOVE, NY FIX	6300
*8000—MRA		
ACOVE, NY FIX	*ATHOS, NY FIX	6300
*6000—MCA ATHOS, NY FIX, W BND		
ATHOS, NY FIX	CHESTER, MA VOR/DME	4500
§ 95.6271 VOR Federal Airway V271 Is Amended To Delete		
MANISTEE, MI VOR/DME	ESCANABA, MI VOR/DME	*3000
*2100—MOCA		
§ 95.6273 VOR Federal Airway V273 Is Amended To Read in Part		
FALLZ, NJ FIX	HUGUENOT, NY VOR/DME	3200
§ 95.6285 VOR Federal Airway V285 Is Amended To Delete		
WHITE CLOUD, MI VOR/DME	MANISTEE, MI VOR/DME	#4000
#WHITE CLOUD R–332 TO MANISTEE UNUSABLE EXCEPT FOR AIRCRAFT EQUIPPED WITH SUITABLE RNAV SYSTEM WITH GPS MANISTEE R–156 TO WHITE UNUSABLE EXCEPT FOR AIRCRAFT EQUIPPED WITH SUITABLE RNAV SYSTEM WITH GPS		
MANISTEE, MI VOR/DME	TRAVERSE CITY, MI VOR/DME	#2800
#MANISTEE R–057 TO COP UNUSABLE EXCEPT FOR AIRCRAFT EQUIPPED WITH SUITABLE RNAV SYSTEM WITH GPS		
§ 95.6412 VOR Federal Airway V412 Is Amended To Read in Part		
REDWOOD FALLS, MN VOR/DME	FLYING CLOUD, MN VOR/DME	*4000
*2800—MOCA		
§ 95.6433 VOR Federal Airway V433 Is Amended To Read in Part		
BRIDGEPORT, CT VOR/DME	*PAWLING, NY VOR/DME	3000
*5700—MCA PAWLING, NY VOR/DME, NW BND		
PAWLING, NY VOR/DME	*CYPER, NY FIX.	
	SE BND	6100
	NW BND	10000
*15000—MRA		
CYPER, NY FIX	*PETER, NY FIX	**10000
*10000—MCA PETER, NY FIX, NW BND *10000—MCA PETER, NY FIX, SE BND **6100—GNSS MEA		
PETER, NY FIX	*ROCKDALE, NY VOR/DME	#**10000
*10000—MCA ROCKDALE, NY VOR/DME, SE BND **6100—GNSS MEA #ROCKDALE R–127 UNUSABLE BELOW 10000.		
§ 95.6438 Alaska VOR Federal Airway V438 Is Amended To Read in Part		
FORT YUKON, AK VORTAC	*UVALL, AK FIX	10000
*10000—MCA UVALL, AK FIX, SE BND		
UVALL, AK FIX	DEADHORSE, AK VOR/DME.	
	NW BND	2300
	SE BND	10000

FROM	TO	MEA
§ 95.6489 VOR Federal Airway V489 Is Amended To Read in Part		
HUGUENOT, NY VOR/DME	*WEARD, NY FIX	**4000
*15000—MCA WEARD, NY FIX, NE BND		
**3500—MOCA		
WEARD, NY FIX	*FILPS, NY FIX	**15000
*15000—MRA		
*15000—MCA FILPS, NY FIX, NE BND		
*15000—MCA FILPS, NY FIX, SW BND		
**6000—MOCA		
**7000—GNSS MEA		
FILPS, NY FIX	*SAGES, NY FIX	**15000
*15000—MCA SAGES, NY FIX, NE BND		
*15000—MCA SAGES, NY FIX, SW BND		
**6400—MOCA		
**7000—GNSS MEA		
SAGES, NY FIX	*CYPER, NY FIX	**15000
*15000—MRA		
*15000—MCA CYPER, NY FIX, NE BND		
*15000—MCA CYPER, NY FIX, SW BND		
**6100—GNSS MEA		
CYPER, NY FIX	*AGNEZ, NY FIX	**15000
*15000—MRA		
*15000—MCA AGNEZ, NY FIX, SW BND		
*15000—MCA AGNEZ, NY FIX, NE BND		
**6300—GNSS MEA		
AGNEZ, NY FIX	*ALBANY, NY VORTAC	**15000
*13300—MCA ALBANY, NY VORTAC, SW BND		
**6200—GNSS MEA		

FROM	TO	MEA	MAA
§ 95.7001 Jet Routes			
§ 95.7042 Jet Route J42 Is Amended To Delete			
TEXARKANA, AR VORTAC	MEMPHIS, TN VORTAC	18000	45000
MEMPHIS, TN VORTAC	NASHVILLE, TN VORTAC	18000	45000
NASHVILLE, TN VORTAC	FOUNT, KY FIX	18000	45000
FOUNT, KY FIX	TONIO, KY FIX	*20000	35000
*18000—GNSS MEA			
TONIO, KY FIX	BECKLEY, WV VOR/DME	18000	35000
BECKLEY, WV VOR/DME	MONTEBELLO, VA VOR/DME	18000	41000
#BECKLEY R–091 UNUSABLE			
MONTEBELLO, VA VOR/DME	GORDONSVILLE, VA VORTAC	18000	41000
GORDONSVILLE, VA VORTAC	NOTTINGHAM, MD VORTAC	18000	45000
NOTTINGHAM, MD VORTAC	*GRACO, MD FIX	18000	35000
*10000—MRA			
GRACO, MD FIX	WOODSTOWN, NJ VORTAC	18000	45000
WOODSTOWN, NJ VORTAC	ROBBINSVILLE, NJ VORTAC	18000	45000
ROBBINSVILLE, NJ VORTAC	HARTFORD, CT VOR/DME	18000	45000
HARTFORD, CT VOR/DME	PUTNAM, CT VOR/DME	18000	45000
PUTNAM, CT VOR/DME	BOSTON, MA VOR/DME	18000	45000
§ 95.7107 Jet Route J107 Is Amended To Delete			
DUPREE, SD VOR/DME	HUMBOLDT, MN VORTAC	21000	45000
HUMBOLDT, MN VORTAC	U.S. CANADIAN BORDER	18000	45000
U.S. CANADIAN BORDER	U.S. CANADIAN BORDER	18000	45000
§ 95.7150 Jet Route J150 Is Amended To Delete			
GORDONSVILLE, VA VORTAC	NOTTINGHAM, MD VORTAC	18000	45000
NOTTINGHAM, MD VORTAC	*GRACO, MD FIX	18000	35000
*10000—MRA			
GRACO, MD FIX	WOODSTOWN, NJ VORTAC	18000	45000
WOODSTOWN, NJ VORTAC	COYLE, NJ VORTAC	18000	45000
COYLE, NJ VORTAC	HAMPTON, NY VORTAC	18000	45000
HAMPTON, NY VORTAC	MONTT, NY FIX	#	
#UNUSABLE			
MONTT, NY FIX	MARCONI, MA VOR/DME	#	
#UNUSABLE			
MARCONI, MA VOR/DME	STOOL, MA FIX	#	
#UNUSABLE			

FROM	TO	MEA	MAA
§ 95.7174 Jet Route J174 Is Amended To Read in Part			
SNOW HILL, MD VORTAC	YAZUU, NJ FIX	18000	45000
YAZUU, NJ FIX	HAMPTON, NY VORTAC	UNUSABLE	
§ 95.7191 Jet Route J191 Is Amended To Delete			
ROBBINSVILLE, NJ VORTAC	DAVYS, NJ FIX	18000	45000
DAVYS, NJ FIX	SMYRNA, DE VORTAC	18000	33000
SMYRNA, DE VORTAC	PATUXENT, MD VORTAC	18000	45000
PATUXENT, MD VORTAC	HUBBS, VA FIX	18000	45000
HUBBS, VA FIX	HOPEWELL, VA VORTAC	18000	22000
§ 95.7193 Jet Route J193 Is Amended To Delete			
WILMINGTON, NC VORTAC	COFIELD, NC VORTAC	18000	45000
COFIELD, NC VORTAC	HARCUM, VA VORTAC	18000	29000
HARCUM, VA VORTAC	HUBBS, VA FIX	18000	28000
§ 95.7222 Jet Route J222 Is Amended To Delete			
ROBBINSVILLE, NJ VORTAC	KENNEDY, NY VOR/DME	18000	45000
KENNEDY, NY VOR/DME	CAMBRIDGE, NY VOR/DME	18000	31000
§ 95.7225 Jet Route J225 Is Amended To Delete			
CEDAR LAKE, NJ VOR/DME	KENNEDY, NY VOR/DME	18000	45000
KENNEDY, NY VOR/DME	PROVIDENCE, RI VOR/DME	18000	45000
§ 95.7515 Jet Route J515 Is Amended To Delete			
FARGO, ND VOR/DME	HUMBOLDT, MN VORTAC	18000	45000
HUMBOLDT, MN VORTAC	U.S. CANADIAN BORDER	18000	45000

AIRWAY SEGMENT		CHANGEOVER POINTS	
FROM	TO	DISTANCE	FROM
§ 95.8003 VOR Federal Airway Changeover Point V266 IS AMENDED TO DELETE CHANGEOVER POINT			
SOUTH BOSTON, VA VORTAC	LAWRENCEVILLE, VA VORTAC	38	SOUTH BOSTON
§ 95.8005 Jet Routes Changeover Points			
J42 Is Amended To Delete Changeover Point			
MEMPHIS, TN VORTAC	NASHVILLE, TN VORTAC	119	MEMPHIS
BEKLEY, WV VOR/DME	MONTEBELLO, VA VORDME	56	BECKLEY
J174 Is Amended To Add Changeover Point			
SNOW HILL, MD VORTAC	HAMPTON, NY VORTAC	106	SNOW HILL
J193 Is Amended To Delete Changeover Point			
COFIELD, NC VORTAC	HARCUM, VA VORTAC	36	COFIELD
J503 Is Amended To Add Changeover Point			
SEATTLE, WA VORTAC	PRINCETON, CA VORTAC	108	SEATTLE

[FR Doc. 2021–24451 Filed 11–8–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2021–0768]

RIN 1625–AA08

Special Local Regulation; San Diego Bay, San Diego, CA

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary special local regulation (SLR) for the San Diego Fleet Week Veterans Day Boat Parade marine event that will be held on the waters of San Diego Bay, California. This action is necessary to provide for the safety of the participants, crew, spectators, sponsor vessels, and general users of the waterway during the event on November 11, 2021. This SLR temporarily encompasses all navigable waters, from surface to bottom, on a pre-determined course in the northern portion of the San Diego Main Ship Channel from Shelter Island Basin, past the Embarcadero, crossing the Federal navigable channel and ending off of Coronado Island.

DATES: This rule is effective from 11:30 a.m. to 2:30 p.m. on November 11, 2021.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2021–0768 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Commander John Santorum, Waterways Management, U.S. Coast Guard Sector, San Diego, CA; telephone (619) 278–7656, email *MarineEventsSD@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the Coast Guard was given short notice from the event sponsor regarding the event, and must establish this special local regulation by November 11, 2021. The event is expected to draw a high concentration of vessels to the San Diego Bay area along the proposed parade route. Traditionally, the San Diego Bay area serves as a major thoroughfare for commercial traffic, naval operations, ferry routes, and a number of other recreational uses. The Coast Guard is establishing this SLR to minimize impacts on this congested waterway. This regulation is necessary to ensure the safety of individuals, property, and the marine environment on the navigable waters of San Diego Bay during this event.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to public interest because immediate action is needed to ensure the safety of life on the navigable waters of San Diego Bay during the marine event on November 11, 2021.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70041 (previously 33 U.S.C. 1236). The Captain of the Port (COTP) Sector San Diego has determined that potential hazards associated with the parade will be a safety concern for anyone within the vicinity of the parade route. This rule is needed to protect personnel, vessels, spectators, and the marine environment in the navigable waters of the San Diego Bay in the vicinity of the marine event during the enforcement period of this rule.

IV. Discussion of the Rule

This rule establishes an SLR from 11:30 a.m. until 2:30 p.m. on November 11, 2021. The SLR will cover all navigable waters on a pre-determined course in the northern portion of the San Diego Main Ship Channel from Shelter Island Basin, past the Embarcadero, crossing the Federal navigable channel and ending off of Coronado Island. The duration of the SLR is intended to protect personnel, vessels, spectators, and the marine environment in these navigable waters before, during, and after the event is scheduled to occur. 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.

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. 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).

This regulatory action determination is based on the size, location, duration, and time-of-day of the SLR. This action will affect only the northern portion of the San Diego Main Ship Channel for three hours. Vessels will still be able to transit the area outside of the regulated area and request permission to enter, as needed. The Coast Guard will publish a Local Notice to Mariners and will issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 that details the vessel restrictions of the regulated area.

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 SLR 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 call or email 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.

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, Rev. 1, associated implementing instructions, 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 SLR lasting less than four hours that will monitor entry to the SLR area for the duration of the enforcement period to cover before, during and after the parade has concluded. It is categorically excluded from further review under paragraph L61 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email 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 100

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 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

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

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

■ 2. Add § 100.T11–0768 to read as follows:

§ 100.T11–0768 San Diego Fleet Week Veterans Day Boat Parade, San Diego Bay, California.

(a) *Regulated area.* The regulations in this section apply to the following area:

(1) *Parade area:* All navigable waters, from surface to bottom, on a pre-determined course in the northern portion of the San Diego Main Ship Channel from Shelter Island Basin, past the Embarcadero, crossing the Federal navigable channel and ending off of Coronado Island.

(2) [Reserved]

(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 and a Federal, State, and local officer designated by or assisting the Captain of the Port Sector San Diego (COTP) in the enforcement of the regulations in this section.

Participant means all persons and vessels registered with the event sponsor as a participants in the parade.

(c) *Regulations.* (1) All non-participants are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area described in paragraph (a) of this section unless authorized by the Captain of the Port Sector San Diego or their designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative by calling the Sector San Diego Joint Harbor Operations Center (JHOC) at 619–278–7033. Those in the regulated area, including participants, must comply with all lawful orders or directions given to them by the COTP or the designated representative.

(3) The COTP will provide notice of the regulated areas through advanced notice via Broadcast Notice to Mariners and by on-scene designated representatives.

(d) *Enforcement period.* This section will be enforced from 11:30 a.m. through 2:30 p.m. on Thursday, November 11, 2021.

Dated: November 4, 2021.

T.J. Barelli,

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

[FR Doc. 2021–24514 Filed 11–8–21; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2021–0770]

Special Local Regulation; Marine Events Within the Eleventh Coast Guard District-San Diego Fall Classic

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the special local regulation on the waters of Mission Bay, San Diego, California, during the San Diego Fall Classic on November 14, 2021. This special local regulation is necessary to provide for the safety of the participants, crew, sponsor vessels of the rowing event, and general users of the waterway. During the enforcement period, persons and vessels are prohibited from entering into, transiting through, or anchoring within this regulated area unless authorized by the Captain of the Port, or his designated representative.

DATES: The regulations in 33 CFR 100.1101 for the location described in Table 1 to § 100.1101, Item No. 1, will be enforced from 5:30 a.m. until 12:30 p.m. on November 14, 2021.

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

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulations in 33 CFR 100.1101 for the location identified in Table 1 to § 100.1101, Item No. 1, from 5:30 a.m. through 12:30 p.m. on November 14, 2021 for the San Diego Fall Classic in Mission Bay, San Diego, CA. This action is being taken to provide for the safety of life on navigable waterways during the rowing event. Our regulation for recurring marine events in the San Diego Captain of the Port Zone, § 100.1101, Table 1 to § 100.1101, Item No. 1, specifies the location of the regulated area for the San Diego Fall Classic, which encompasses portions of Mission Bay. Under the provisions of § 100.1101, persons and vessels are prohibited from entering into, transiting through, or anchoring 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 and marine information broadcasts.

Dated: November 4, 2021.

T.J. Barelli,

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

[FR Doc. 2021–24515 Filed 11–8–21; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 4

RIN 2900–AQ67

Schedule for Rating Disabilities: The Cardiovascular System

AGENCY: Department of Veterans Affairs.

ACTION: Final rule; correction.

SUMMARY: On September 30, 2021, the Department of Veterans Affairs (VA) published in the **Federal Register** a final rule that amended the portion of the VA Schedule for Rating Disabilities (''VASRD'' or ''rating schedule'') that addresses the cardiovascular system. This correction addresses the instructions for evaluating peripheral arterial disease in the published final rule and corrects another minor technical error.

DATES: This correction is effective November 14, 2021.

FOR FURTHER INFORMATION CONTACT: Gary Reynolds, M.D., VASRD Program Management Office (210), Compensation Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, (202) 461–9700. (This is not a toll-free telephone number.)

SUPPLEMENTARY INFORMATION: VA is correcting its final rule, ''RIN 2900–AQ67, Schedule for Rating Disabilities: The Cardiovascular System'', that was published on September 30, 2021, in the **Federal Register** at 86 FR 54089. The error is with new Note (2) for diagnostic code (DC) 7114 peripheral arterial disease which fails to identify which of the four tests are necessary before an evaluation can be assigned. In the proposed rule, VA identified two major shortcomings in the rating criteria for DC 7114 that were addressed by creating evaluation criteria that use the ankle/brachial index (ABI), ankle pressure (AP), toe pressure (TP) and transcutaneous oximetry (T_cPO_2) to describe four different levels of impairment. See 84 FR 37594, 37599 (Aug. 1, 2019). New Note (2) instructed raters to select the highest impairment value of ABI, AP, TP, or T_cPO_2 for evaluation when rating a condition under DC 7114. Upon further consideration, we believe the note could be misconstrued as requiring medical examiners to conduct all four tests. This is inconsistent with our intent, which was to provide examiners with multiple options in the event that ABI was unreliable due to non-compressible arteries. To address this issue, we are correcting new Note (2) to read, ''If AP, TP, and T_cPO_2 testing are not of record, evaluate based on ABI unless the examiner states that an AP, TP, or T_cPO_2 test is needed in a particular case because ABI does not sufficiently reflect the severity of the veteran's peripheral arterial disease. In all other cases, evaluate based on the test that provides the highest impairment value.'' This correction serves two purposes: (1) It reflects VA's intent that although ABI should be the primary testing by which conditions should be rated under DC 7114, raters should request AP, TP, or T_cPO_2 testing when the record reflects that an examiner believes ABI testing does not sufficiently reflect a veteran's level of impairment, and (2) when multiple tests are of record, it allows the rater to select the test result that would grant the veteran the highest evaluation.

Additionally, VA is fixing a technical error with the section heading for 38 CFR 4.100 to ensure that it is applicable to all diagnostic codes that could use the general rating formula for diseases of the heart in its evaluation criteria, such as DCs 7009 and 7110.

Correction

In FR Rule Doc. No. 2021–19998, published September 30, 2021, at 86 FR 54089, make the following corrections:

§ 4.100 [Corrected]

■ 1. On page 54093, at the top of the third column, remove the section heading ''§ 4.100 Application of the evaluation criteria for diagnostic codes 7000–7007, 7011, and 7015–7020.'' and add in its place ''§ 4.100 Application of the general rating formula for diseases of the heart.''

■ 2. On page 54095, in § 4.104, correct Note (2) in the entry for diagnostic code 7114 ''Peripheral arterial disease'' to read as follows:

§ 4.104 Schedule of ratings—cardiovascular system.

* * * * *

DISEASES OF THE HEART

							Rating
	*	*	*	*	*	*	*
7114	Peripheral arterial disease:						
	*	*	*	*	*	*	*
Note (2): If AP, TP, and T_cPO_2 testing are not of record, evaluate based on ABI unless the examiner states that an AP, TP, or T_cPO_2 test is needed in a particular case because ABI does not sufficiently reflect the severity of the veteran's peripheral arterial disease. In all other cases, evaluate based on the test that provides the highest impairment value.							
	*	*	*	*	*	*	*

Jeffrey M. Martin,

Assistant Director, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

[FR Doc. 2021–24419 Filed 11–8–21; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R10–OAR–2020–0648; FRL–8787–02–R10]

Air Plan Approval; AK; Eagle River Second 10-Year PM_{10} Limited Maintenance Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving the Eagle River, Alaska (AK) limited maintenance plan (LMP) submitted on November 10, 2020, by the Alaska Department of Environmental Conservation (ADEC or ''the State''). This plan addresses the second 10-year maintenance period after redesignation for particulate matter with an aerodynamic diameter less than or equal to a nominal 10 micrometers (PM_{10}). The plan relies upon control measures contained in the first 10-year maintenance plan and the determination that the Eagle River area currently monitors PM_{10} levels well below the PM_{10} National Ambient Air Quality Standard (NAAQS or ''the standard''). The EPA is approving Alaska's LMP as meeting Clean Air Act (CAA) requirements.

DATES: This final rule is effective December 9, 2021.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R10–OAR–2020–0648. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information or other information the disclosure of which is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available at *https://www.regulations.gov,* or please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Christi Duboiski, EPA Region 10, 1200 Sixth Avenue (Suite 155), Seattle, WA 98101, at (360) 753–9081, or *duboiski.christi@epa.gov.*

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

I. Background

On November 10, 2020, ADEC submitted to the EPA for approval a second 10-year PM_{10} LMP for Eagle River. The SIP revision, State effective November 7, 2020, fulfills the second 10-year planning requirement of CAA section 175A(b) to ensure PM_{10} NAAQS compliance through 2033. The Eagle River area has been meeting the PM_{10} standard for multiple years and was redesignated to attainment on March 8, 2013 with an approved 10-year PM_{10} maintenance plan. The area currently monitors PM_{10} levels well below the PM_{10} NAAQS.

We proposed to approve the Eagle River second 10-year LMP on September 2, 2021 (86 FR 49278). The reasons for our approval are included in that proposal and will not be restated here. The public comment period for our proposed action closed on October 4, 2021. We received no public comments. Therefore, we are finalizing our action as proposed.

II. Final Action

In this final action, the EPA is approving Alaska's second 10-year LMP for Eagle River submitted on November 10, 2020, as satisfying the requirements of section 175A of the CAA.

III. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves State law as meeting Federal requirements and does not impose additional requirements beyond those imposed by State law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive

Order 13132 (64 FR 43255, August 10, 1999);

- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and it will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 10, 2022. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. See section 307(b)(2).

List of Subjects in 40 CFR Part 52

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

Dated: November 1, 2021.

Michelle L. Pirzadeh,

Acting Regional Administrator, Region 10.

For the reasons set forth in the preamble, 40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart C—Alaska

■ 2. In § 52.70, the table in paragraph (e) is amended by:

■ a. Adding entry ''II.III.D.2.b. Eagle River Second 10-year PM_{10} Limited Maintenance Plan'' after the entry ''II.III.D.2.a. Eagle River PM_{10} Limited Maintenance Plan''; and

■ b. Revising the entry ''III.III.D.2. Eagle River PM_{10} Control Plan''.

The addition and revision read as follow:

§ 52.70 Identification of plan.

* * * * *

(e) * * *

EPA-APPROVED ALASKA NONREGULATORY PROVISIONS AND QUASI-REGULATORY MEASURES

Name of SIP provision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Explanations
State of Alaska Air Quality Control Plan: Volume II. Analysis of Problems, Control Actions				
* *	*	*	* *	*
Section III. Areawide Pollutant Control Program				
* *	*	*	* *	*
II.III.D.2.b. Eagle River Second 10-year PM_{10} Limited Maintenance Plan.	Eagle River	11/10/2020	11/9/2021, [INSERT **FEDERAL REGISTER** CITATION].	
* *	*	*	* *	*
State of Alaska Air Quality Control Plan: Volume II. Appendices				
* *	*	*	* *	*
Section III. Areawide Pollutant Control Program				
* *	*	*	* *	*
III.III.D.2. Eagle River PM_{10} Control Plan	Eagle River	11/10/2020	11/9/2021, [INSERT **FEDERAL REGISTER** CITATION].	

EPA-APPROVED ALASKA NONREGULATORY PROVISIONS AND QUASI-REGULATORY MEASURES—Continued

Name of SIP provision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Explanations
*	*	*	*	*	*	*

[FR Doc. 2021–24258 Filed 11–8–21; 8:45 am]
BILLING CODE P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[EPA–R08–OAR–2021–0004; FRL–8789–02–R8]

Approval and Promulgation of State Plans for Designated Facilities and Pollutants; Colorado; Control of Emissions From Existing Municipal Solid Waste Landfills

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a Clean Air Act (CAA or the ''Act'') section 111(d) state plan submitted by the Colorado Department of Public Health and Environment (CDPHE or the ''Department'') on March 23, 2021. This state plan was submitted to fulfill the requirements of the CAA and is responsive to the EPA's promulgation of Emission Guidelines and Compliance Times (EG) for existing municipal solid waste (MSW) landfills. The Colorado state plan establishes performance standards and other operating requirements for existing MSW landfills within the State of Colorado and provides for the implementation and enforcement of those standards and requirements by the Department. The EPA is taking this action pursuant to the CAA.

DATES: This rule is effective on December 9, 2021. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of December 9, 2021.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R08–OAR–2021–0004. All documents in the docket are listed on the *http://www.regulations.gov* website. 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 material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *http://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Allison Reibach, Air and Radiation Division, EPA, Region 8, Mailcode 8ARD–TRM, 1595 Wynkoop Street, Denver, Colorado 80202–1129, (303) 312–6949, *reibach.allison@epa.gov.*

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

I. Background

The background for this action is discussed in detail in our July 1, 2021 proposed rule (86 FR 35044). In that document we proposed to approve the Colorado CAA section 111(d) state plan for existing MSW landfills as the plan was submitted by the CDPHE on March 23, 2021. The EPA's analysis of the Colorado state plan may be found in the aforementioned proposed rule and the technical support document (TSD) associated with the docket for today's action. Comments on the EPA's proposed approval of the state plan for existing MSW landfills were due on or before August 2, 2021. We received feedback from two commenters during the public comment period opened by the proposed rule. Our responses to the comments are addressed in section II. below.

II. Response to Comments

Comment: Commenter, which represents solid waste management professionals, stated that Colorado's state plan should include all standards outlined in the Federal Plan Requirements for MSW Landfills (40 CFR part 62, subpart OOO), as the Colorado state plan currently includes standards from the Emission Guidelines and Compliance Times for MSW Landfills (40 CFR part 60, subpart Cf). The commenter cites significant differences for ''legacy controlled landfills,'' between the state plan and the federal plan, with the federal plan exempting ''legacy-controlled landfills'' from tasks that they completed under 40 CFR part 60, subpart WWW; subpart GGG of this part; or a state plan implementing 40 CFR part 60, subpart Cc. Without these exemptions, the commenter asserts that Colorado's plan indirectly imposes additional administrative requirements for these ''legacy controlled landfills'' that would not apply if Colorado adopted the language of the federal plan. The commenter urges EPA to ask the CDPHE to adopt the federal plan standards and withdraw their state plan.

Response: Section 111(d) of the CAA gives EPA the authority to prescribe regulations for states to submit plans that establish standards of performance for certain existing sources of air pollutants. Section 111(d) plans adress existing sources for any air pollutant for which air quality criteria have not been issued or which is not included on a list published under section 108(a) of the CAA, but to which a standard of performance would apply if such existing source were a new source. CAA Section 111(d) also requires states to provide in their plans the implementation and enforcement of such standards of performance. In addition, CAA section 111(d)(2)(A) provides EPA with the authority to establish and enforce a plan in cases where the state fails to submit a satisfactory plan. 40 CFR 62.13 addresses instances where a state has failed to submit a satisfactory plan. Commenter should reference 40 CFR 62.13(b) which states, ''[a]fter June 21, 2021, per paragraph (j) of this section, the substantive requirements of the MSW landfills Federal plan are contained in subpart OOO of this part and owners and operators of MSW landfills must comply with subpart OOO of this part or a state/tribal plan implementing 40 CFR part 60, subpart Cf of this chapter . . .''

As stated in our proposal, Colorado's 111(d) state plan for MSW landfills meets all requirements under 40 CFR part 60, subpart Cf of this chapter. The commenter does not state that Colorado's 111(d) state plan for MSW landfills does not meet the requirements under 40 CFR part 60, subpart Cf of this chapter, but asks EPA to request that Colorado withdraw their state plan

because it does not contain language for ''legacy-controlled landfills.'' EPA is aware of the differences between Colorado's plan which meets the requirements for state plans under 40 CFR part 60, subpart Cf and the federal plan requirements under 40 CFR part 62, subpart OOO. We have discussed these differences in detail with Colorado, but whether or not Colorado addresses these changes remains at their discretion since Colorado is in compliance with the requirements of 40 CFR part 60, subpart Cf. Section 110(k)(3) of the CAA requires EPA to approve a plan if it meets all of the CAA applicable requirements for state implementation plans. Therefore, we are approving Colorado's 111(d) state plan for MSW landfills as meeting the requirements for 40 CFR part 60, subpart Cf of this chapter. Upon approval of Colorado's 111(d) plan, the Federal plan will no longer apply to MSW landfills in the State.

Comment: Commenter stated that establishing performance standards and operating requirements for MSW landfills is a necessary measure in tackling air pollution and that air pollutants from landfills can cause adverse health effects. Commenter further suggests that addressing these existing MSW landfills could help to achieve the National Ambient Air Quality Standards (NAAQS) that are often under non-attainment for various pollutants including carbon monoxide (CO), sulfur dioxide (SO_2), nitrogen oxide (NO_X), and more. CAA section 111(d) requires the EPA to establish procedures for requiring states to submit a plan that establishes standards for their existing sources. However, Executive Order 12898 states that section 111(d) does not provide the EPA with the discretionary authority to address disproportionate human health or environmental effects. The EPA's mission is to protect the environment and human health, so the commenter believes the EPA should have the authority to address these matters. The only way to achieve better regulations is for federal agencies to hold sources accountable for their emissions. Using evidence collected from a nearby MSW landfill of emissions in regard to human and environmental health, the EPA could uphold section 111(d) and aid in its overall effectiveness.

Response: 40 CFR part 60, subpart Cf addresses the emission guidelines and compliance timeframes for MSW landfills in accordance with section 111(d) of the CAA and subpart B. In particular, subpart Cf requires CAA 111(d) state plans to address the emissions of landfill gas for MSW landfills. Commenter suggests that Colorado's CAA 111(d) plan could help Colorado achieve the NAAQS, however that is beyond the scope of CAA 111(d) and the regulations for MSW landfills (found in 40 CFR part 60, subpart Cf). Our authority in reviewing the State's submission is limited to evaluating whether it meets the requirements of the MSW landfill emission guidelines. We evaluated this in our proposal, finding that the State of Colorado met the requirements of the MSW landfill emission guidelines for landfill gas. *See* 86 FR 35044 (July 1, 2021) and related docket # EPA–R08–OAR–2021–0004. The EPA does not, in the context of this action, have the authority to require the State to regulate pollutants beyond ''landfill gas,'' which is comprised primarily of carbon dioxide and methane, with smaller amounts of other gases, including nitrogen, oxygen, and non-methane organic compounds. CAA 111(d) state plans implementing the regulations under subpart Cf for emission guidelines do not cover the additional pollutants named by the commenter.

EPA acknowledges the commenter's desire for this action to address disproportionate human health and environmental effects, and as an agency, we strive to incorporate environmental justice considerations into our actions and decisions. However, since this action merely approves state law as meeting Federal requirements and does not impose any additional requirements, this action does not provide EPA with the discretionary authority to address disproportionate human health or environmental effects. While the commenter states that the only way to achieve better regulations is for federal agencies to hold sources accountable for their emissions, we believe that we are holding MSW landfill sources accountable for their emissions with this Colorado plan since the state plan meets the requirements for MSW landfills under CAA 111(d) and 40 CFR part 60, subpart Cf.

III. Final Action

The EPA is finalizing approval of Colorado's CAA section 111(d) plan for MSW landfills. The state plan was submitted in full compliance with the requirements of 40 CFR part 60, subparts B and Cf. Therefore, the EPA is amending 40 CFR part 62, subpart G to reflect this approval action. This approval is based on the rationale provided in section II of the proposed rule for this action (86 FR 35044) and discussed in detail in the TSD associated with this rulemaking action. The Agency's approval is in accordance with the general provisions of plan approval found in 40 CFR part 60, subpart B and in part 62, subpart A of that Title and is pursuant to the Agency's role under 42 U.S.C. 7411(d). The EPA's approval of the Colorado plan is limited to those landfills that meet the criteria established in 40 CFR part 60, subpart Cf and grants the State authority to implement and enforce the performance standards and source requirements of the EG, except in those cases where authorities are specifically reserved for the EPA Administrator or his designee. Authorities retained by the EPA Administrator are those listed in 40 CFR 60.30f(c).

IV. Incorporation by Reference

In accordance with the requirements of 1 CFR 51.5, we are finalizing regulatory text that includes the incorporation by reference of 5 CCR 1001–8 from the Code of Colorado Regulations (CCR), as effective on July 15, 2020. 5 CCR 1001–8 is part of the Colorado CAA section 111(d) state plan applicable to existing MSW landfills. The regulatory provisions of this section of the CCR incorporate the required CAA 111(d) state plan elements required by the EG for existing MSW landfills promulgated at 40 CFR part 60, subpart Cf. This incorporation establishes emission standards and compliance times for the control of air pollutants from certain MSW landfills that commenced construction, modification, or reconstruction on or before July 17, 2014. The emissions standards and compliance times established within this CCR section and the Colorado state plan are at least as stringent as those required by the EG for existing MSW landfills. The EPA has made, and will continue to make, 5 CCR 1001–8 (as well as the Colorado state plan documents for existing MSW landfills) generally available electronically through *www.regulations.gov,* Docket No. EPA–R08–OAR–2021–0004 and at the EPA Region 8 office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). This incorporation by reference has been approved by the Office of the Federal Register and the Plans are federally enforceable under the CAA as of the effective date of this final rulemaking.

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve section 111(d) state plan submissions that comply with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7411(d);

40 CFR part 60, subparts B and Cf, and 40 CFR part 62, subpart A. Thus, in reviewing CAA section 111(d) state plan submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the Act and implementing regulations. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the Colorado CAA 111(d) state plan for existing MSW landfills is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the proposed rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 10, 2022. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 62

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Landfills, Methane, Ozone, Reporting and recordkeeping requirements.

Dated: November 1, 2021.

Debra H. Thomas,

Acting Regional Administrator, Region 8.

40 CFR part 62 is amended as follows:

PART 62—APPROVAL AND PROMULGATION OF STATE PLANS FOR DESIGNATED FACILITIES AND POLLUTANTS

■ 1. The authority citation for part 62 continues to read as follows:

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

Subpart G—Colorado

■ 2. Revise §§ 62.1350, 62.1351, and 62.1352 to read as follows:

§ 62.1350 Identification of plan.

Section 111(d) State Plan for Municipal Solid Waste Landfills and the associated State regulations contained in the Code of Colorado Regulations (CCR) at 5 CCR 1001–8 part A, subpart Cf (incorporated by reference, see § 62.1490), submitted by the State on March 23, 2021.

§ 62.1351 Identification of sources.

The plan applies to all existing municipal solid waste landfills under the jurisdiction of the Colorado Department of Public Health and Environment for which construction, reconstruction, or modification was commenced on or before July 17, 2014, and are subject to the requirements of 40 CFR part 60, subpart Cf.

§ 62.1352 Effective date.

The effective date of the plan for existing municipal solid waste landfills is December 9, 2021.

■ 3. Add an undesignated center heading and § 62.1490 to read as follows:

Incorporation by Reference

§ 62.1490 Incorporation by reference.

(a) The material incorporated by reference in this subpart was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. All approved material may be inspected or obtained from the EPA Region 8 office, 1595 Wynkoop Street, Denver, CO 80202–1129, 303–312–6312 or from the other sources listed in this section. It may also be inspected at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

(b) State of Colorado, Colorado Department of State, 1700 Broadway, Suite 550, Denver, CO 80290, (303) 894–2200, *https://www.sos.state.co.us/CCR/NumericalDeptList.do,* Code of Colorado Regulations (CCR).

(1) 5 CCR 1001–8, part A, subpart Cf: Department of Public Health and Environment—Air Quality Control Commission—Regulation Number 6—Standards of Performance for New Stationary Sources—5 CCR 1001–8. Part A—**Federal Register** Regulations Adopted by Reference, Subpart Cf—Emission Guidelines and Compliance Times for Municipal Solid Waste Landfills, 40 CFR part 60, subpart Cf (July 1, 2019), as amended March 26, 2020; effective July 15, 2020; IBR approved for § 62.1350.

(2) [Reserved]

[FR Doc. 2021–24207 Filed 11–8–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0326; FRL–9180–01–OCSPP]

Calcium Bisulfate; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of calcium bisulfate when used as an inert ingredient (acidifying/buffering agent) in antimicrobial formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils, limited to 2,000 parts per million (ppm). Burdock Group on behalf of SCG Solutions, LLC., submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of calcium bisulfate.

DATES: This regulation is effective November 9, 2021. Objections and requests for hearings must be received on or before January 10, 2022, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2021–0326, is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805.

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

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

You may access a frequently updated electronic version of 40 CFR part 180 through the Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40.*

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2021–0326 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before January 10, 2022. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2021–0326, 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 CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets/contacts.html.*

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

II. Petition for Exemption

In the **Federal Register** of June 28, 2021 (86 FR 33890) (FRL–10025–08), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN–11436) by the Burdock Group (859 Outer Road, Orlando, FL 32814) on behalf of SCG Solutions, LLC (1358 South 9th St., DePere, WI 54115). The petition requested that 40 CFR 180.940(a) be amended by establishing an exemption from the requirement of a tolerance for residues of calcium bisulfate when used as an inert ingredient (acidifying/buffering agent) in antimicrobial formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils, limited to 2,000 parts per million (ppm) in the final formulation. That document referenced a summary of the petition prepared by the Burdock Group on behalf of SCG Solutions, LLC, the petitioner, which is available in the docket, *https://www.regulations.gov.* There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and

diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

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

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

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

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by calcium bisulfate as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *https://www.regulations.gov* in the document ''Calcium Bisulfate; Human Health Risk Assessment and Ecological Effects Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as an Inert Ingredient in Pesticide Formulations'' in docket ID number EPA–HQ–OPP–2021–0326.

Calcium bisulfate readily dissociates to the bisulfate anion and the respective calcium cation. Similarly, sodium bisulfate readily dissociates to the bisulfate anion and the sodium cation. Since the bisulfate anion is converted to sulfate in aqueous solution, toxicology studies for sodium sulfate are generally considered relevant for sodium bisulfate and calcium bisulfate. Therefore, toxicity data on sodium sulfate are used as surrogate data for calcium bisulfate.

The acute oral and dermal toxicity of calcium bisulfate is low in rats. It is slightly irritating to the rabbit skin. It is expected to be mildly irritating to the eyes.

Based on the toxicity database for sodium sulfate, no toxicity is observed in a 30-day oral toxicity study and developmental study in rats at >2,000 mg/kg/day. No toxicity and no tumors are seen in a 27 and 44-week oral toxicity study in rats up to 400 mg/kg/day, the highest dose tested. No mutagenicity is seen in the Ames test.

Neurotoxicity and immunotoxicity toxicity studies are not available for review. However, no evidence of neurotoxicity or immunotoxicity is seen in the available studies.

Calcium bisulfate is expected to readily undergo hydrolysis and dissociate to calcium ions and sulfate ions in the body. Sulfate anions are excreted mainly in the urine.

B. Toxicological Points of Departure/Levels of Concern

The available toxicity studies indicate that calcium bisulfate has a very low overall toxicity. No toxicity was observed in any of the available studies. In the 30-day oral and the developmental toxicity studies with the calcium bisulfate surrogate (sodium sulfate), no toxicity is seen at >2,000 mg/kg/day which is well above the limit dose of 1,000 mg/kg/day. In addition, calcium bisulfate readily dissociates to the bisulfate anion and the calcium cation. Bisulfate/sulfate anion is a naturally occurring constituent in many food substances as well as an essential component in a large number of mammalian (human) metabolic processes. The sulfate anion is a normal constituent in the body, predominantly resulting from the body's metabolism of sulfur-containing food sources such as foods containing the essential amino acids cysteine and methionine. Sulfate anions are vital components in a number of human biosynthetic pathways such as cartilage production and the formation of pancreatic digestive enzymes. Also, the sulfate anion is an important conjugate in the Phase II conjugation/elimination of oxidized (OH) aromatic ring metabolites and for hydroxyl steroid hormones. The Agency did not identify an endpoint of concern for risk assessment purposes because no signs of toxicity were observed, and calcium and sulfate ions are present ubiquitously in the human body. Since no endpoint of concern was identified for the acute and chronic dietary exposure assessment and short and intermediate dermal and inhalation exposure, a quantitative risk assessment for calcium bisulfate is not necessary.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to calcium bisulfate, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from calcium bisulfate in food as follows:

Dietary exposure (food and drinking water) to calcium bisulfate may occur following ingestion of foods with residues from their use in accordance with this exemption. However, a quantitative dietary exposure

assessment was not conducted and is not necessary since a toxicological endpoint for risk assessment was not identified.

2. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

Calcium bisulfate may be used in pesticide products and non-pesticide products that may be used in and around the home. Based on the discussion above regarding the low toxicity of the calcium bisulfate, a quantitative residential exposure assessment was not conducted and is not necessary.

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

Based on the lack of toxicity in the available data, calcium bisulfate and its metabolites are not expected to share a common mechanism of toxicity with other chemicals. For the purposes of this action, therefore, EPA has assumed that calcium bisulfate do not have a common mechanism of toxicity with other substances.

D. Safety Factor for Infants and Children

Section 408(b)(2)(C) of the FFDCA requires EPA to retain an additional tenfold margin of safety in the case of threshold effects to ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. Based on the lack of threshold effects, EPA has not identified any toxicological endpoints of concern and is conducting a qualitative assessment of calcium bisulfate. The qualitative assessment does not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children.

E. Aggregate Risks and Determination of Safety

Taking into consideration all available information on calcium bisulfate, EPA has determined that there is a reasonable certainty that no harm to the general population or any population subgroup, including infants and children, will result from aggregate exposure to calcium bisulfate residues. Therefore, the establishment of exemptions from the requirement of a tolerance under 40 CFR 180.940(a) for residues of calcium bisulfate when used as an inert ingredient in antimicrobial pesticide formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils at a maximum end-use concentration of 2,000 ppm is safe under FFDCA section 408.

V. Other Considerations

Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of calcium bisulfate in or on any food commodities. EPA is establishing a limitation on the amount of calcium bisulfate that may be used in pesticide formulations. This limitation will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (''FIFRA''), 7 U.S.C. 136 *et seq.* EPA will not register any pesticide formulation for food use that exceeds 2,000 ppm calcium bisulfate in the final pesticide formulation.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180. 940(a) for calcium bisulfate when used as an inert ingredient (acidifying/buffering agent) in antimicrobial formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils under 40 CFR 180.940(a), limited to 2,000 ppm in the final formulation.

VII. Statutory and Executive Order Reviews

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

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

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

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

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal**

Register. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: November 1, 2021.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

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

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

■ 2. In § 180.940, in paragraph (a), amend table 180.940(a) by adding in alphabetical order an entry for the inert ingredient ''Calcium bisulfate'' to read as follows:

§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).

* * * * *

(a) * * *

TABLE 180.940(a)

Inert ingredients	CAS Reg. No.	Limits
* * * * * * *		
Calcium bisulfate		When ready for use, the end-use concentration is not to exceed 2,000 ppm.
* * * * * * *		

* * * * *

[FR Doc. 2021–24268 Filed 11–8–21; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 61

[Docket ID FEMA–2018–0026]

RIN 1660–AA95

National Flood Insurance Program: Conforming Changes To Reflect the Biggert-Waters Flood Insurance Reform Act of 2012 (BW–12) and the Homeowners Flood Insurance Affordability Act of 2014 (HFIAA), and Additional Clarifications for Plain Language; Correction

AGENCY: Federal Emergency Management Agency, Department of Homeland Security (DHS).

ACTION: Correcting amendment.

SUMMARY: On July 20, 2020, FEMA published in the **Federal Register** a final rule revising the National Flood Insurance Program (NFIP) regulations to codify certain provisions of the Biggert-Waters Flood Insurance Reform Act of 2012 and the Homeowner Flood Insurance Affordability Act of 2014, and to clarify certain existing NFIP rules relating to NFIP operations and the Standard Flood Insurance Policy. This document provides corrections to information provided in a table.

DATES: This correction is effective November 9, 2021.

ADDRESSES: The docket for this rulemaking is available for inspection using the Federal eRulemaking Portal at *https://www.regulations.gov* and can be viewed by following that website's instructions.

FOR FURTHER INFORMATION CONTACT: Kelly Bronowicz, Director, Policyholder Services Division, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 400 C Street SW, Washington, DC 20472, (202) 557–9488.

SUPPLEMENTARY INFORMATION: On July 20, 2020, FEMA published in the **Federal Register** a final rule revising the National Flood Insurance Program (NFIP) regulations to codify certain provisions of the Biggert-Waters Flood Insurance Reform Act of 2012 and the Homeowner Flood Insurance Affordability Act of 2014, and to clarify certain existing NFIP rules relating to NFIP operations and the Standard Flood Insurance Policy. In 44 CFR 61.6(a), Table 1, ''Maximum Amounts of Coverage Available,'' contained two inadvertently placed asterisks next to ''Non-Residential Building'' in the ''Building Coverage'' heading. The ''**'' denotes that the maximum amount of coverage for Non-Residential Buildings in Alaska, Guam, and Hawaii is $150,000.00. However, the presence of ''**'' was an error, as 42 U.S.C. 4013 contains no such maximum. Accordingly, this correction removes the incorrectly-placed ''**''.

List of Subjects in 44 CFR Part 61

Flood insurance, Reporting and recordkeeping requirements.

For the reasons set forth above, 44 CFR part 61 is corrected by making the following correcting amendment:

PART 61—INSURANCE COVERAGE AND RATES

■ 1. The authority citation for part 61 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.;* 6 U.S.C. 101 *et seq.*

■ 2. In § 61.6, amend table 1 to paragraph (a) under the heading ''Building Coverage'' by revising the entry ''Non-Residential Building'' to read as follows:

§ 61.6 Maximum amounts of coverage available.

(a) * * *

TABLE 1 TO PARAGRAPH (a)—MAXIMUM AMOUNTS OF COVERAGE AVAILABLE [1]

Occupancy	Emergency program	Regular program
	Amount	Amount
Building Coverage		
* * * * * * *		
Non-Residential Building	100,000	$500,000
* * * * * * *		

[1] This Table provides the maximum coverage amounts available under the Emergency Program and the Regular Program, and the columns cannot be aggregated to exceed the limits in the Regular Program, which are established by statute. The aggregate limits for building coverage are the maximum coverage amounts allowed by statute for each building included in the relevant Occupancy Category.

* * * * *

Deanne B. Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2021–24489 Filed 11–8–21; 8:45 am]

BILLING CODE 9111–52–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Parts 393 and 396

[Docket No. FMCSA–2019–0211]

RIN 2126–AC31

Parts and Accessories Necessary for Safe Operation; Rear Impact Guards and Rear Impact Protection

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: FMCSA amends the Federal Motor Carrier Safety Regulations (FMCSRs) to include rear impact guards on the list of items that must be examined as part of the required annual inspection for each commercial motor vehicle (CMV). In addition, FMCSA amends the labeling requirements for rear impact guards, and excludes road construction controlled (RCC) horizontal discharge trailers from the rear impact guard requirements, consistent with changes made by the National Highway Traffic Safety Administration (NHTSA) to the corresponding Federal Motor Vehicle Safety Standards (FMVSS). This final rule responds to rulemaking petitions, as well as a recommendation from the Government Accountability Office (GAO).

DATES: This final rule is effective December 9, 2021.

FOR FURTHER INFORMATION CONTACT: Mr. Luke Loy, Vehicle and Roadside Operations, Office of Carrier, Driver, and Vehicle Safety, FMCSA, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, (202) 366–0676, *luke.loy@dot.gov.* If you have questions on viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION: FMCSA organizes this final rule as follows:

I. Availability of Rulemaking Documents

To view any documents mentioned as being available in the docket, go to *https://www.regulations.gov/docket/FMCSA-2019-0211/document* and choose the document to review. To view comments, click this final rule, and click ''Browse Comments.'' If you do not have access to the internet, you may view the docket online by visiting Dockets Operations in Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

II. Executive Summary

Section 393.86 of the FMCSRs, ''Rear impact guards and rear end protection,'' requires rear impact guards to be installed on most CMVs to reduce the incidence of passenger compartment intrusion during underride crashes in which a passenger vehicle strikes the rear of the CMV. Regulations requiring rear impact guards have been in the FMCSRs since 1952. The FMCSRs require that all CMVs be systematically inspected, repaired, and maintained to ensure that all required parts and accessories—including rear impact guards—are in safe and proper operating condition at all times (§ 396.3(a)(1)). Operation of a CMV with a missing or noncompliant rear impact guard is a violation of the FMCSRs.

Every CMV must be inspected at least once every 12 months. 49 CFR 396.17. A motor carrier may not use a CMV unless each component identified in Appendix A to Part 396, Code of Federal Regulations, ''Minimum Periodic Inspection Standards,'' has passed the required annual inspection. While the FMCSRs have required rear impact guards for more than 65 years, they have not been included on the list of components in Appendix G that must be inspected during the annual CMV inspection. This means that a vehicle can pass an annual inspection with a missing or damaged rear impact guard.

In response to petitions from the Commercial Vehicle Safety Alliance (CVSA) and Jerry and Marianne Karth

(''the Karths'' [1]), a recommendation included in GAO Report GAO–19–264, ''Truck Underride Guards: Improved Data Collection, Inspections, and Research Needed,'' [2] and Congressional correspondence,[3] this final rule amends the FMCSRs to include rear impact guards on the list of items that must be examined as part of the required annual inspection for each CMV.

NHTSA published two final rules on November 19, 2004, relating to rear impact guards. First, NHTSA amended the labeling requirement in FMVSS No. 223, ''Rear impact guards,'' to permit the rear impact guard certification label to be mounted on either the forward- or rearward-facing surface of the horizontal member of the guard, provided the label does not interfere with the retroreflective sheeting required by the FMVSS (69 FR 67660).[4] Prior to the amendment, the certification label was required to be mounted on the forward-facing surface of the horizontal member, 12 inches inboard of the right end of the guard. Second, NHTSA amended the applicability section of FMVSS No. 224, ''Rear impact protection,'' to exclude RCC horizontal discharge semitrailers from the requirements of the standard (69 FR 67663).[5] NHTSA concluded that installation of rear impact guards on RCC horizontal discharge trailers would interfere with the intended function of the trailers and was therefore impracticable due to the unique design and purpose of those vehicles. However, neither of NHTSA's November 2004 amendments to the FMVSS was incorporated into the corresponding rear impact requirements in section 393.86 of the FMCSRs. FMCSA amends the FMCSRs to adopt the changes above to maintain consistency with FMVSS Nos. 223 and 224.

This final rule does not result in incremental costs or benefits beyond the baseline established in the FMCSRs. Although rear impact guards are not currently among the items that must be examined during annual inspections, 49 CFR 393.86 requires that certain CMVs operated in interstate commerce be equipped with the devices, and 49 CFR 396.3(a) requires that parts and accessories, including rear impact guards, remain in safe and proper operating conditions at all times. Therefore, for the purposes of assessing the economic impact of this final rule on motor carriers, the Agency assumes compliance as part of the baseline established by the existing FMCSRs in section 393.86. Neither the labeling requirements resulting from this final rule, nor the exclusion of RCC horizontal discharge semitrailers from these requirements, will result in incremental costs or benefits.

III. Legal Basis for the Rulemaking

This rulemaking is based on the authority of the Motor Carrier Act of 1935 (1935 Act) and the Motor Carrier Safety Act of 1984 (1984 Act). The 1935 Act, as amended, provides that ''[t]he Secretary of Transportation may prescribe requirements for—(1) qualifications and maximum hours of service of employees of, and safety of operation and equipment of, a motor carrier; and (2) qualifications and maximum hours of service of employees of, and standards of equipment of, a private motor carrier, when needed to promote safety of operation'' (49 U.S.C. 31502(b)). This final rule amends the FMCSRs to respond to petitions for rulemaking. The adoption and enforcement of such rules is specifically authorized by the 1935 Act. This final rule rests squarely on that authority.

The 1984 Act provides concurrent authority to regulate drivers, motor carriers, and vehicle equipment. It requires the Secretary to ''prescribe regulations on commercial motor vehicle safety.'' The regulations shall prescribe minimum safety standards for CMVs. At a minimum, the regulations shall ensure that: (1) CMVs are maintained, equipped, loaded, and operated safely; (2) the responsibilities imposed on operators of CMVs do not impair their ability to operate the vehicles safely; (3) the physical condition of operators of CMVs is adequate to enable them to operate vehicles safely; (4) the operation of CMVs does not have a deleterious effect on the physical condition of the operators; and (5) drivers are not coerced by motor carriers, shippers, receivers, or transportation intermediaries to operate a vehicle in violation of a regulation promulgated under 49 U.S.C. 31136 (which is the basis for much of the FMCSRs) or 49 U.S.C. chapters 51 or 313 (49 U.S.C. 31136(a)(5)).

This final rule concerns parts and accessories necessary for the safe operation of CMVs, and the inspection, repair, and maintenance of CMVs. It is based on section 31136(a)(1) because it deals with CMV maintenance of rear impact guards. The final rule does not address the driver-centered requirements of sections 31136(a)(2)–(4). As the amendments adopted by this final rule are primarily technical changes that clarify existing requirements and improve enforcement consistency, FMCSA believes there will be stakeholder support for this initiative and that coercion to violate the amendments, which is already prohibited by section 31136(a)(5), will not be an issue.

Before prescribing any such regulations, FMCSA must consider the ''costs and benefits'' of any proposal (49 U.S.C. 31136(c)(2)(A) and 31502(d)). As discussed in greater detail in the ''Regulatory Analyses'' section, FMCSA has determined that this final rule is not a significant regulatory action.

IV. Background

A. History of Rear Impact Guard Requirements

The first Federal requirements concerning heavy vehicle rear underride protection were issued in 1952 by the Bureau of Motor Carriers of the Interstate Commerce Commission (ICC). The regulation required all heavy trucks, trailers, and semitrailers manufactured after December 31, 1952, to be equipped with a rear-end protection device designed to help prevent underride. The rule required that the ground clearance of the underride guard be no more than 30 inches when the vehicle is empty. The rule also required that the underride guard be located no more than 24 inches forward of the rear of the vehicle and extend laterally to within 18 inches of each side. The underride device was required to be ''substantially constructed and firmly attached'' (17 FR 4445, May 15, 1952). The ICC's authority over motor carrier safety was transferred to DOT by Section 6(e)(6)(C) of the Department of Transportation Act (Pub. L. 89–670, 80 Stat. 931, 939–940, Oct. 15, 1966). The authority was delegated by the Secretary to the Federal Highway Administration (FHWA).

NHTSA was established in 1970 and authorized to prescribe safety standards for motor vehicles and motor vehicle equipment in interstate commerce, *i.e.,* the FMVSS applicable to vehicle and equipment manufacturers. On January

[1] Copies of the petitions from CVSA and the Karths are available online at *https://www.regulations.gov/docket?D=FMCSA-2019-0211* and in Dockets Operations.

[2] A copy of the GAO Report is available in the docket for this final rule.

[3] A copy of the letter is in the docket for this final rule.

[4] You may view the NHTSA rule online at *https://www.federalregister.gov/documents/2004/11/19/04-25704/federal-motor-vehicle-safety-standards-rear-impact-guard-labels.*

[5] RCC horizontal discharge trailers are used in the road construction industry to deliver asphalt to construction sites and gradually discharge asphalt mix into the paving machines overlaying the road surface. Federal Motor Vehicle Safety Standards; Rear Impact Guards; Final Rule, 69 FR 67663 (Nov. 19, 2004). You may view the NHTSA rule online at *https://www.federalregister.gov/documents/2004/11/19/04-25703/federal-motor-vehicle-safety-standards-rear-impact-guards-final-rule.*

24, 1996, NHTSA published a final rule creating FMVSS Nos. 223 and 224 (61 FR 2004). The requirements apply to most trailers and semitrailers with a gross vehicle weight rating of 4,536 kg (10,000 pounds) or more, manufactured on or after January 26, 1998.

FMVSS No. 223 specifies requirements that rear impact guards must meet before they can be installed on new trailers or semitrailers. It specifies strength and energy absorption requirements, as well as test procedures that manufacturers and NHTSA will use to determine compliance with the standard. The standard also requires the guard manufacturer to permanently label the impact guard to certify that it meets the requirements, and to provide instructions on the proper installation of the guard.

FMVSS No. 224 requires that most new trailers and semitrailers with a GVWR of 4,536 kg (10,000 pounds) or more be equipped with a rear impact guard meeting the requirements of FMVSS No. 223. The guards must extend laterally to within 4 inches of the sides of the trailer, have a ground clearance of no more than 22 inches, and be placed as close as possible to, but not more than 12 inches from, the rear of the vehicle. To ensure that the guard will perform properly, the standard also requires it to be mounted on the trailer or semitrailer in accordance with the installation instructions provided by the guard manufacturer.

On September 1, 1999, FHWA published a final rule amending the FMCSRs to require trailers and semitrailers manufactured on or after January 26, 1998, with a GVWR of 4,536 kg (10,000 pounds) or more, be equipped with rear impact guards that meet the requirements of FMVSS No. 223. The rear impact guards must be installed to ensure that the trailer or semitrailer meets the rear end protection requirements of FMVSS No. 224. This rule was intended to ensure that the rear impact protection requirements of the FMCSRs are consistent with the FMVSS (64 FR 47703).

As stated previously, NHTSA published two final rules on November 19, 2004, relating to rear impact guards. NHTSA amended the labeling requirement in FMVSS No. 223 to permit the rear impact guard certification label to be mounted on either the forward- or rearward-facing surface of the horizontal member of the guard (69 FR 67660), and amended the applicability section of FMVSS No. 224 to exclude RCC horizontal discharge semitrailers from the requirements of the standard (69 FR 67663). However, neither of NHTSA's November 2004 amendments to the FMVSS was incorporated into the corresponding rear impact requirements in section 393.86 of the FMCSRs.

B. History of Appendix A Requirements

Section 210 of the 1984 Act required the Secretary of Transportation to establish standards for the annual or more frequent (*i.e.,* periodic) inspection of all CMVs engaged in interstate or foreign commerce (49 U.S.C. 31142(b)). In response, FHWA adopted new section 396.17 on December 7, 1988, which requires all CMVs to be inspected at least once every 12 months (53 FR 49380, as amended on Dec. 8, 1989 (54 FR 50722)). In establishing specific criteria for the newly required annual inspection, FHWA looked to inspection criteria that had been developed based on the specifications in part 393, notably (1) the CVSA vehicle out-of-service criteria and (2) the vehicle portion of the FHWA National Uniform Driver-Vehicle Inspection Procedure (NUD–VIP). FHWA decided to use the vehicle portion of the NUD–VIP as the criteria for successful completion of the annual inspection, and in the December 1988 rule, established Appendix G to the FMCSRs as the minimum periodic inspection standards for § 396.17. FHWA noted that utilization of the FHWA NUD–VIP would (1) provide the necessary inspection-related pass/fail criteria for the periodic inspection at a more stringent level than the vehicle out-of-service criteria, and (2) provide the proper level of Federal oversight in establishing and revising the criteria. On October 14, 2021, the final rule titled, ''Federal Motor Carrier Safety Regulations; General Technical, Organizational, Conforming, and Correcting Amendments'' (86 FR 57060) redesignated Appendix G to Subchapter B of Chapter III as Appendix A to Part 396.

V. Discussion of Proposed Rulemaking and Comments

A. Background and Proposed Rulemaking

Rear Impact Guards in Appendix A.[6] In its petition, CVSA requested that the Agency amend Appendix G to include specific language regarding the inspection of rear impact guards during annual inspections. The petition stated:

> A vehicle's rear impact guard/rear end protection is inspected roadside as part of the North American Standard Inspection Program. However, the majority of commercial motor vehicles do not come into contact with an inspector on an annual basis. . . .
>
> According to data available through FMCSA's Analysis and Information Online web page, in fiscal year 2017 inspectors document[ed] more than 2,300 violations related to rear impact guards and rear end protection, more than half of which are for components that are missing, damaged or improperly constructed. Including rear impact guards and rear end protection in the periodic inspection requirements in Appendix G will call additional attention to this critical safety component and help ensure that each vehicle is checked at least once a year, improving compliance and helping to prevent fatalities and injuries when rear-end collisions occur. Furthermore, including rear impact guards and rear end protection in the periodic annual inspection standards will harmonize U.S. regulations with those in Canada and Mexico, which include rear impact guards and rear end protection as part of their annual inspection programs.

The Karths' petition requested that FMCSA ''[a]dd underride guards to Appendix [A] and 396.17 (Periodic Inspection).''

In addition, several Senators asked GAO to review data on truck underride crashes and information on underride guards. Between January 2018 and March 2019, GAO conducted a performance audit that included a literature review and interviews with stakeholders familiar with underride crashes and guards.

GAO Report GAO–19–264, published in March 2019, examines (1) the data that DOT reports on underride crashes, and (2) the development and use of underride guard technologies in the United States. GAO analyzed DOT's underride crash data for 2008 through 2017; reviewed NHTSA's proposed regulations and research on new guard technologies (80 FR 78418, Dec. 16, 2015); and interviewed stakeholders including DOT officials, industry and safety groups, and State officials.

With respect to FMCSA, GAO concluded that the lack of an annual inspection requirement for rear impact guards potentially affects the safety of the traveling public and FMCSA's ability to achieve its safety mission. GAO stated that ''without explicitly including the inspection of the rear guard in Appendix G, there is no assurance that rear guards in operation will be inspected at least annually to ensure they perform as designed to prevent or mitigate an underride crash.'' In its ''Recommendations for Executive Action,'' GAO stated:

[6] At the time of the petitions for rulemaking, the GAO report, and publication of the NPRM, Appendix A to Part 396 was codified as Appendix G to Subchapter B of Chapter III. Therefore, those petitions and the comments on the NPRM refer to Appendix G. However, this final rule discusses them as referring to Appendix A.

The Administrator of the Federal Motor Carrier Safety Administration should revise Appendix [A] of the agency's regulations to require that rear guards are inspected during commercial vehicle annual inspections. (Recommendation 3)

While the GAO review was being conducted, a group of Senators urged the Agency to ''add 'underride guards' to the list of annual inspection items required [for] trucks and trailers under current periodic inspection regulations.'' The Senators stated:

Requiring an annual inspection of rear underride guards, in addition to the current list of items already checked during annual inspections, would ensure trucks and trailers are complying with regulations already on the books. Therefore, we ask that FMCSA consider initiating a rulemaking to amend federal Minimum Periodic Inspection Standards to include a subsection on ''underride guards.'' Should you decide to move forward with this rulemaking, we respectfully request that an inserted subsection be identical to the already mandated minimum standards of rear impact guards and rear end protection.

FMCSA published a notice of proposed rulemaking (NPRM) on December 29, 2020 (85 FR 85571). In the NPRM, FMCSA proposed to amend then Appendix G to Subchapter B of Chapter III, now Appendix A to Part 396, ''Minimum Periodic Inspection Standards,'' by adding rear impact guards to the list of items required to be inspected pursuant to § 396.17 as part of the required annual inspection for each CMV. FMCSA proposed to amend § 393.86(a)(6) to clarify that the certification label may be on the forward- or rear-facing surface of the horizontal member of the guard, provided it does not interfere with the retroreflective sheeting required by the FMVSS. FMCSA also proposed to amend (1) § 393.5 to add a definition of *road construction controlled horizontal discharge trailer* consistent with the NHTSA definition in FMVSS No. 224, and (2) §§ 393.86(a)(1) and 393.86(b)(1) to make it clear that RCC horizontal discharge trailers are not required to have a rear impact guard installed, consistent with the amendments made by NHTSA in 2004.

Although neither of NHTSA's November 2004 amendments had been incorporated into the rear impact requirements in section 393.86, FMCSA stated in the NPRM that it was not aware of any enforcement or compliance issues with respect to these items in the ensuing 15 years. As such, FMCSA stated that it did not expect the proposed amendments to have any impact on motor carriers.

B. Comments and Responses

FMCSA solicited comments to the NPRM for a 60-day period, ending on March 1, 2021. The Agency received a total of 23 comments from the following parties: The Academy of Truck Accident Attorneys, Advocates for Highway and Auto Safety, the American Trucking Associations (ATA), the CVSA, the Institute for Safer Trucking, the Law Firm for Truck Safety, the Owner-Operator Independent Drivers Association (OOIDA), the National Association of Trailer Manufacturers (NATM), the National Automobile Dealers Association (NADA), the Truck Trailer Manufacturers Association (TTMA), the Truckload Carriers Association, and 12 individuals (Lois Durso, Stephen Eimers, Cathy Forman, Mark Hawkins, Eric Hein, Jerry and Marianne Karth, Sulev Oun, Michael Poplaski, Roderick Throgmorton, and three anonymous commenters).

1. Rear Impact Guards in Appendix A. All commenters supported the proposal to amend Appendix G to require rear impact guards to be inspected as part of the annual inspection required under section 396.17, and this rule adopts the amendments largely as proposed in the NPRM.

TTMA suggested alternative language from that proposed in the NPRM to clarify certain elements in Appendix A.

TTMA stated that the phrase ''not securely attached'' in the proposed 15.a.2 of Appendix A ''is vague and insufficient to catch many unsafe, damaged or improperly repaired guards.'' TTMA suggested that the inspection should not allow ''broken or missing fasteners, cracked welds, corrosion that evidences any loss of original or parent material, bends that indicate prior impact damage not yet repaired, or asymmetrical repairs indicating the use [of] non-OEM approved components.''

FMCSA response: FMCSA agrees that the proposed language was somewhat broad, and—consistent with other sections of Appendix A—has amended the language of 15.a.2 to include examples of specific conditions that could constitute ''not securely attached.'' FMCSA emphasizes that the amended language is not an all-inclusive list, and that motor carriers will have discretion to determine that a guard is not securely attached (and thus, needs to be repaired/replaced) as a result of other conditions observed during the annual inspection.

TTMA stated that the phrase ''and not beyond'' in the proposed 15.a.3 of Appendix A ''is vague and could refer to either 'the side extremity of the trailer' or to the point 4 inches inboard.'' To avoid confusion, TTMA suggested using the phrase ''. . . and not beyond the side extremity of the trailer.''

FMCSA response: FMCSA agrees, and has amended the language of 15.a.3 to make it clear that the guard must extend to within 4 inches of the side extremity of the vehicle, but may not extend beyond the side extremity of the vehicle.

TTMA stated that the proposed language in 15.a.4–6 and 15.b.4–5 of Appendix A starts with ''Guard,'' and since the guard is the whole system including the uprights, horizontal member, and attachments, TTMA suggested that ''Guard'' should more appropriately be ''Guard horizontal member'' in these sections.

FMCSA response: FMCSA agrees, and has amended the language as suggested. (FMCSA notes that this applies to 15.a.3–6, as opposed to 15.a.4–6, and to 15.b.3–5, as opposed to 15.b.4–5, respectively).

2. Rear Impact Guard Labeling. Most commenters supported the NPRM proposal to amend the labeling requirements in § 393.86(a)(6) to be consistent with the changes made by NHTSA in 2004.

While ATA supported the proposed amendment to make the FMCSR labeling requirement consistent with the corresponding FMVSS labeling requirement, it noted support for a CVSA petition for rulemaking submitted to FMCSA requesting that the rear impact guard labeling requirement be removed from section 393.86(a)(6) of the FMCSRs. CVSA and NADA opposed the proposed amendment, and both recommended that FMCSA instead eliminate the labeling requirement.

FMCSA response: As noted in the NPRM, the proposal to amend the labeling requirement in section 393.86(a)(6) was simply an action to make the labeling requirement in the FMCSRs consistent with a change made to the corresponding FMVSS by NHTSA in 2004. While CVSA has submitted petitions for rulemaking to both FMCSA and NHTSA requesting elimination of the labeling requirement for rear impact guards, FMCSA action on that petition is outside the scope of this rulemaking and will be addressed separately.

3. Applicability—RCC Horizontal Discharge Trailers. Most commenters supported the NPRM proposal to add a definition of *road construction controlled horizontal discharge trailer,* and to make it clear that RCC horizontal discharge trailers are not required to have a rear impact guard installed,

consistent with the amendments made by NHTSA in 2004.

The Law Firm for Truck Safety opposed the proposal to exclude RCC horizontal discharge trailers from the requirement to have a rear impact guard, stating that ''NHTSA is wrong to have amended the applicability section of FMVSS No. 224, 'Rear impact protection,' to exclude RCC horizontal discharge semitrailers from the requirements of the standard.'' The commenter noted that there are rear impact guards on various trucks in Europe ''that this rule making is attempting to exclude.''

FMCSA response: As noted in the NPRM, the proposal to exclude RCC horizontal discharge trailers from the requirement to have a rear impact guard installed was simply an action to make the applicability requirements in the FMCSRs consistent with those made via an amendment to the FMVSS made by NHTSA in 2004. Any action to remove RCC horizontal discharge trailers from the list of excluded vehicles in FMVSS No. 224 would have to be done by NHTSA through a notice and comment rulemaking proceeding and is outside the scope of this rulemaking.

4. Other comments. In addition to comments on the proposed amendments to Appendix A, labeling, and RCC horizontal discharge trailers, FMCSA also received comments regarding a wide range of other issues relating to underride protection, including (a) enhanced strength requirements for rear impact guards, (b) the lack of regulations for side underride protection, (c) rear impact protection for single unit trucks, (d) the recommendations from the GAO Report, and (e) automatic emergency braking. All these issues are outside of the scope of this rulemaking.

VI. International Impacts

The FMCSRs, and any exceptions to the FMCSRs, apply only within the United States (and, in some cases, U.S. territories). Motor carriers and drivers are subject to the laws and regulations of the countries in which they operate, unless an international agreement states otherwise. Drivers and carriers should be aware of the regulatory differences among nations.

VII. Section-by-Section Analysis

A. Part 393—Parts and Accessories Necessary for Safe Operation

§ 393.5 Definitions

FMCSA amends this section by adding a definition of *Road construction controlled horizontal discharge trailer.*

§ 393.86(a)(1) General Requirements for Trailers and Semitrailers Manufactured on or After January 26, 1998

FMCSA amends this section by adding RCC horizontal discharge trailers to the list of vehicles that are not required to have a rear impact guard.

§ 393.86(a)(6) Certification and Labeling Requirements for Rear Impact Protection Guards

FMCSA amends this section to clarify that the label may be on the forward- or rear-facing surface of the horizontal member of the guard, provided it does not interfere with the retroreflective sheeting required by the FMVSS.

§ 393.86(b)(1) Requirements for Motor Vehicles Manufactured After December 31, 1952 (Except Trailers or Semitrailers Manufactured on or After January 26, 1998)

FMCSA amends this section by adding RCC horizontal discharge trailers to the list of vehicles that are not required to have a rear impact guard.

B. Appendix A to Part 396 Minimum Periodic Inspection Standards

FMCSA amends Appendix A by adding rear impact guards to the list of items required to be inspected pursuant to § 396.17.

VIII. Regulatory Analyses

A. Executive Order (E.O.) 12866 (Regulatory Planning and Review), E.O. 13563 (Improving Regulation and Regulatory Review), and DOT Regulatory Policies and Procedures

FMCSA has considered the impact of this final rule under E.O. 12866 (58 FR 51735, Oct. 4, 1993), Regulatory Planning and Review, E.O. 13563 (76 FR 3821, Jan. 21, 2011), Improving Regulation and Regulatory Review, and DOT's regulatory policies and procedures. The Office of Information and Regulatory Affairs within the Office of Management and Budget (OMB) determined that this final rulemaking is not a significant regulatory action under section 3(f) of E.O. 12866, as supplemented by E.O. 13563, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. Accordingly, OMB has not reviewed it under that E.O.

In response to rulemaking petitions and a recommendation from the GAO, FMCSA amends Appendix G to Subchapter B of Chapter III in 49 CFR. This amendment adds rear impact guards to the list of items that must be examined as part of the required annual inspection for each CMV.

Section 393.86(a) currently requires most trailers and semitrailers manufactured on or after January 26, 1998, to be equipped with rear impact guards. This final rule does not require installation or maintenance of rear impact guards beyond the current requirements in section 393.86.

This final rule does not result in incremental costs or benefits beyond the baseline established in the FMCSRs. As required by 49 CFR 396.17, motor carriers currently complete annual inspections of all items identified in Appendix G. FMCSA assumes that motor carriers currently review rear impact guards in their annual inspection programs to remain in compliance with the current requirements in 49 CFR 396.3(a)(1), which states that parts and accessories, including rear impact guards, must be in safe and proper operating conditions at all times. Additionally, CMVs are subject to inspections conducted in accordance with the CVSA's North American Standard Inspection Program that may occur throughout the year, which include the examination of rear impact guards. According to data contained in the Motor Carrier Management Information System (MCMIS), most motor carriers comply with 49 CFR 396.3(a)(1). Specifically, there were approximately 2.1 million vehicle roadside inspections conducted in the United States in 2019, and there were approximately 3.1 million vehicle violations cited during those inspections. Only 3,189—or about 0.103 percent—were rear impact guard violations.[7]

FMCSA also makes two minor changes to maintain consistency between the FMCSRs and NHTSA's FMVSS Nos. 223 and 224. As described above, these changes provide consistent labeling requirements and exclude RCC horizontal discharge semitrailers from the requirements of this standard. These administrative changes do not result in incremental impacts.

B. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801–808), the Office of Information and Regulatory Affairs designated this rule as not a ''major rule.'' [8]

[7] Data Source: MCMIS data snapshot as of 5/28/2021, including current year-to-date information for CY 2021. The data presented are accurate as of the date listed, but are subject to update as new or additional information may be reported to MCMIS following the snapshot date.

[8] A ''major rule'' means any rule that OMB finds has resulted in or is likely to result in (a) an annual effect on the economy of $100 million or more; (b) a major increase in costs or prices for consumers,

Continued

C. Regulatory Flexibility Act (Small Entities)

The Regulatory Flexibility Act of 1980 (RFA) (5 U.S.C. 601 *et seq.*) requires Federal agencies to consider the effects of their regulatory actions on small businesses and other small entities and to minimize any significant economic impact. The term *small entities* comprises small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields and governmental jurisdictions with populations of less than 50,000 (5 U.S.C. 601(6)). Accordingly, DOT policy requires an analysis of the impact of all regulations on small entities and mandates that agencies strive to lessen any adverse effects on these businesses.

Small entity is defined in 5 U.S.C. 601(3) as having the same meaning *small business concern* under Section 3 of the Small Business Act. This includes any small business concern that is independently owned and operated and is not dominant in its field of operation. Section 601(4), likewise, includes within the definition of ''small entities'' not-for-profit enterprises that are independently owned and operated and are not dominant in their fields of operation. In addition, Section 601(5) defines *small entities* as governments of cities, counties, towns, townships, villages, school districts, or special districts with populations less than 50,000. The Small Business Administration develops the size standards used to classify entities as small, and establishes separate standards for each industry, as defined by the North American Industry Classification System. The motor carriers affected by this final rule fall into many different industry codes with differing size standards. Because this final rule impacts all motor carriers, including those considered to be small entities, this rule will impact a substantial number of small entities.

However, FMCSA has determined that this final rule does not have a significant impact on the affected entities. This final rule requires motor carriers to include rear impact guards on the list of items that must be examined as part of the required annual CMV inspection. FMCSA believes that motor carriers have been inspecting the rear impact guards on their CMVs to remain in compliance with requirements that have been in the FMCSRs since 1952. As such, this final rule does not have incremental impacts on the affected entities. The two minor changes to maintain consistency between the FMCSRs and NHTSA's FMVSS Nos. 223 and 224 do not result in incremental impacts. The impacts of this final rule are de minimis, and therefore, the final rule does not have a significant economic impact on a substantial number of small entities.

Consequently, I certify that the final rule does not have a significant economic impact on a substantial number of small entities.

D. Assistance for Small Entities

In accordance with section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996,[9] FMCSA wants to assist small entities in understanding this final rule so that they can better evaluate its effects on themselves and participate in the rulemaking initiative. If the final rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

Small businesses may send comments on the actions of Federal employees who enforce or otherwise determine compliance with Federal regulations to the Small Business Administration's Small Business and Agriculture Regulatory Enforcement Ombudsman (Office of the National Ombudsman, see *https://www.sba.gov/about-sba/oversight-advocacy/office-national-ombudsman*) and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of FMCSA, call 1–888–REG–FAIR (1–888–734–3247). DOT has a policy regarding the rights of small entities to regulatory enforcement fairness and an explicit policy against retaliation for exercising these rights.

E. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) (UMRA) 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 $170 million (which is the value equivalent of $100,000,000 in 1995, adjusted for inflation to 2020 levels) or more in any one year. Though this final rule would not result in such an expenditure, and the analytical requirements of UMRA do not apply as a result, the Agency discusses the effects of this rule elsewhere in this preamble.

F. Paperwork Reduction Act

This final rule contains no new information collection under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

G. Executive Order 13132 (Federalism)

A rule has implications for federalism under Section 1(a) of Executive Order 13132 if it has ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' FMCSA determined that this final rule does not have substantial direct costs on or for States, nor does it limit the policymaking discretion of States. Nothing in this document preempts any State law or regulation. Therefore, this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Impact Statement.

H. Privacy

The Consolidated Appropriations Act, 2005,[10] requires the Agency to assess the privacy impact of a regulation that will affect the privacy of individuals. This rule would not require the collection of personally identifiable information (PII).

The Privacy Act (5 U.S.C. 552a) applies only to Federal agencies and any non-Federal agency that receives records contained in a system of records from a Federal agency for use in a matching program.

The E-Government Act of 2002,[11] requires Federal agencies to conduct a PIA for new or substantially changed technology that collects, maintains, or disseminates information in an identifiable form. No new or substantially changed technology will collect, maintain, or disseminate information as a result of this rule. Accordingly, FMCSA has not conducted a PIA.

In addition, the Agency submitted a Privacy Threshold Assessment to evaluate the risks and effects the proposed rulemaking might have on

individual industries, geographic regions, Federal, State, or local government agencies; or (c) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets (49 CFR 389.3).

[9] Public Law 104–121, 110 Stat. 857, (Mar. 29, 1996).

[10] Public Law 107–347, sec. 208, 116 Stat. 2899, 2921 (Dec. 17, 2002).

[11] Public Law 108–447, 118 Stat. 2809, 3268, note following 5 U.S.C. 552a (Dec. 4, 2014).

collecting, storing, and sharing personally identifiable information. The DOT Privacy Office has determined that this rulemaking does not create privacy risk.

I. Executive Order 13175 (Indian Tribal Governments)

This final 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.

J. National Environmental Policy Act of 1969

FMCSA analyzed this final rule pursuant to the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and determined this action is categorically excluded from further analysis and documentation in an environmental assessment or environmental impact statement under FMCSA Order 5610.1 (69 FR 9680, March 1, 2004), Appendix 2, paragraph (aa). The Categorical Exclusion (CE) in paragraph (aa) covers regulations requiring motor carriers, their officers, drivers, agents, representatives, and employees directly in control of CMVs to inspect, repair, and provide maintenance for every CMV used on a public road. The requirements adopted in this rule are covered by this CE and the final rule does not have any effect on the quality of the environment.

List of Subjects in 49 CFR Part 393

Highway safety, Motor carriers, Motor vehicle safety, Reporting and recordkeeping requirements.

In consideration of the foregoing, FMCSA amends 49 CFR part 393 and Appendix G to Subchapter B of Chapter III as follows:

PART 393—PARTS AND ACCESSORIES NECESSARY FOR SAFE OPERATION

■ 1. The authority citation for part 393 continues to read as follows:

Authority: 49 U.S.C. 31136, 31151, and 31502; sec. 1041(b) of Pub. L. 102–240, 105 Stat. 1914, 1993 (1991); sec. 5301 and 5524 of Pub. L. 114–94, 129 Stat. 1312, 1543, 1560; and 49 CFR 1.87.

■ 2. Amend § 393.5 by adding a definition for *Road construction controlled horizontal discharge trailer* in alphabetical order to read as follows:

§ 393.5 Definitions.

* * * * *

Road construction controlled horizontal discharge trailer means a trailer or semitrailer that is equipped with a mechanical drive and a conveyor to deliver asphalt and other road building materials, in a controlled horizontal manner, into a lay down machine or paving equipment for road construction and paving operations.

* * * * *

■ 3. In § 393.86 revise paragraphs (a)(1), (a)(6) introductory text, and (b)(1) introductory text to read as follows:

§ 393.86 Rear impact guards and rear end protection.

(a)(1) *General requirements for trailers and semitrailers manufactured on or after January 26, 1998.* Each trailer and semitrailer with a gross vehicle weight rating of 4,536 kg (10,000 pounds) or more, and manufactured on or after January 26, 1998, must be equipped with a rear impact guard that meets the requirements of Federal Motor Vehicle Safety Standard No. 223 (49 CFR 571.223) in effect at the time the vehicle was manufactured. When the rear impact guard is installed on the trailer or semitrailer, the vehicle must, at a minimum, meet the requirements of FMVSS No. 224 (49 CFR 571.224) in effect at the time the vehicle was manufactured. The requirements of paragraph (a) of this section do not apply to pole trailers (as defined in § 390.5 of this chapter); pulpwood trailers, low chassis vehicles, special purpose vehicles, wheels back vehicles, and road construction controlled horizontal discharge trailers (as defined in § 393.5); and trailers towed in driveaway-towaway operations (as defined in § 390.5).

* * * * *

(6) *Certification and labeling requirements for rear impact protection guards.* Each rear impact guard used to satisfy the requirements of paragraph (a)(1) of this section must be permanently marked or labeled as required by FMVSS No. 223 (49 CFR 571.223, S5.3). The label shall be placed on the forward or rearward facing surface of the horizontal member of the guard, provided that the label does not interfere with the retroreflective sheeting required by S5.7.1.4.1(c) of FMVSS No. 108 (49 CFR 571.108), and is readily accessible for visual inspection. The certification label must contain the following information:

* * * * *

(b)(1) *Requirements for motor vehicles manufactured after December 31, 1952 (except trailers or semitrailers manufactured on or after January 26, 1998).* Each motor vehicle manufactured after December 31, 1952, (except truck tractors, pole trailers, pulpwood trailers, road construction controlled horizontal discharge trailers, or vehicles in driveaway-towaway operations) in which the vertical distance between the rear bottom edge of the body (or the chassis assembly if the chassis is the rearmost part of the vehicle) and the ground is greater than 76.2 cm (30 inches) when the motor vehicle is empty, shall be equipped with a rear impact guard(s). The rear impact guard(s) must be installed and maintained in such a manner that:

* * * * *

PART 396—INSPECTION, REPAIR, AND MAINTENANCE

■ 4. The authority citation for part 396 continues to read as follows:

Authority: 49 U.S.C. 504, 31133, 31136, 31151, 31502; sec. 32934, Pub. L. 112–141, 126 Stat. 405, 830; sec. 5524, Pub. L. 114–94, 129 Stat. 1312, 1560; and 49 CFR 1.87.

■ 5. Amend Appendix A to Part 396 by adding Section 15 to read as follows:

Appendix A to Part 396—Minimum Periodic Inspection Standards

* * * * *

15. Rear Impact Guard

a. Trailers and semitrailers with a GVWR of 4,536 kg (10,001 lbs.) or more, manufactured on or after January 26, 1998 (see exceptions in § 393.86(a)(1)).

1. Missing guard.

2. Guard is not securely attached to trailer, including broken or missing fasteners, any welds or parent metal cracked, or other damage that compromises secure attachment of the guard.

3. Guard horizontal member does not extend to within 100 mm (4 inches) of each, or extends beyond either, side extremity of the vehicle.

4. Guard horizontal member is more than 560 mm (22 inches) above the ground.

5. Guard horizontal member is more than 305 mm (12 inches) forward of the rear extremity of the vehicle.

6. Guard horizontal member does not have a cross sectional vertical height of at least 100 mm (4 inches) across its entire width.

b. Commercial motor vehicles manufactured after December 31, 1952 (except trailers and semitrailers manufactured on or after January 26, 1998) (see exceptions in § 393.86(b)(1) and § 393.86(b)(3)).

1. Missing guard.

2. Guard is not securely attached to trailer by bolts, welding, or other comparable means.

3. Guard horizontal member is more than 762 mm (30 inches) above the ground.

4. Guard horizontal member does not extend to within 457 mm (18 inches) of each side extremity of the vehicle.

5. Guard horizontal member is more than 610 mm (24 inches) forward of the rear extremity of the vehicle.

Issued under authority delegated in 49 CFR 1.87.

Meera Joshi,

Deputy Administrator.

[FR Doc. 2021–23796 Filed 11–8–21; 8:45 am]

BILLING CODE 4910–EX–P

Proposed Rules

Federal Register
Vol. 86, No. 214
Tuesday, November 9, 2021

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

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2021–0840]

RIN 1625–AA08

Special Local Regulation; San Juan Bay for El Morro Downwind Challenge, San Juan, PR

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to establish a temporary special local regulation for certain waters of Bahía de San Juan. This action is necessary to provide for the safety of life on these navigable waters east of Anegado Channel and San Antonio Channel, San Juan, PR, during a paddle board race on January 8, 2022. This proposed rulemaking would prohibit persons and vessels from being in the regulated area unless authorized by the Captain of the Port San Juan or a designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before December 9, 2021.

ADDRESSES: You may submit comments identified by docket number USCG–2021–0840 using the Federal Decision Making Portal at *https://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Commander Christopher O'Connor, Sector San Juan Prevention Department, Waterways Management Division U.S. Coast Guard; telephone 787–729–2374, email *Christopher.M.OConnor@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background, Purpose, and Legal Basis

On October 21, 2021, the School of Stand Up Paddle Board (SUP) notified the Coast Guard that it will be conducting a paddle board race from 8 a.m. until 12:00 p.m., on January 8, 2022. The paddle board race is schedule to start from Escuela Deportiva de Vela de Carolina going westward to El Morro, entering the San Juan Bay and finish at Bahía Urbana in San Juan, PR. Hazards from the paddle board race include boarding in shallow rocky waters and bad weather conditions that lead to radical waves, currents, and winds. The Captain of the Port San Juan (COTP) has determined that potential hazards associated with the paddle board race would be a safety concern for anyone within a 100-yard radius of the paddle board race participants.

The purpose of this rulemaking is to ensure the safety of participants, vessels, and the navigable waters within a 100-yard radius of the paddle board race route before, during, and after the scheduled event. The Coast Guard is proposing this rulemaking under authority in 46 U.S.C. 70034.

III. Discussion of Proposed Rule

The COTP is proposing to establish a temporary special local regulation from 8 a.m. until 12 p.m., on January 8, 2022. The School of SUP is sponsoring the El Morro Downwind Challenge, where approximately 50 competitors will participate in the SUP race around Isleta de San Juan. The regulated area would cover all navigable waters within 100 yards of the paddle board race route from Escuela Deportiva de Vela de Carolina to the San Juan Bay in San Juan, PR. The duration of the zone is intended to ensure the safety of participants, vessels and these navigable waters before, during, and after the scheduled 8 a.m. until 12 p.m. paddle board race. All persons and non-participating vessels are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area without obtaining permission from the COTP or a designated representative. The regulatory text we are proposing appears at the end of this document.

IV. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This NPRM has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the size, location, duration, and time-of-day of the regulated area. The regulated area will affect a small-designated area of Isleta de San Juan and San Juan Bay, during the event and thus is limited in scope. The temporary special local regulation will be enforced for only a total period of 4 hours and thus is limited in time, and during the evening when vessel traffic is normally low. Although persons and vessels will not be able to enter, transit through, anchor in, or remain within the zone without authorization from the Captain of the Port San Juan or a designated representative, they may operate in the surrounding area during the enforcement period. The rule will allow vessels to seek permission to enter the regulated area. Persons and vessels may still enter, transit through, anchor in, or remain within the regulated area during the enforcement period if authorized by the Captain of the Port San Juan or a designated representative. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule would allow vessels to seek permission to enter the regulated area.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on

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

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves the creation of a temporary special local regulation in conjunction with a regatta or marine parade, lasting 4 hours that would prohibit entry of all non-participant personnel and vessels within 100 yards of the SUP race route to ensure the safety of the participants, participant vessels and the general public during the event. Normally such actions are categorically excluded from further review under paragraph L61 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A preliminary Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

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

V. Public Participation and Request for Comments

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

Submitting comments. We encourage you to submit comments through the Federal Decision Making Portal at *https://www.regulations.gov.* To do so, go to *https://www.regulations.gov,* type USCG- 2021–0840 in the search box and click ''Search.'' Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. If you cannot submit your material by using *https://www.regulations.gov,* call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this proposed rule for alternate instructions.

Viewing material in docket. To view documents mentioned in this proposed rule as being available in the docket, find the docket as described in the previous paragraph, and then select ''Supporting & Related Material'' in the Document Type column. Public comments will also be placed in our online docket and can be viewed by following instructions on the *https://www.regulations.gov* Frequently Asked Questions web page. We review all comments received, but we will only post comments that address the topic of the proposed rule. We may choose not to post off-topic, inappropriate, or duplicate comments that we receive.

Personal information. We accept anonymous comments. Comments we post to *https://www.regulations.gov* will include any personal information you have provided. For more about privacy and submissions to the docket in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

List of Subjects in 33 CFR Part 100

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

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

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

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

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

■ 2. Add § 100.T799–0945 to read as follows:

§ 100.T799–0945 Special Local Regulation Safety zones; El Morro Downwind Challenge, from Carolina, PR to San Juan Bay, San Juan, PR.

(a) *Regulated area.* The regulations in this section apply to the following area: Waters around Isleta San Juan including certain waters of San Juan Bay, from surface to bottom, encompassed by a line connecting the following points beginning at Escuela Deportiva de Vela de Carolina with coordinates 18°27′5.4″ N, 65°59′44.088″ W; thence east to 18°27′35.316″ N, 65°59′39.624″ W; thence north-west to 18°27′42.48″ N, 66°0′2.556″ W; thence north to 18°28′3.504″ N, 66°0′6.264″ W; thence west to 18°28′22.548″ N, 66°7′31.044″ W; thence south to 18°27′28.476″ N, 66°6′59.328″ W; thence north-east to 18°27′48.708″ N, 66°6′25.092″ W at the end point in Bahia Urbana. These coordinates are based on North American Datum 1983.

(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 and a Federal, State, and local officer designated by or assisting the Captain of the Port San Juan (COTP) in the enforcement of the regulations in this section.

Participant means all persons and vessels registered with the event sponsor as a participants in the race.

(c) *Regulations.* (1) All non-participants are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area described in paragraph (a) of this section unless authorized by the Captain of the Port San Juan or their designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative by telephone at (787) 289–2041, or a designated representative via VHF radio on channel 16. Those in the regulated area must comply with all lawful orders or directions given to them by the COTP or the designated representative.

(3) The COTP will provide notice of the regulated area through advanced notice via broadcast notice to mariners and by on-scene designated representatives.

(d) *Enforcement period.* This section will be enforced from 8 a.m. until 12 p.m., on January 8, 2022.

Gregory H. Magee,

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

[FR Doc. 2021–24461 Filed 11–8–21; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF LABOR

Office of Federal Contract Compliance Programs

41 CFR Part 60–1

RIN 1250–AA09

Proposal To Rescind Implementing Legal Requirements Regarding the Equal Opportunity Clause's Religious Exemption

AGENCY: Office of Federal Contract Compliance Programs, Labor.

ACTION: Notification of proposed rescission; request for comments.

SUMMARY: The Office of Federal Contract Compliance Programs (OFCCP) is proposing to rescind the regulations established in the final rule titled ''Implementing Legal Requirements Regarding the Equal Opportunity Clause's Religious Exemption,'' which took effect on January 8, 2021.

DATES: Comments must be received on or before December 9, 2021.

ADDRESSES: You may submit comments, identified by RIN 1250–AA09, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 693–1304 (for comments of six pages or less).
- *Mail:* Tina Williams, Director, Division of Policy and Program Development, Office of Federal Contract Compliance Programs, Room C–3325, 200 Constitution Avenue NW, Washington, DC 20210.

Instructions: Please submit only one copy of your comments by only one method. Commenters submitting file attachments on *http://www.regulations.gov* are advised that uploading text-recognized documents—*i.e.,* documents in a native file format or documents that have undergone optical character recognition (OCR)—enable staff at the Department to more easily search and retrieve specific content included in your comment for consideration. Please be advised that comments received will become a matter of public record and will be posted without change to *http://www.regulations.gov,* including any personal information provided. Commenters submitting comments by mail should transmit comments early to ensure timely receipt prior to the close of the comment period, as the Department continues to experience delays in the receipt of mail.

Docket: For access to the docket to read background documents or comments, go to the Federal eRulemaking Portal at *http://www.regulations.gov.* Copies of this notice of proposed rescission will be made available, upon request, in the following formats: Large print, Braille, audiotape, and disc. To obtain this notice of proposed rescission in an alternate format, contact OFCCP at the telephone numbers or address listed below.

FOR FURTHER INFORMATION CONTACT: Tina Williams, Director, Division of Policy and Program Development, Office of Federal Contract Compliance Programs, 200 Constitution Avenue NW, Room C–3325, Washington, DC 20210. Telephone: (202) 693–0104 (voice) or (202) 693–1337 (TTY).

SUPPLEMENTARY INFORMATION:

I. Background

OFCCP enforces Executive Order 11246, which requires federal government contractors and subcontractors to provide equal employment opportunity. Section 202 of Executive Order 11246, as amended, requires that every non-exempt contract and subcontract include an equal opportunity clause, which specifies the nondiscrimination and affirmative action obligations each contractor or subcontractor assumes as a condition of its government contract or subcontract. Among other obligations, each contractor agrees, as a condition of its government contract, not to discriminate in employment on the basis of race, color, religion, sex, sexual orientation, gender identity, or national origin. Executive Order 11246, as amended, and its predecessors reflect the government's long-standing policy of requiring its contractors to prevent discrimination and provide equal employment opportunity. *See, e.g.,* Exec. Order 8802, 6 FR 3109 (June 27, 1941) (''reaffirm[ing] the policy of the

United States that there shall be no discrimination in the employment of workers in defense industries or government because of race, creed, color, or national origin''); Exec. Order 10479, 18 FR 4899 (Aug. 18, 1953) (reiterating ''the policy of the United States Government to promote equal employment opportunity for all qualified persons employed or seeking employment on government contracts because such persons are entitled to fair and equitable treatment in all aspects of employment on work paid for from public funds''); Exec. Order 10925, 26 FR 1977 (Mar. 8, 1961) (describing it as ''the plain and positive obligation of the United States Government to promote and ensure equal opportunity for all qualified persons, without regard to race, creed, color, or national origin, employed or seeking employment with the Federal Government and on government contracts''); Exec. Order 13672, 79 FR 42971 (July 23, 2014) (amending Executive Order 11246 to include sexual orientation and gender identity to ''provide for a uniform policy for the Federal Government to prohibit discrimination and take further steps to promote economy and efficiency in Federal Government procurement''). This policy effectuates the government's interest in promoting economy and efficiency in federal procurement. *See* 40 U.S.C. 101 (providing for ''an economical and efficient [procurement] system''); 40 U.S.C. 121(a) (authorizing the President to prescribe policies and directives to carry out that aim); *Contractors Ass'n of E. Pa.* v. *Sec'y of Labor,* 442 F.2d 159, 170 (3d Cir. 1971) (''[I]t is in the interest of the United States in all procurement to see that its suppliers are not over the long run increasing its costs and delaying its programs by excluding from the labor pool available minority work[ers].''). It also ensures that taxpayer funds are not used to discriminate, especially in the performance of functions for the government itself and, thus, for the public.

It is OFCCP's long-standing policy and practice, when analyzing potential discrimination under Executive Order 11246, to follow the principles of Title VII of the Civil Rights Act of 1964, which prohibits employers from discriminating against applicants and employees on the basis of race, color, religion, sex (including pregnancy, sexual orientation, and gender identity), or national origin. 42 U.S.C. 2000e–2; *OFCCP* v. *Bank of Am.,* No. 13–099, Final Decision & Order, 2016 WL 2892921, at *7 (ARB Apr. 21, 2016) (''[I]n addition to relevant provisions of E.O. 11246, its implementing regulations, and Department precedent, we also look to federal appellate court decisions addressing similar pattern or practice claims of intentional discrimination adjudicated under Title VII . . . .''); *OFCCP* v. *Greenwood Mills, Inc.,* Nos. 00–044, 01–089, Final Decision & Order, 2002 WL 31932547, at *4 (ARB Dec. 20, 2002) (''The legal standards developed under Title VII of the Civil Rights Act of 1964 apply to cases brought under [Executive Order 11246]''). As amended in 1972, Title VII contains an exemption for religious corporations, associations, educational institutions, and societies with regard to the employment of individuals of a particular religion to perform work connected with their activities. Equal Employment Opportunity Act of 1972, Public Law 92–261, 3, 86 Stat. at 104 (codified at 42 U.S.C. 2000e–1(a)). In the decades since the enactment of the Title VII religious exemption, a robust body of case law interpreting the exemption has developed, establishing its scope and application.

In 2002, President George W. Bush amended Executive Order 11246 to include, almost verbatim, Title VII's exemption for religious organizations. Sec. 4, Exec. Order 13279, 67 FR 77143 (Dec. 16, 2002) (codified at sec. 204(c), Exec. Order 11246). The amendment was intended ''to ensure the economical and efficient administration and completion of Government contracts.'' *Id.* The only substantive difference between the text of the Title VII religious exemption and that of the Executive Order 11246 religious exemption is that the latter *expressly* provides that, although a government contractor or subcontractor that is a religious corporation, association, educational institution, or society is exempt from having to comply with section 202 (the equal opportunity clause of Executive Order 11246) ''with respect to the employment of individuals of a particular religion,'' it is ''not exempted or excused from complying with the other requirements contained in this Order.'' Sec. 204(c), Exec. Order 11246. The text of the Title VII religious exemption does not contain that express proviso. However, the proviso is based on Title VII case law, which has consistently held that the Title VII religious exemption permits qualifying religious employers to employ individuals of a particular religion but requires them to comply with Title VII's prohibitions against discrimination on other protected bases. *See, e.g., Kennedy* v. *St. Joseph's Ministries, Inc.,* 657 F.3d 189, 192 (4th Cir. 2011); *Cline* v. *Catholic Diocese of Toledo,* 206 F.3d 651, 658 (6th Cir. 2000); *DeMarco* v. *Holy Cross High Sch.,* 4 F.3d 166, 173 (2d Cir. 1993).

Further, the Executive Order 11246 proviso and the Title VII case law on which it is based reflect Congress's intent that nondiscrimination obligations based on other protected characteristics continue to apply to religious employers. *See* 118 Cong. Rec. 7167 (1972) (Senate Managers' section-by-section analysis presented by Sen. Williams) (''The limited exemption from coverage in this section for religious corporations, associations, educational institutions or societies has been broadened to allow such entities to employ individuals of a particular religion in all their activities. . . . *Such organizations remain subject to the provisions of Title VII with regard to race, color, sex or national origin.*'') (emphasis added). This limitation on the scope of the Title VII religious exemption has long been recognized by the Department of Justice Office of Legal Counsel. *See* Memorandum for William P. Marshall, Deputy Counsel to the President, from Randolph D. Moss, Assistant Attorney General, Office of Legal Counsel, Re: Application of the Coreligionists Exemption in Title VII of the Civil Rights Act of 1964, 42 U.S.C. 2000e–1(a), to Religious Organizations that Would Directly Receive Substance Abuse and Mental Health Services Administration Funds Pursuant to Section 704 of H.R. 4923, the ''Community Renewal and New Markets Act of 2000'' at 30–32, 31 n.62 (Oct. 12, 2000), *https://www.justice.gov/olc/page/file/936211/download.*

In 2003, OFCCP published a final rule amending its Executive Order 11246 regulations to incorporate this religious exemption.[1] Affirmative Action and Nondiscrimination Obligations of Government Contractors, Executive Order 11246, as amended; Exemption for Religious Entities, Final Rule, 68 FR 56392 (Sept. 30, 2003) (codified at 41 CFR 60–1.5(a)(5)). In the preamble to that rule, OFCCP explained that the religious exemption recently added to Executive Order 11246 was ''modeled on'' the Title VII religious exemption. *Id.* In turn, OFCCP noted, the new regulation itself ''directly tracks the

[1] Since 1978, OFCCP's regulations implementing Executive Order 11246 have contained an exemption allowing certain educational institutions to hire and employ individuals of a particular religion. *See* Compliance Responsibility for Equal Employment Opportunity: Consolidation of Functions Pursuant to Executive Order 12086, 43 FR 49240, 49243 (Oct. 20, 1978) (codified at 41 CFR 60–1.5(a)(6)). This exemption is modeled on Title VII's exemption for religiously affiliated educational institutions. *See* 42 U.S.C. 2000e–2(e).

President's amendment to'' Executive Order 11246 and ''simply incorporates'' the amendment in the regulation. *Id.* The preamble and regulation did not provide further guidance regarding the scope or application of the religious exemption. OFCCP continued its long-standing policy and practice of applying Title VII principles and case law when analyzing claims of discrimination under Executive Order 11246. OFCCP provided compliance assistance on the interpretation and application of the religious exemption through hosting webinars and publishing guidance on its website. In doing so, OFCCP abided by relevant religious liberty authorities, including the Religious Freedom Restoration Act (RFRA) and the ministerial exception mandated by the religion clauses of the First Amendment; maintained a policy of considering RFRA claims raised by contractors on a case-by-case basis; and refrained from applying any regulatory requirement to a case in which it would violate RFRA. *See, e.g.,* OFCCP Compliance Webinar (Mar. 25, 2015), *https://www.dol.gov/ofccp/LGBT/FTS_TranscriptEO13672_PublicWebinar_ES_QA_508c.pdf;* OFCCP Frequently Asked Questions: E.O. 13672 Final Rule (2015), archived at *https://web.archive.org/web/20150709220056/ http:/www.dol.gov/ofccp/LGBT/LGBT_FAQs.html.* OFCCP recommended that contractors with questions about the applicability of the religious exemption to their employment practices seek guidance from OFCCP. *See, e.g.,* Discrimination on the Basis of Sex, Final Rule, 81 FR 39108, 39120 (June 15, 2016).

In 2019, OFCCP proposed a rule purporting to clarify the scope and application of the Executive Order 11246 religious exemption. Implementing Legal Requirements Regarding the Equal Opportunity Clause's Religious Exemption, Notice of Proposed Rulemaking, 84 FR 41677 (Aug. 25, 2019). The rule was finalized with some modifications in 2020 and took effect on January 8, 2021.[2] Implementing Legal Requirements Regarding the Equal Opportunity Clause's Religious Exemption, Final Rule, 85 FR 79324 (Dec. 9, 2020) (hereinafter ''2020 rule''). The 2020 rule does not alter the text of the religious exemption at 41 CFR 60–1.5(a)(5); instead, it defines the terms ''particular religion''; ''religion''; ''religious corporation, association, educational institution, or society''; and ''sincere.'' *Id.* at 79371–72 (codified at 41 CFR 60–1.3). The 2020 rule further provides a rule of construction for all of subpart A of 41 CFR part 60–1, specifying that the subpart must be construed in favor of the broadest protection of religious exercise ''permitted by the U.S. Constitution and law.'' *Id.* at 79372 (codified at 41 CFR 60–1.5(e)).

The preamble to the 2020 rule accurately described section 204(c) of Executive Order 11246 as ''expressly importing Title VII's exemption for religious organizations'' and as ''spring[ing] directly from the Title VII exemption.'' *Id.* at 79324. The preamble continued that the Executive Order 11246 religious exemption should therefore ''be given a parallel interpretation.'' *Id.* (citing *Northcross* v. *Bd. of Educ. of Memphis City Sch.,* 412 U.S. 427, 428 (1973) (per curiam) (''The similarity of language in [two statutes] is, of course, a strong indication that the two statutes should be interpreted pari passu.''). Nevertheless, as discussed below, the 2020 rule departs from OFCCP's long-standing reliance on Title VII principles and case law. In so doing, the 2020 rule runs contrary to the intent of Executive Order 13279's amendment of Executive Order 11246 to incorporate the scope and application of the Title VII religious exemption. OFCCP believes the 2020 rule's departures from Title VII principles and case law are likely to increase rather than decrease confusion about the application of the Executive Order 11246 religious exemption. Furthermore, to the extent the 2020 rule reflects the previous Administration's policy judgments regarding deviating from Title VII case law and principles, the present Administration has evaluated the range of permissible policy options and determined that a return to its traditional approach of applying Title VII case law and principles will promote clarity and consistency in the application of the exemption.

II. Proposal To Rescind

OFCCP proposes to rescind the regulations established in the 2020 rule in their entirety. OFCCP believes that the 2020 rule creates a lack of clarity regarding the scope and application of the exemption because, as explained in more detail below, it misstates the law in key respects. In addition, as a threshold matter, OFCCP has reevaluated the need for the rule. For the 17 years prior to 2020, OFCCP implemented the Executive Order 11246 religious exemption without seeking to codify its scope and application in specific regulatory language. Instead, OFCCP included the language of the exemption in its regulations at 41 CFR 60–1.5(a)(5) and adopted a policy of applying Title VII case law as it developed, with reference to relevant religious liberty authorities where appropriate. Significantly, the agency already recognized that the 2020 rule has ''no effect on the overwhelming majority of federal contractors.'' 85 FR at 79367. OFCCP therefore believes that the 2020 rule is unnecessary and, for the same reason, that no affirmative rulemaking to modify or replace the 2020 rule is needed at this time. With this rescission, OFCCP would return to its traditional approach, which recognizes the validity of applying the religious exemption in section 204(c) of Executive Order 11246, as codified in OFCCP's regulations at 41 CFR 60–1.5(a)(5), where it is supported by Title VII principles and applicable law.

OFCCP also believes that the 2020 rule misstates the law in key respects. Most notably, the 2020 rule creates its own religious employer test, independent of Title VII case law interpreting the identical term. The test adopted in the 2020 rule permits a contractor whose purpose and/or character is not primarily religious to qualify for the Executive Order 11246 religious exemption. This not only places the rule in tension with the President's intent in expressly incorporating the Title VII religious exemption into Executive Order 11246 in 2003 but also undermines the government's long-standing policy of requiring that federal contractors provide equal employment opportunity, subject to a religious exemption for contractors with primarily religious purpose and character. *See, e.g.,* Exec. Order 8802, 6 FR 3109; Exec. Order 10479, 18 FR 4899; Exec. Order 10925, 26 FR 1977; Exec. Order 13279, 67 FR 77143; Exec. Order 13672, 79 FR 42971.

In addition, the 2020 rule retreats from the general principle that qualifying religious employers are prohibited from taking employment actions that amount to discrimination on the basis of protected characteristics other than religion, even if the decisions are made for sincerely held religious reasons. In so doing, the 2020 rule disregards the text of Executive Order 11246, undermines the government's interest in ensuring equal employment opportunity by federal contractors, and deviates from Congress's understanding of how the Title VII religious exemption should operate—an understanding courts have confirmed in Title VII cases.

[2] Shortly after it took effect, the religious exemption rule was challenged in two district courts. *New York* v. *U.S. Dep't of Labor,* No. 21–cv–00536 (S.D.N.Y. filed Jan. 21, 2021); *Or. Tradeswomen, Inc.* v. *U.S. Dep't of Labor,* No. 21–cv–00089 (D. Or. filed Jan. 21. 2021). Both matters have been stayed, and the courts have not yet issued any substantive rulings.

Finally, the preamble to the 2020 rule appeared to promote a categorical approach to the analysis of RFRA claims. OFCCP believes this categorical approach is inappropriate because it extends exemptions more broadly than RFRA requires and fails to allow sufficient flexibility to weigh competing governmental and third-party interests against the interests of individuals asserting religious exemptions. *Cf., e.g., Cutter* v. *Wilkinson,* 544 U.S. 709, 720 (2005) (''Properly applying [the Religious Land Use and Institutionalized Persons Act, to which ''Congress carried over from RFRA the 'compelling governmental interest''/ ''least restrictive means' standard,'' *id.* at 716], courts must take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries . . . .''). As the Court recognized in *Fulton* v. *City of Philadelphia,* 141 S. Ct. 1868 (2021), the government has a ''weighty'' interest in enforcing nondiscrimination protections.

As it did prior to implementation of the 2020 rule, if the rule is rescinded, OFCCP would continue to follow Title VII principles and case law; would continue to apply the First Amendment and RFRA to the facts and circumstances of each case, where applicable; and would offer compliance assistance as needed with regard to the proper scope and application of the Executive Order 11246 religious exemption.

A. Reasons for Rescission of the Rule

1. Unprecedented Religious Employer Test

The entities entitled to the religious exemption as codified by OFCCP's 2020 rule are the comparatively few contractors and subcontractors (and potential contractors and subcontractors) that meet the regulatory definition of ''religious corporation, association, educational institution, or society.'' *See* 85 FR at 79371–72 (codified at 41 CFR 60–1.3), 79367 (''[T]his rule will have no effect on the overwhelming majority of federal contractors.'').[3] Because that term is borrowed directly from the Title VII religious exemption at 42 U.S.C. 2000e–1(a), there is extensive Title VII case law interpreting the term—case law that has historically guided OFCCP (and contractors themselves) in determining whether an employer is entitled to the Executive Order 11246 religious exemption. Although there is no uniform test that all courts use, the ultimate inquiry focuses on whether the employer's purpose and character are primarily religious—a determination typically made by weighing some or all of the following factors:

(1) Whether the entity operates for a profit, (2) whether it produces a secular product, (3) whether the entity's articles of incorporation or other pertinent documents state a religious purpose, (4) whether it is owned, affiliated with or financially supported by a formally religious entity such as a church or synagogue, (5) whether a formally religious entity participates in the management, for instance by having representatives on the board of trustees, (6) whether the entity holds itself out to the public as secular or sectarian, (7) whether the entity regularly includes prayer or other forms of worship in its activities, (8) whether it includes religious instruction in its curriculum, to the extent it is an educational institution, and (9) whether its membership is made up by coreligionists.

LeBoon v. *Lancaster Jewish Cmty. Ctr.,* 503 F.3d 217, 226 (3d Cir. 2007); *see also, e.g., Garcia* v. *Salvation Army,* 918 F.3d 997, 1003 (9th Cir. 2019); *Spencer* v. *World Vision, Inc.,* 633 F.3d 723, 724 (9th Cir. 2011) (per curiam); *Hall* v. *Baptist Mem'l Health Care Corp.,* 215 F.3d 618, 624 (6th Cir. 2000); *Killinger* v. *Samford Univ.,* 113 F.3d 196, 198–99 (11th Cir. 1997)).

OFCCP's 2020 rule, however, adopted a religious employer test that largely did not account for these precedents—including the ultimate requirement that the employer's purpose and character be primarily religious—and instead adopted a test that no court has applied under Title VII. 85 FR 79371 (codified at 41 CFR 60–1.3).

The preamble to the 2020 rule explained that OFCCP was taking this approach because it found fault with the federal appellate courts' ''confusing variety of tests, [which] themselves often involve unclear or constitutionally suspect criteria.'' 85 FR at 79331. The agency commended two concurring opinions in *Spencer* v. *World Vision* for recognizing that ''assess[ing] the religiosity of an organization's various characteristics[ ] can lead the court into a 'constitutional minefield.' '' 84 FR at 41681 (quoting *Spencer,* 633 F.3d at 730 (O'Scannlain, J., concurring), and citing *Spencer,* 633 F.3d at 741 (Kleinfeld, J., concurring)); *see also* 85 FR at 79361. Yet, as the preamble acknowledged, the 2020 rule itself does not even incorporate any of the religious employer tests set forth in the *World Vision* opinions. Rather, it adopts a definition of Title VII's term ''religious corporation, association, educational institution, or society'' that does not require an inquiry into whether a contractor is ''primarily religious'' because that inquiry, the preamble argued, requires ''*comparison* between the amount of religious and secular activity at an organization.'' 85 FR at 79336.

In this respect, the 2020 rule deviates from established Title VII interpretations and creates its own new test.[4] No court has ever applied a standard under which a for-profit employer whose purpose and character are not primarily religious could be eligible for the Title VII religious exemption.[5] Yet under the 2020 rule, contrary to decades of Title VII case law, just such a for-profit contractor may qualify for the religious exemption.

With this rescission, OFCCP would return to its previous approach, which would preserve the availability of the Executive Order 11246 religious exemption for employers whose purpose and character are primarily religious, and would consider the applicability of the religious exemption to the facts of each case in accordance with Title VII case law. Recognizing as exempt only those contractors that have a primarily religious purpose and character would provide contractors and potential contractors with the clarity of a single religious employer test under both Executive Order 11246 and Title VII.

Thus, upon reconsideration, OFCCP views the 2020 rule's departure from

[3] OFCCP's records indicate that since 2004, the earliest date for which it has records, and continuing to the present, no contractor has invoked the religious exemption.

[4] Moreover, the 2020 rule departs even from the Title VII opinions that it purports to follow, rejecting both the prerequisite that the entity be a nonprofit, *Spencer,* 633 F.3d at 734 (O'Scannlain, J., concurring), and an alternative requirement that the entity ''not engage primarily or substantially in the exchange of goods or services for money beyond nominal amounts,'' *id.* at 748 (Kleinfeld, J., concurring). *See* 85 FR at 79331–32. Of course, both of these alternatives themselves are outliers from Title VII case law, which gives weight to an entity's nonprofit status as one factor in the multifactor analysis but does not treat it as an absolute prerequisite, and does not consider as a factor at all whether the entity engages in exchanges of more than nominal amounts. *See, e.g., LeBoon,* 503 F.3d at 226; *Hall,* 215 F.3d at 624; *Killinger,* 113 F.3d at 198–99.

[5] Significantly, the Supreme Court has considered and upheld the Title VII religious exemption against an Establishment Clause challenge only as applied ''to the secular *nonprofit* activities of religious organizations.'' *Corp. of the Presiding Bishop of the Church of Jesus Christ of Latter-day Saints* v. *Amos,* 483 U.S. 327, 330 (1987) (emphasis added). It remains an open question whether and under what circumstances it would be constitutional to apply the Title VII exemption to for-profit enterprises. *See Spencer,* 633 F.3d at 734 n. 13 (O'Scannlain, J., concurring) (''In *Amos,* the Supreme Court expressly left open the question of whether a for-profit entity could ever qualify for a Title VII exemption.'' (citing 483 U.S. at 349 (O'Connor, J., concurring))). The vast majority of federal contractors are for-profit entities that have never been deemed to qualify as religious corporations, associations, educational institutions, or societies.

Title VII precedent as both unsupported and confusing due to its creation of a religious employer test that has never before been applied. The substantial body of case law in which courts—including the Ninth Circuit post–*World Vision*—have applied the traditional Title VII test to identify employers with primarily religious purpose and character without infringing on employers' religious liberties undermines the 2020 rule's assertion that OFCCP needed to abandon a ''primarily religious'' inquiry to avoid purported constitutional minefields. *See, e.g., Garcia,* 918 F.3d 997; *LeBoon,* 503 F.3d 217; *Hall,* 215 F.3d 618; *Killinger,* 113 F.3d 196. Moreover, OFCCP is concerned that the 2020 rule's definition of ''religious corporation, association, educational institution, or society,'' in departing from the interpretation of that term under Title VII, may decrease procurement efficiency and increase uncertainty within the contracting community about the applicability of the religious exemption. Further, OFCCP is concerned that extending the religious exemption to contractors whose purpose and character are *not* primarily religious runs contrary to the government's long-standing equal employment opportunity policy for federal contractors. Most important, the definition adopted by the 2020 rule is inconsistent with the President's decision in Executive Order 13279 to incorporate Title VII doctrine as the touchstone for the Executive Order 11246 religious exemption.

2. Exemption of Unlawful Employment Actions

Under both Executive Order 11246 section 204(c) and Title VII at 42 U.S.C. 2000e–1(a), qualifying religious organizations are permitted to make decisions ''with respect to the employment of individuals of a particular religion.'' The 2020 rule's definition of ''particular religion'' authorizes the contractor to require, as a condition of employment, the applicant's or employee's ''acceptance of or adherence to sincere religious tenets as understood by the employer.'' 85 FR at 79371 (codified at 41 CFR 60–1.3). The weight of Title VII case law reflects that qualifying religious employers generally may make decisions about whether to employ individuals based on acceptance of and adherence to religious tenets, as long as those decisions do not violate the other nondiscrimination provisions of Title VII, apart from the prohibition on religious discrimination. *See, e.g., Kennedy,* 657 F.3d at 190–92 (stating that Title VII's religious exemption does not exempt religious organizations from complying with prohibitions on race, sex, or national origin discrimination, but holding that a Catholic nursing center's termination of a nursing assistant based on her non-Catholic religious attire was permissibly based on religion and not other protected bases); *Little* v. *Wuerl,* 929 F.2d 944, 946–48 (3d Cir. 1991) (stating that Title VII bars, for example, race and sex discrimination against non-minister employees, but holding that a Catholic school's decision not to rehire a teacher based on her remarriage without validation by the Catholic Church was permissibly based on religion). However, under the 2020 rule as explained in the preamble, the agency would not enforce Executive Order 11246 against a contractor for an adverse employment action motivated ''solely'' by its sincerely held religious tenets, even when the contractor's actions violate another nondiscrimination prohibition of Executive Order 11246 (other than race, as discussed below). *Id.* at 79350; *cf. id.* at 79356 (''OFCCP will enforce E.O. 11246 against any contractor or subcontractor that takes employment actions on the basis of race, even if religiously motivated.''). As an example, the preamble noted that a religious organization might maintain ''sincerely held religious tenets regarding matters such as marriage and intimacy which may implicate certain protected classes.'' *Id.* at 79364.

Upon reconsideration, OFCCP is concerned that the 2020 rule's suggestion that qualifying religious organizations may be broadly exempted from Executive Order 11246's nondiscrimination requirements is contrary to the text of the religious exemption itself, which permits the contractor to discriminate on the basis of religion in favor of ''individuals of a particular religion'' while expressly not exempting or excusing the contractor from the other requirements of Executive Order 11246. Sec. 204(c), Exec. Order 11246. It is also contrary to well-established Title VII case law. *See, e.g., Kennedy,* 657 F.3d at 192 (''Section 2000e–1(a) does not exempt religious organizations from Title VII's provisions barring discrimination on the basis of race, gender, or national origin.''); *Cline,* 206 F.3d at 658 (''[W]hile Title VII exempts religious organizations for 'discrimination based on religion,' it does not exempt them 'with respect to all discrimination. . . . [ ] Title VII still applies . . . to a religious institution charged with sex discrimination.'') (quoting *Boyd* v. *Harding Acad. of Memphis, Inc.,* 88 F.3d 410, 413 (6th Cir. 1996)); *DeMarco,* 4 F.3d at 173 (''[R]eligious institutions that otherwise qualify as 'employer[s]' are subject to Title VII provisions relating to discrimination based on race, gender and national origin.''). Further, as the Department of Justice has explained with regard to Title VII, Congress clearly intended for qualifying religious employers to ''remain subject to the provisions of Title VII with regard to race, color, sex or national origin.'' Memorandum for William P. Marshall, Deputy Counsel to the President, from Randolph D. Moss, Assistant Attorney General, Office of Legal Counsel, Re: Application of the Coreligionists Exemption in Title VII of the Civil Rights Act of 1964, 42 U.S.C. 2000e–1(a), to Religious Organizations that Would Directly Receive Substance Abuse and Mental Health Services Administration Funds Pursuant to Section 704 of H.R. 4923, the ''Community Renewal and New Markets Act of 2000'' (Oct. 12, 2000), *https://www.justice.gov/olc/page/file/936211/download* (quoting Senate managers' analysis, *id.* at 31, and numerous cases, *id.* at 30–32 & n.62).

Accordingly, courts typically have rejected claims that qualifying religious employers are exempt from Title VII's other nondiscrimination provisions where the employers claim that their actions were based on sincere religious beliefs and tenets. In *Herx* v. *Diocese of Ft. Wayne–S. Bend, Inc.,* for example, the Seventh Circuit dismissed a Catholic elementary school's appeal of an order denying summary judgment, thus requiring adjudication of a language arts teacher's claim that the school's application of the church's ban on in vitro fertilization discriminated against women because only women undergo the procedure. 772 F.3d 1085, 1091 (7th Cir. 2014). The Seventh Circuit observed that ''[t]he district court has not ordered a religious question submitted to the jury for decision'' and confirmed that the jury would be instructed ''not to weigh or evaluate the Church's doctrine regarding in vitro fertilization.'' *Id.; see also, e.g., Cline,* 206 F.3d at 667 (reversing the district court's grant of summary judgment to a religious school on the sex discrimination claim of a preschool teacher allegedly fired for violating the religious school's policy against extramarital sex, noting that the plaintiff was entitled to ''pursue several avenues of discovery,'' including seeking evidence ''that St. Paul enforced its premarital sex policy in a discriminatory manner—against only pregnant women, or against only

women''); *Maguire* v. *Marquette Univ.,* 814 F.2d 1213, 1218 (7th Cir. 1987) (adjudicating the sex discrimination claim of an associate professor of theology not hired by a religious university based on ''her perceived hostility to the institutional church and its teachings,'' particularly with regard to abortion, but affirming dismissal because the employer would have rejected a male applicant who held similar views about abortion).

To be sure, the Constitution imposes some constraints on nondiscrimination laws such as Title VII, even apart from the statutory accommodation for religious organizations. For example, the religion clauses of the First Amendment create a ''ministerial exception'' from certain nondiscrimination laws, including Title VII, for positions of particular religious significance in certain religious organizations. *See Our Lady of Guadalupe Sch.* v. *Morrissey-Berru,* 140 S. Ct. 2049 (2020); *Hosanna-Tabor Evangelical Lutheran Church & Sch.* v. *EEOC,* 565 U.S. 171 (2012). Where the ministerial exception applies, ''judicial intervention into disputes between the [religious organization] and the [employee] threatens the [religious organization's] independence in a way that the First Amendment does not allow.'' *Our Lady of Guadalupe Sch.,* 140 S. Ct. at 2069.

And where a religious organization applies a ''religious tenets'' requirement under Title VII's religious exemption, courts and agencies must be careful not to unduly interrogate the plausibility of the religious justification in assessing whether the religious tenets claim is a pretext for some other, impermissible form of employment discrimination. *See, e.g., Curay-Cramer* v. *Ursuline Acad. of Wilmington, Delaware, Inc.,* 450 F.3d 130, 141 (3d Cir. 2006); *Mississippi College,* 626 F.2d at 485; *Little* v. *Wuerl,* 929 F.2d 944, 948 (3d Cir. 1991).

As the Supreme Court recognized in *Bostock,* however, ''how these doctrines protecting religious liberty interact with Title VII are questions for future cases.'' *Bostock* v. *Clayton Cnty.,* 140 S. Ct. 1731, 1754 (2020). In *Bostock,* the Court explained:

> [W]orries about how Title VII may intersect with religious liberties are nothing new; they even predate the statute's passage. As a result of its deliberations in adopting the law, Congress included an express statutory exception for religious organizations. § 2000e-1(a). This Court has also recognized that the First Amendment can bar the application of employment discrimination laws ''to claims concerning the employment relationship between a religious institution and its ministers.'' And Congress has gone a step further yet in [RFRA]. . . . Because RFRA operates as a kind of super statute, displacing the normal operation of other federal laws, it might supersede Title VII's commands in appropriate cases.

Id. (quoting *Hosanna-Tabor,* 565 U.S. at 188).

These possible context-specific constitutional and statutory limits, however, do not affect the general rule under both Executive Order 11246 and relevant Title VII case law to date: The religious exemption does not permit qualifying employers to make employment decisions about non-ministerial positions that amount to discrimination on the basis of protected characteristics other than religion, even if those decisions are based on sincere religious beliefs and tenets.

Thus, OFCCP now believes that, in purporting to establish a categorical exemption for religious organizations from Executive Order 11246's requirements of nondiscrimination on other protected bases when making employment decisions based on sincere religious beliefs, the 2020 rule conflicts with the text of Executive Order 11246 and does not comport with the weight of Title VII case law. OFCCP is also concerned that the 2020 rule's definition of ''particular religion,'' together with the discussion in the preamble, could decrease procurement efficiency by setting forth an unclear standard that purports to exempt a broader range of employment actions than is covered by the plain language of the religious exemption. Finally, OFCCP is concerned that the religious exemption thus broadened by the 2020 rule is inconsistent with the government's interest in ensuring equal employment opportunity by federal contractors.

3. Inappropriately Categorical Approach to RFRA Analysis

The rule of construction added in the 2020 rule at 41 CFR 60–1.5(e) requires that subpart A of 41 CFR part 60–1 be construed in favor of the broadest lawful protection of religious exercise. *See* 85 FR at 79372. Applying that rule of construction, the preamble to the 2020 rule described how RFRA would ''guide the agency's determination if and when a particular case presents a situation where a religiously motivated employment action implicates a classification protected under the Executive Order.'' 85 FR at 79350. In that discussion, the preamble expressed certain views about RFRA's application that were both questionable and not pertinent to the proper construction of Executive Order 11246.

RFRA provides that when application of a federal government rule or other law would substantially burden a person's exercise of religion, the government must afford that person an exemption to the rule unless it can demonstrate that applying the burden to that person furthers a compelling governmental interest and is the least restrictive means of doing so. 42 U.S.C. 2000bb-1(b). Prior to the 2020 rule, recognizing that ''claims under RFRA are inherently individualized and fact specific,'' OFCCP's express policy was to consider RFRA claims, if they ever arose, based on the facts of the particular case, and to refrain from applying any regulatory requirement that would violate RFRA. Discrimination on the Basis of Sex, Final Rule, 81 FR at 39119; *see also* 85 FR at 79353; OFCCP Frequently Asked Questions: Religious Employers and Religious Exemption, *http://www.dol.gov/agencies/ofccp/faqs/religious-employers-exemption*).

The preamble to the 2020 rule, however, announced that OFCCP ''has less than a compelling interest in enforcing E.O. 11246 when a religious organization takes employment action solely on the basis of sincerely held religious tenets that also implicate a protected classification, other than race.'' 85 FR at 79354. The preamble repeatedly mentioned marriage and sexual intimacy as likely subjects of such religious beliefs requiring accommodation, *see id.* at 79349, 79352, 79364, suggesting that protection from discrimination on the bases of sex, sexual orientation, and gender identity in particular could be compromised under this analysis.[6] Executive Order 11246, however, lists all the protected bases on equal terms, making no distinction among them. *See, e.g.,* sec. 202(1), Exec. Order 11246.

Since the 2020 rule's publication, the Court has reemphasized the inadequacy of a categorical approach to defining the government's compelling interest in the broader context of nondiscrimination enforcement: ''The question . . . is not whether the [government] has a compelling interest in enforcing its non-discrimination policies generally, but whether it has such an interest in denying an exception to [the particular religious claimant].'' *Fulton,* 141 S. Ct. at 1881. It is beyond dispute that the government's interests in preventing

[6] By contrast, the present Administration has committed to a policy of fully enforcing laws prohibiting discrimination based on sexual orientation and gender identity and protecting religious freedom. *See, e.g.,* sec. 1, Exec. Order 14015, 86 FR 10007 (Feb. 14, 2021); sec. 1, Exec. Order 13988, 86 FR 7023 (Jan. 25, 2021).

and remedying the harms of discrimination, and in ensuring equal employment opportunity, are ''weighty.'' *Id.* at 1882. But especially in light of *Fulton,* OFCCP believes it is appropriate to ground any compelling interest assessment in the specific facts presented by particular religious claimants, an individualized analysis that cannot properly be conducted in the context of a rulemaking, where it is not possible to weigh competing governmental and third-party interests in a particular case.

Therefore, upon reconsideration, OFCCP believes that the correct approach is to return to considering any RFRA claims raised by contractors on a case-by-case basis, without announcing any categorical conclusions about hypothetical RFRA claims related to Executive Order 11246's nondiscrimination obligations.

B. Effect of Rescission

OFCCP remains committed to protecting religious freedom in accordance with applicable law. If the 2020 rule is rescinded as proposed here, OFCCP will return to its policy and practice of interpreting and applying the religious exemption in section 204(c) of Executive Order 11246, as codified in OFCCP's regulations at 41 CFR 60–1.5(a)(5), in accordance with Title VII principles and case law. In so doing, OFCCP will abide by relevant religious liberty authorities, including the ministerial exception mandated by the religion clauses of the First Amendment. OFCCP will return to its policy of considering any RFRA claims raised by contractors on a case-by-case basis and refraining from applying any regulatory requirement to a case in which it would violate RFRA. If the 2020 rule is rescinded, nothing in that rule or its preamble could be relied on as a statement of OFCCP's interpretation or application of the Executive Order 11246 religious exemption or relevant religious liberty authorities. OFCCP will continue to provide any needed compliance assistance on the religious exemption through various means.

OFCCP invites any interested party to comment on the proposal to rescind the 2020 rule.

III. Regulatory Procedures

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

Under Executive Order 12866, OMB's Office of Information and Regulatory Affairs (OIRA) determines whether a regulatory action is significant and, therefore, subject to the requirements of Executive Order 12866 and OMB review. Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule that: (1) Has an annual effect on the economy of $100 million or more, or adversely affects in a material way 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) creates serious inconsistency or otherwise interferes with an action taken or planned by another agency; (3) materially alters the budgetary impacts of entitlement grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or (4) raises novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866. This proposed rescission has been designated a ''significant regulatory action,'' although not economically significant, under section 3(f) of Executive Order 12866. The Office of Management and Budget has reviewed this proposed rescission.

Executive Order 13563 directs agencies to adopt a regulation only upon a reasoned determination that its benefits justify its costs; tailor the regulation to impose the least burden on society, consistent with obtaining the regulatory objectives; and in choosing among alternative regulatory approaches, select those approaches that maximize net benefits. Executive Order 13563 recognizes that some benefits are difficult to quantify and provides that, where appropriate and permitted by law, agencies may consider and discuss qualitatively values that are difficult or impossible to quantify, including equity, human dignity, fairness, and distributive impacts.

1. The Need for the Rescission

The proposed rescission of the 2020 rule is needed to enable OFCCP to properly apply and enforce Executive Order 11246 by returning to its policy and practice of interpreting and applying the religious exemption contained in section 204(c) of Executive Order 11246 consistent with Title VII principles and case law.

2. Discussion of Impacts

The proposed rescission does not include any costs because it would add no new compliance requirements for contractors. The proposal would remove the definitions of Particular religion; Religion; Religious corporation, association, educational institution, or society; and Sincere from 41 CFR 60–1.3; remove paragraphs (a) and (b) from 41 CFR 60–1.3; and remove paragraphs (e) and (f) from 41 CFR 60–1.5.

The proposed rescission would not include any cost savings. The only quantitative cost assessed in the 2020 rule was for rule familiarization. This was a one-time cost assessed on contractors at the time of publication of the final rule.

3. Benefits

Executive Order 13563 recognizes that some rules have benefits that are difficult to quantify or monetize but are nevertheless important, and states that agencies may consider such benefits. Those benefits include equity and fairness. This proposed rescission would promote economy and efficiency in federal procurement by preventing the arbitrary exclusion of qualified and talented employees on the basis of characteristics that have nothing to do with their ability to do work on government contracts. It also ensures that taxpayer funds are not used to discriminate. It would also ensure that federal contractors provide equal employment opportunity on all protected bases. Finally, it would provide clarity and consistency for contractors and would-be contractors that are religious corporations, associations, educational institutions, and societies: Those with a primarily religious purpose and character, that are eligible for the Title VII religious exemption, are also eligible for the Executive Order 11246 religious exemption.

B. Regulatory Flexibility Act and Executive Order 13272 (Consideration of Small Entities)

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601 *et seq.,* establishes ''as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation.'' Public Law 96–354, section 2(b). The RFA requires agencies to consider the impact of a regulatory action on a wide range of small entities, including small businesses, nonprofit organizations, and small governmental jurisdictions.

Agencies must review whether a regulatory action would have a significant economic impact on a substantial number of small entities. *See* 5 U.S.C. 603. If the regulatory action would, then the agency must prepare a regulatory flexibility analysis as

described in the RFA. *See id.* However, if the agency determines that the regulatory action would not be expected to have a significant economic impact on a substantial number of small entities, then the head of the agency may so certify and the RFA does not require a regulatory flexibility analysis. See 5 U.S.C. 605. The certification must provide the factual basis for this determination.

The proposed rescission will not have a significant economic impact on a substantial number of small entities because the proposal will not impose any costs. Accordingly, OFCCP certifies that the proposed rescission will not have a significant economic impact on a substantial number of small entities.

C. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 requires that OFCCP consider the impact of paperwork and other information collection burdens imposed on the public. *See* 44 U.S.C. 3507(d). An agency may not collect or sponsor the collection of information or impose an information collection requirement unless the information collection instrument displays a currently valid OMB control number. *See* 5 CFR 1320.5(b)(1).

OFCCP has determined that there would be no new requirement for information collection associated with this proposed rescission. Consequently, this proposal does not require review by OMB under the authority of the Paperwork Reduction Act.

D. Unfunded Mandates Reform Act of 1995

For purposes of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1532, this proposed rescission would not include any federal mandate that may result in excess of $100 million in expenditures by state, local, and tribal governments in the aggregate or by the private sector.

E. Executive Order 13132 (Federalism)

OFCCP has reviewed this proposed rescission in accordance with Executive Order 13132 regarding federalism and has determined that it would not have ''federalism implications.'' The proposed regulatory action would 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.''

F. Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments)

This proposed rescission would not have tribal implications under Executive Order 13175 that would require a tribal summary impact statement. The proposal would not ''have substantial direct effects 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.''

List of Subjects in 41 CFR Part 60–1

Administrative practice and procedure, Civil rights, Employment, Equal employment opportunity, Government contracts, Government procurement, Investigations, Labor, Reporting and recordkeeping requirements.

Jenny R. Yang,

Director, Office of Federal Contract Compliance Programs.

For the reasons set forth in the preamble, OFCCP proposes to amend 41 CFR part 60–1 as follows:

PART 60–1—OBLIGATIONS OF CONTRACTORS AND SUBCONTRACTORS

■ 1. The authority citation for part 60–1 continues to read as follows:

Authority: Sec. 201, E.O. 11246, 30 FR 12319, 3 CFR, 1964–1965 Comp., p. 339, as amended by E.O. 11375, 32 FR 14303, 3 CFR, 1966–1970 Comp., p. 684, E.O. 12086, 43 FR 46501, 3 CFR, 1978 Comp., p. 230, E.O. 13279, 67 FR 77141, 3 CFR, 2002 Comp., p. 258 and E.O. 13672, 79 FR 42971.

§ 60–1.3 [Amended]

■ 2. Amend § 60–1.3 by removing the following:

■ a. Definitions of ''Particular religion,'' ''Religion,'' ''Religious corporation, association, educational institution, or society,'' and ''Sincere.''

■ b. Paragraphs (a) and (b).

§ 60–1.5 [Amended]

■ 3. Amend § 60–1.5 by removing paragraphs (e) and (f).

[FR Doc. 2021–24376 Filed 11–8–21; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–HQ–ES–2020–0114; FF09E22000 FXES1111090FEDR 223]

RIN 1018–BD04

Endangered and Threatened Wildlife and Plants; Threatened Species Status With Section 4(d) Rule for Egyptian Tortoise

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose to list the Egyptian tortoise (*Testudo kleinmanni*), a terrestrial tortoise from Libya, Egypt, and Israel, as a threatened species under the Endangered Species Act of 1973, as amended (Act). This determination also serves as our 12-month finding on a petition requesting that the Egyptian tortoise be listed as an endangered or threatened species under the Act. After a review of the best scientific and commercial information available, we find that listing the species is warranted. Accordingly, we propose to list the Egyptian tortoise, as a threatened species with a rule issued under section 4(d) of the Act (''4(d) rule''). If we finalize this rule as proposed, it would add this species to the List of Endangered and Threatened Wildlife and extend the Act's protections to the species.

DATES: We will accept comments received or postmarked on or before January 10, 2022. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES**, below) must be received by 11:59 p.m. Eastern Time on the closing date. We must receive requests for a public hearing, in writing, at the address shown in **FOR FURTHER INFORMATION CONTACT** by December 27, 2021.

ADDRESSES: You may submit comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* In the Search box, enter FWS–HQ–ES–2020–0114, which is the docket number for this rulemaking. Then, click on the Search button. On the resulting page, in the Search panel on the left side of the screen, under the Document Type heading, check the Proposed Rule box to locate this document. You may submit a comment by clicking on ''Comment.''

(2) *By hard copy:* Submit by U.S. mail to: Public Comments Processing, Attn:

FWS–HQ–ES–2020–0114, U.S. Fish and Wildlife Service, MS: PRB/3W, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

We request that you send comments only by the methods described above. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see Information Requested, below, for more information).

Availability of supporting materials: Documentation used to prepare this proposed rule, including the species status assessment (SSA) report, are available on the internet at *http://www.regulations.gov* under Docket No. FWS–HQ–ES–2020–0114.

FOR FURTHER INFORMATION CONTACT: Elizabeth Maclin, Chief, Branch of Delisting and Foreign Species, Ecological Services, U.S. Fish and Wildlife Service, MS: ES, 5275 Leesburg Pike, Falls Church, VA 22041–3803; telephone, 703–358–2171. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under the Act, if we determine that a species warrants listing as an endangered or threatened species throughout all or a significant portion of its range, we are required to promptly publish a proposal in the **Federal Register** and make a determination on our proposal within 1 year. Listing a species as an endangered or threatened species can only be completed by issuing a rule.

What this document does. We propose to list the Egyptian tortoise as a threatened species with a 4(d) rule under the Act.

The basis for our action. Under the Act, we may determine that a species is an endangered or threatened species because of any of 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. We have determined that the Egyptian tortoise is likely to become endangered throughout all of its range in the foreseeable future, meeting the definition of a threatened species. The primary threats to the Egyptian tortoise are loss and degradation of habitat and collection of the species for the pet trade. Habitat destruction throughout the range of the species caused by human activities is the major factor limiting the availability of suitable habitat necessary for the species' survival. Collection is a significant threat to the species in Libya.

We are also proposing a section 4(d) rule. When we list a species as threatened, section 4(d) of the Act (16 U.S.C. 1533(d)) allows us to issue regulations that are necessary and advisable to provide for the conservation of the species. Accordingly, we are proposing a 4(d) rule for the Egyptian tortoise that would prohibit import, export, take, possession and other acts with unlawfully taken specimens, interstate or foreign commerce in the course of a commercial activity, or sale or offer for sale. It would also be unlawful to attempt to commit, to solicit another to commit, or to cause to be committed any such conduct. The proposed 4(d) rule would provide an exception for interstate commerce from public institutions to other public institutions, specifically museums, zoological parks, and scientific institutions that meet the definition of ''public'' at 50 CFR 10.12. We may issue permits to carry out otherwise prohibited activities, including those described above, involving threatened wildlife under certain circumstances, such as for scientific purposes, or the enhancement of propagation or survival of the species in the wild.

Peer review. In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270) and our August 22, 2016, memorandum updating and clarifying the role of peer review of listing actions under the Act, we sought the expert opinion of five appropriate specialists for peer review of the Species Status Assessment report. We received responses from three specialists, which informed this proposed rule. The purpose of peer review is to ensure that our listing determinations and 4(d) rules are based on scientifically sound data, assumptions, and analyses.

Information Requested

We intend that any final action resulting from this proposed rule will be based on the best scientific and commercial data available and be as accurate and as effective as possible. Therefore, we request comments or information from other concerned governmental agencies, wildlife management agencies in the range countries, the scientific community, industry, or any other interested parties concerning this proposed rule.

We particularly seek comments concerning:

(1) The species' biology, range, and population trends, including:

(a) Biological or ecological requirements of the species, including habitat requirements for feeding, breeding, and sheltering;

(b) Genetics and taxonomy;

(c) Historical and current range, including distribution patterns;

(d) Historical and current population levels, and current and projected trends; and

(e) Past and ongoing conservation measures for the species, its habitat, or both.

(2) Factors that may affect the continued existence of the species, which may include destruction, modification, or curtailment of habitat or range; overutilization for commercial, recreational, scientific, or educational purposes; disease; predation; the inadequacy of existing regulatory mechanisms; or other natural or manmade factors.

(3) Biological, commercial trade, or other relevant data concerning any threats (or lack thereof) to this species and existing regulations that may be addressing those threats.

(4) Additional information concerning the historical and current status, range, distribution, and population size of this species, including the locations of any additional populations of this species.

(5) Information on regulations that are necessary and advisable to provide for the conservation of the Egyptian tortoise and that the Service can consider in developing a 4(d) rule for the species. In particular, information concerning the extent to which we should include any of the section 9 prohibitions in the 4(d) rule or whether any exceptions from the prohibitions should be provided in the 4(d) rule.

Please include sufficient information with your submission (such as scientific journal articles or other publications) to allow us to verify any scientific or commercial information you include.

Please note that submissions merely stating support for, or opposition to, the action under consideration without providing supporting information, although noted, do not provide substantial information necessary to support a determination. Section 4(b)(1)(A) of the Act directs that determinations as to whether any species is an endangered or a threatened species must be made ''solely on the basis of the best scientific and commercial data available.''

You may submit your comments and materials concerning this proposed rule by one of the methods listed in

ADDRESSES. We request that you send comments only by the methods described in **ADDRESSES.**

If you submit information via *http://www.regulations.gov,* your entire submission—including any personal identifying information—will be posted on the website. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *http://www.regulations.gov.*

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on *http://www.regulations.gov.*

Because we will consider all substantive comments and information received during the comment period, and base our determination on the best scientific and commercial data available, our final determinations may differ from this proposal. Upon consideration of comments and information we receive, we may conclude based on the best scientific and commercial data available after considering all of the relevant factors that the species is endangered instead of threatened, or we may conclude that the species does not warrant listing as either an endangered species or a threatened species. In addition, we may change the provisions in the 4(d) rule if we conclude it is appropriate in light of comments and new information we receive. For example, we may narrow the proposed exception to interstate commerce prohibitions for certain public institutions in order to prohibit additional activities if we conclude that those additional activities are not compatible with conservation of the species. Conversely, we may establish additional exceptions to the interstate commerce prohibitions in the final rule if we conclude that the activities would facilitate the conservation and recovery of the species.

Public Hearing

Section 4(b)(5) of the Act provides for a public hearing on this proposal, if requested. Requests must be received by the date specified in **DATES.** Such requests must be sent to the address shown in **FOR FURTHER INFORMATION CONTACT.** We will schedule a public hearing on this proposal, if requested, and announce the date, time, and place of the hearing, as well as how to obtain reasonable accommodations, in the **Federal Register** at least 15 days before the hearing. For the immediate future, we will provide these public hearings using webinars that will be announced on the Service's website, in addition to the **Federal Register**. The use of these virtual public hearings is consistent with our regulations at 50 CFR 424.16(c)(3).

Previous Federal Actions

On June 9, 2014, we received a petition from Friends of Animals to list the Egyptian tortoise as threatened or endangered under the Act. On April 10, 2015, we published a 90-day finding that found that the petition presented substantial scientific and commercial information indicating that the petitioned action may be warranted and initiated a status review for the Egyptian tortoise (80 FR 19259).

Supporting Documents

We prepared an SSA report for the Egyptian tortoise, in consultation with species experts (Service 2020, entire). The SSA report represents a compilation of the best scientific and commercial data available concerning the status of the species, including the impacts of past, present, and future factors (both negative and beneficial) affecting the species. The Service sent the SSA report to five independent peer reviewers and received three responses.

I. Proposed Listing Determination

Background

A thorough review of the taxonomy, life history, and ecology of the Egyptian tortoise is presented in the SSA report (Service 2020, entire; available at *http://www.regulations.gov* under the FWS–HQ–ES–2020–0114 docket).

Taxonomy

The species Egyptian tortoise *(Testudo kleinmanni)* is a valid taxon (ITIS 2014, unpaginated) with *Testudo leithii* as a synonym (International Union for Conservation of Nature and Natural Resources (IUCN) 2014, p. 1), and *Testudo werneri* as a junior synonym (Attum *et al.* 2007a, p. 399).

Description

The Egyptian tortoise is the only dwarf tortoise occurring in the northern hemisphere, the smallest and least-known tortoise species inhabiting the Mediterranean basin (Buskirk 1985, pp. 35, 37), and the second smallest species of tortoise in the world (Woodland Park Zoo 2014, p. 1). The head, neck, limbs, feet, nails, and tail vary from yellow to yellowish-brown to ivory colored (Loveridge and Williams 1957, p. 280; Flower 1933, p. 748; Highfield and Martin 2014, p. 1; Ernst *et al.* 2014, p. 1). The high-domed carapace (top shell) is pale yellow with lemon and yellow-green shades, with each scute (bony plates) edged with brown or black (Buskirk 1985, p. 36; Loveridge and Williams 1957, p. 279; Woodland Park Zoo 2014, p. 1). These marks vary in individuals, regardless of sex or locality, and may be strong and broad, wide or narrow, or merely outlines to the shields (Flower 1933, p. 749; Loveridge and Williams 1957, p. 279; Ernst *et al.* 2014, p. 1). The plastron (bottom shell) is greenish to yellow and the vast majority of specimens feature two V-shaped brown or black markings upon the abdominal scutes (Buskirk 1985, p. 36; Loveridge and Williams 1957, p. 279). This feature is quite different from the abdominal marks seen on the plastron of other Palaearctic land-tortoises (Greek tortoise (*Testudo graeca*), Hermann's tortoise (*Testudo hermanni*), Marginated tortoise (*Testudo marginata*), and Russian tortoise (*Testudo horsfieldii*); Flower 1933, p. 749; Highfield and Martin 2014, p. 1).

The most distinguishing characteristic of the Egyptian tortoise is its remarkably small size (Highfield and Martin 2014, p. 1). Females are generally a bit larger than males (Woodland Park Zoo, p. 1; Buskirk 1985, p. 36). Females usually have a carapace length over 110 millimeters (4.33 inches) and weigh approximately 300–350 grams (10.6–12.4 ounces). Male's carapace length is between 90 and 100 millimeters (3.54–3.93 inches), and weigh 160–250 grams (5.6–8.8 ounces).

Habitat

The Egyptian tortoise is mostly found in desert and semi-desert areas, shoreline grasses at the edges of salt lakes or salt marshes, and areas of scrub thorn in a narrow coastal zone along the southeast Mediterranean coast (Lortet 1887, and Werner 1982, in Buskirk 1985, p. 40; Maryland Zoo 2015, p. 1; Ernst et al 2014, p. 1; Mendelssohn 1982, p. 133). The species prefers areas ranging from sandy soils and dunes to solidified sands with fair to dense plant cover of bushes and small shrubs, and short-lived annual vegetation to eat (Baha El Din 1994, p. 4; Mendelssohn 1982, pp. 133–134).

Life History

Egyptian tortoises are active during the cooler part of the year. Peak activity is from December to March. By April, activity is reduced, although tracks are occasionally seen as early as October and as late as May (Geffen and Mendelssohn 1989, p. 405; Mendelssohn 1982, p. 134). During the summer, tortoises aestivate or experience prolonged dormancy from

mid-May or early June through the end of September, a period characterized by extremely high ambient temperatures, no rainfall, and the lowest food availability (Attum *et al.* 2006, 2007b, 2008, in Attum *et al.* 2013, pp. 74, 76–77; Geffen and Mendelssohn 1989, p. 406). Bushes and shrubs provide cover and thermal refuges, especially during prolonged dormancy during the summer, and are essential to the survival of the species (Geffen and Mendelssohn 1989, p. 408; Mendelssohn 1982, p. 134). Two major factors that seem to stimulate the onset of aestivation in the Egyptian tortoise are rising ambient temperature (over 30 °C (86 °F)) and withering of food plants (Ernst *et al.* 2014, p. 1; Geffen and Mendelssohn 1989, p. 408).

Reproductive potential is low. Female Egyptian tortoises produce a maximum of three eggs in one clutch with up to two clutches for the season (Baha El Din 2020, pers. comm.). Eggs are laid in a solitary nesting site that does not require specific location or structure, during a prolonged nesting period (Geffen and Mendelssohn 1991, p. 576). It is likely that Egyptian tortoises do not reproduce at all during years of low rainfall (Mendelssohn 1982, p. 136). Males reach maturity at 5 years old, and females take at least 8 years because of physical limitations of laying eggs (Baha El Din 2020, pers. comm.; Attum *et al.* 2011, p. 10). One generation in the wild is estimated to be about 20 years (Perälä 2006, p. 60; Macale *et al.* 2009, p. 143), although the average age can be much less (Egyptian Environmental Affairs Agency 2009, p. 222). Information of survival rate specific to Egyptian tortoises is lacking. Generally, survivorship for other closely related tortoise species in the genus *Testudo* spp. during the egg stage and first year of life is significantly lower than during later life stages (Iverson 1991, p. 385; Henry *et al.* 1998, p. 192).

Diet

The Egyptian tortoise is an herbivore (Maryland Zoo 2015, p. 1), although the diet of wild tortoises is not well understood. Because food is likely to be most abundant when Egyptian tortoises are active in the cooler part of the year, they feed intensely on annual vegetation and leaves of perennial bushes and shrubs when active; however, most parts of shrubs may be out of reach (Mendelssohn 1982, p. 134; Groombridge 1982, p. 134). Annual precipitation facilitates the growth of short-lived annual vegetation. The relatively high level of precipitation of 100–200 mm (3.94–7.87 in) along the Mediterranean coast may be the main factor restricting the species to coastal areas that receive higher rainfall than areas further inland (Mendelssohn 1982, p. 134).

Range and Distribution

Historically, the Egyptian tortoise occurred on both sides of the Nile River, distributed along the southeast Mediterranean coast, in three regions (Tripolitania, Sirte, and Cyrenaica) in Libya, two regions (North Coast and North Sinai) in Egypt, and in the western Negev Desert in Israel. Rangewide surveys have never been conducted; however, based on hydrobasins and known records of the species throughout the range, the historical range was estimated at 79,288 km^2 (30,613 mi^2) (Rhodin 2020, pers. comm.). Taking into account areas lost to and degraded by human development activities, recent estimates state that the range has decreased to between 7,929 and 15,857 km^2 (3,061–6,122 mi^2) (Perälä 2005, p. 894; Perälä 2006, p. 61; Rhodin 2020, pers. comm.). The species currently exists in the three regions in Libya, in five small subpopulations in North Sinai in Egypt, and in the western Negev Desert in Israel. The Egyptian tortoise has been extirpated from the North Coast of Egypt, and no longer occupies the historical part of the range in Egypt from the Libyan border east to the Nile River.

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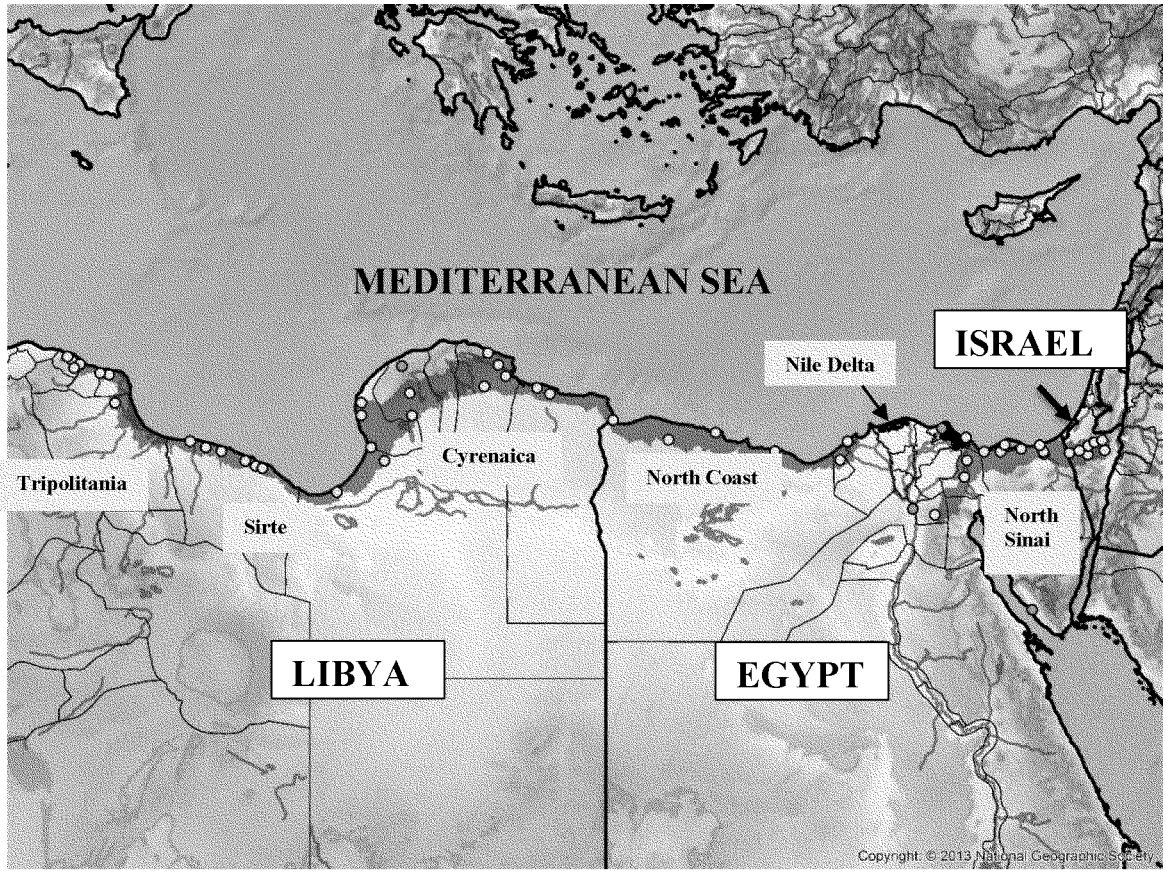

Figure 1. Distribution of the Egyptian tortoise, from Libya through Israel. The shaded area along the southeastern Mediterranean coast, on the coastline of Libya and Egypt, and into the Western Negev Desert in Israel on the map above reflects the approximate historical range of the species. The Egyptian tortoise has been extirpated from the North Coast of Egypt; therefore, the species no longer occupies the historical part of the range in Egypt from the Libyan border east to the Nile Delta. The dots are recorded locations from the literature including both historical and current occurrence of the species. (Rhodin 2020, pers. comm; Rhodin *et al.* 2017).

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The Egyptian tortoise is restricted to a narrow coastal zone in North Africa and the western Negev Desert in Israel, in the southeast Mediterranean, and has the most restricted range of all tortoises in the Mediterranean Basin (Baha El Din 2003, entire). It currently occurs within scrub habitat (see *Habitat*) up to 40–50 km (25–31 mi) from the Mediterranean coast, depending on the location. Historically, the range of the species in Egypt potentially encompassed the whole Mediterranean coastal desert east and west of the Nile Delta as far as 100 km (62 mi) inland (Baha El Din 1994, p. 3).

Population Estimate

Over the last three generations (or about 60 years), the Egyptian tortoise population has been reduced by approximately 90 percent throughout its range, including the extirpation of the species in North Coast, Egypt, which accounted for about 30 percent of the species' historical population (Perälä 2005, p. 894; Perälä 2006, p. 61; Rhodin 2020, pers. comm; Rhodin *et al.* 2017, p. 154; Baha El Din 1994, p. 6; Baha El Din *et al.* 2003, p. 651). No accurate fieldwork-based data on population sizes exist for the species. Based on an average population density in Israel from a study in the 1980s, and the area of occupancy as defined by the IUCN, the rangewide population size was estimated in 2005 and 2006 to be approximately 10,650 individuals (Perälä 2005, p. 894; Perälä 2006, p. 61). Taking into account comments from peer reviewers of the SSA report, we estimate that the current population size is approximately 11,000 individuals, with at least 7,500 individuals in Libya, 200–250 individuals in North Sinai, Egypt, and approximately 3,000 individuals in Israel. However, we do not have any recent estimates of the population size in Israel (Perälä 2005, p. 894; Perälä 2006, p. 61; Attum 2019,

pers. comm.; Baha El Din 2020, pers. comm.).

TABLE 1—ESTIMATES OF THE HISTORICAL AND CURRENT POPULATIONS FOR THE EGYPTIAN TORTOISE

(Perälä 2005, p. 894; Perälä 2006, p. 61).

Population Name	Historical individuals (estimate of individuals present in the 1950s) [1]	Estimated population in 2005 and 2006 [2]	Best estimate in 2020 [3]
Libya (Cyrenaica)	22,600	5,000	*Libya:* At least 7,500 adults, not including non-breeding adults.
Libya (Sirte)	Unknown	unknown.	
Libya (Tripolitania)	2,500	2,500.	
Egypt (North Coast)	30,500	0 (was previously reintroduced in El Omayed Protected Area).	0.
Egypt North Sinai and Israel.	45,000	3,150, which are mostly in Israel	*Israel:* unknown. The best estimate is 3,000, based on the population estimated in 2005 and 2006.
		The population in North Sinai is about 100	*North Sinai:* 5 very small subpopulations in one small population contain a total of 200–250 individuals.
Total Individuals	100,600	10,650	≈ 11,000 *

* The current total population could be similar to the population estimated in 2005 and 2006. The population in Libya is uncertain due to a lack of any field surveys, and we do not have information regarding the population size in Israel since 2006. Egyptian tortoise populations have experienced habitat degradation because of human activities since the population estimates in 2005 and 2006.

[1] (Perälä 2005; Perälä 2006).

[2] (Perälä 2005; Perälä 2006; Schneider and Schneider 2008).

[3] (Baha El Din 2020, pers. comm.; Attum 2019, pers. comm.; Attum 2020, pers. comm.).

Regulatory and Analytical Framework

Regulatory Framework

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the procedures for determining whether a species is an endangered species or a threatened species. The Act defines an endangered species as a species that is ''in danger of extinction throughout all or a significant portion of its range,'' and a threatened species as a species that is ''likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.'' The Act requires that we determine whether any species is an endangered species or a threatened species because of any of the following 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.

These factors represent broad categories of natural or human-caused actions or conditions that could have an effect on a species' continued existence. In evaluating these actions and conditions, we look for those that may have a negative effect on individuals of the species, as well as other actions or conditions that may ameliorate any negative effects or may have positive effects.

We use the term ''threat'' to refer in general to actions or conditions that are known to or are reasonably likely to negatively affect individuals of a species. The term ''threat'' includes actions or conditions that have a direct impact on individuals (direct impacts), as well as those that affect individuals through alteration of their habitat or required resources (stressors). The term ''threat'' may either encompass—together or separately—the source of the action or condition, or the action or condition itself.

However, the mere identification of any threat(s) does not necessarily mean that the species meets the statutory definition of an ''endangered species'' or a ''threatened species.'' In determining whether a species meets either definition, we must evaluate all identified threats by considering the expected response by the species, and the effects of the threats—in light of those actions and conditions that will ameliorate the threats—on an individual, population, and species level. We evaluate each threat and its expected effects on the species, and then analyze the cumulative effect of all of the threats on the species as a whole. We also consider the cumulative effect of the threats in light of those actions and conditions that will have positive effects on the species, such as any existing regulatory mechanisms or conservation efforts. The Secretary determines whether the species meets the definition of an ''endangered species'' or a ''threatened species'' only after conducting this cumulative analysis and describing the expected effect on the species now and in the foreseeable future.

The Act does not define the term ''foreseeable future,'' which appears in the statutory definition of ''threatened species.'' Our implementing regulations at 50 CFR 424.11(d) set forth a framework for evaluating the foreseeable future on a case-by-case basis. The term ''foreseeable future'' extends only so far into the future as the Service can reasonably determine that both the future threats and the species' responses to those threats are likely. In other words, the foreseeable future is the period of time in which we can make reliable predictions. ''Reliable'' does not mean ''certain''; it means sufficient to provide a reasonable degree of confidence in the prediction. Thus, a prediction is reliable if it is reasonable to depend on it when making decisions.

It is not always possible or necessary to define foreseeable future as a particular number of years. Analysis of the foreseeable future uses the best scientific and commercial data available and should consider the timeframes applicable to the relevant threats and to

the species' likely responses to those threats in view of its life-history characteristics. Data that are typically relevant to assessing the species' biological response include species-specific factors such as lifespan, reproductive rates or productivity, certain behaviors, and other demographic factors.

For the purposes of considering the future condition of Egyptian tortoise, we considered the threats of habitat loss and degradation and collection for the pet trade, along with demographic factors of Egyptian tortoises, and determined that the foreseeable future was approximately 60 years. This timeline for the foreseeable future is based on several factors. The Egyptian tortoise matures slowly, and in the best of conditions has a low reproductive rate. Thus, the species depends on high survival rates and long reproductive lifespans of adults to increase population size (Wilbur and Morin 1988, in Díaz-Paniagua *et al.* 2001, p. 707). Some threats to species manifest themselves through demographic changes to the species over a number of generations. Because of the long generation length (up to 20 years) and slow reproductive rate, demographic responses of the species to the threats that are already ongoing will manifest increasingly over a significant period of time. Existing studies already document the species' responses to threats over the past three generations, or approximately 60 years (Perälä 2005, p. 894; Perälä 2006, p. 61; Rhodin 2020, pers. comm; Rhodin *et al.* 2017, p. 154; Baha El Din 1994, p. 6; Baha El Din *et al.* 2003, p. 651). Therefore, we conclude that we can reasonably determine the response of the Egyptian tortoise to the threats described below for at least 60 years.

In addition, world experts have assessed factors relevant to the status of the species as far out as 60 years, and we conclude that it is reasonable to rely on that information. For example, as part of our review we considered and incorporated the information underlying IUCN's Red List assessment of the species that also takes into account the decline in abundance and range of the species, levels of exploitation, and direct observations by experts (IUCN 2012, unpaginated; Perälä 2005, p. 897; Perälä 2006, p. 65). The IUCN Red List is a membership organization of worldwide experts that assesses the conservation status of species throughout the world, and uses a set of qualitative criteria to evaluate extinction risk of species (IUCN 2021, unpaginated). IUCN's standards and criteria differ from those in the Act, and the designations are not interchangeable. However, we found the IUCN's information to be part of the best scientific and commercial information available for this species, and that predictions based on IUCN's information for this species can be reliable over approximately the next 60 years. We also note that IUCN reasonably projects that the species faces a greater-than-80-percent chance of extinction in the wild within the next 60 years.

Similarly, the human population is projected to increase within the range of the species, which will contribute to future habitat loss and continue the threat of collection of the Egyptian tortoise. The human population in the species' range has been reliably projected out to at least 2080 (World Population Review 2020a,b, unpaginated; Osman 2013, unpaginated; CIA World Fact Book—Israel 2019, unpaginated; World Population Review 2020c, unpaginated). Climate change projections reveal it is likely that warming and reduced precipitation across the region within the next 60 years will also contribute to habitat loss and affect the species because Egyptian tortoises are highly sensitive to thermal stress (IPCC 2013, p. 1266; Al-Olaimy 2017, unpaginated; Baha El Din 2020, pers. comm.). Therefore, based on the best scientific and commercial data available, we conclude that over a period of 60 years we can reasonably determine that both the future threats to the species and the species' response to those threats are likely. Consequently, we identified 60 years, or 2080, as the foreseeable future for the Egyptian tortoise.

Analytical Framework

The SSA report documents the results of our comprehensive biological review of the best scientific and commercial data available regarding the status of the species, including an assessment of the potential threats to the species. The SSA report does not represent a decision by the Service on whether the species should be proposed for listing as an endangered or threatened species under the Act. However, it does provide the scientific basis that informs our regulatory decisions, which involve the further application of standards within the Act and its implementing regulations and policies. The following is a summary of the key results and conclusions from the SSA report; the full SSA report can be found at Docket FWS–HQ–ES–2020–0114 on *http://www.regulations.gov.*

To assess Egyptian tortoise viability, we used the three conservation-biology principles of resiliency, redundancy, and representation (Shaffer and Stein 2000, pp. 306–310). Resiliency supports the ability of the species to withstand environmental and demographic stochastic events (for example, those that arise from random factors), redundancy supports the ability of the species to withstand catastrophic events (for example, droughts, large pollution events), and representation supports the ability of the species to adapt over time to long-term changes in the environment (for example, climate changes). In general, the more resilient and redundant a species is and the more representation it has, the more likely it is to sustain populations over time, even under changing environmental conditions. Using these principles, we identified the species' ecological requirements for survival and reproduction at the individual, population, and species levels, and described the beneficial and risk factors influencing the species' viability.

The SSA process can be categorized into three sequential stages. During the first stage, we evaluated the species' life-history needs. The next stage involved an assessment of the historical and current condition of the species' demographics and habitat characteristics, including an explanation of how the species arrived at its current condition. The final stage of the SSA involved making predictions about the species' responses to positive and negative environmental and anthropogenic (human-caused) influences. Throughout all of these stages, we used the best available scientific and commercial information to characterize viability as the ability of a species to sustain populations in the wild over time. We use this information to inform our regulatory decision.

Summary of Biological Status and Threats

In this discussion, we review the biological condition of the species and its resources, and the threats that influence the species' current and future condition, in order to assess the species' overall viability and the risks to that viability.

The Egyptian tortoise needs areas of sandy dunes to more solidified sands with plant cover from bushes and small shrubs and annual plants to eat. Based on the Egyptian tortoise's life history and habitat needs, and in consultation with species' experts, we identified the stressors that likely affect the species' current condition and overall viability, as well as the sources of the stressors, and the existing conservation and regulatory measures that address certain stressors (Service 2020, pp. 29–51). We

evaluated all the known stressors that may be currently affecting the species and to what extent the stressors may affect the species in the future (Service 2020, pp. 51–55).

Egyptian tortoises face similar threats to their viability throughout their range, although the magnitude may vary among Libya, Egypt, and Israel. The primary threats to the Egyptian tortoise are degradation and loss of habitat and collection of the species for the pet trade (Service 2020, pp. 30–39). Habitat destruction throughout the range of the species caused by human activities is the major factor limiting the availability of suitable habitat necessary for the species' survival. Habitat loss may also occur because of changing environmental conditions from climate change.

Habitat Degradation and Loss

Ongoing threats to the species' habitat throughout its range include urban development, agriculture conversion, grazing activities, and military exercises (Baha El Din 1994, pp. 2, 6, 11–14; Attum 2019, pers. comm; Perälä 2006, p. 62; Baha El Din 2003, pp. 652–653; Schneider and Schneider 2008, p. 150; Baha El Din 2002, p. 2; Portnov and Safriel 2004, pp. 667–668; Service 2020, pp. 30–34). Much of the species' habitat along the Mediterranean coast has been altered by urban development and agriculture conversion. Additionally, livestock grazing has dramatically increased in any pockets of habitat not already converted for agriculture (Baha El Din 1994, p. 11). The impact of grazing is more subtle than conversion of habitat for agricultural purposes, but just as devastating because goats and sheep directly compete with tortoises for annual plants, the tortoise's main food resource (Baha El Din 1994, p. 12; Baha El Din 2003, p. 653; Schneider and Schneider 2008, p. 150). Agriculture and grazing are most intense in the spring, which coincides with peak activity of the Egyptian tortoise and the growth of annual plants (Baha El Din 1994, pp. 11, 14). Furthermore, military exercises cause considerable damage to habitat throughout the species' range (Baha El Din 1994, p. 2; Attum 2019, pers. comm; Perälä 2006, p. 62).

Most of the land-use changes (urbanization, agriculture conversion, and grazing) occur within 50 km (31 mi) of the coastline, where the species and its habitat occur. Over the last 25 years, shrub land decreased by approximately 22 percent throughout the Libyan and Egyptian coastline (USGS 2019, unpaginated). Throughout Libya, shrub land decreased between 9 and 21 percent, with more shrub land lost in eastern Libya (Cyrenaica). In North Coast and North Sinai, Egypt, shrub land decreased by 37 and 34 percent, respectively. No information was available for Israel. Because of the land-use changes and loss of habitat, the populations in each country have no connectivity across international borders, including the populations in North Sinai, Egypt and Israel that are both on the east side of the Nile and are relatively close in proximity.

Protected areas, national parks, and nature reserves offer some suitable habitat and protection for the Egyptian tortoise. However, even the habitat in these areas is degraded and is also used for pastoral livestock grazing that competes with Egyptian tortoise for vegetation (Attum et al. 2007b, entire; Baha El Din et al. 2003, p. 653; Attum et al. 2013, p. 74). In Egypt, suitable habitat for the species currently exists in a few protected areas that are designated to conserve natural habitats, biodiversity, and optimize economic and social value (see Figure 9; SSA Report, Service 2020; NCS 2006, pp. 8–10); however, the species only exists in and on the periphery of Zaranik Protected Area in North Sinai. In Israel, the species partially occurs within Holot Agur Nature Reserve (Perälä 2005, p. 895; Baha El Din 2003a, in Attum et al. 2007b); the reserve overlaps about one-fifth of the population in Israel and provides some protection for a portion of its habitat. Although one Egyptian tortoise was found 20 years ago in Kouf National Park in northeast Libya, we do not have recent information on the presence or absence of tortoises at this park. No other protected lands exist in areas of known tortoise activity in Libya.

Collection

Large numbers of Egyptian tortoises were collected from Egypt through much of the first half of the 20th century for sale as pets (Baha El Din 1994, p. 25). The mass collection of the species for the pet trade was recognized as early as 1933 (Flower 1933, p. 746) and continued until the late 1970s, by which time the species' population was extirpated from large parts of the North Coast of Egypt. With the return of Sinai to Egypt in 1982, another area was open for collectors, and by the late 1980s, the species' population was severely depleted throughout Egypt (Baha El Din 1994, p. 25). The population of Egyptian tortoises in Egypt is very small and managed by locals in the Zaranik Protected Area and commercial collection of the species is not currently a factor for the population in North Sinai, Egypt. However, fear exists that poachers will target the tortoises in this area to collect for the pet trade (McGrath 2011, unpaginated). Egypt is a major conduit for smugglers, and Egyptian tortoises are smuggled from Libya into Egypt.

Currently, collection for the pet trade is the biggest threat to the species in Libya, which has the largest remaining population of the species. After political relations between Egypt and Libya improved and the border between the two countries opened in 1989, Egyptians working as herders in Libya collected tortoises (both Egyptian tortoises and Greek tortoises) and smuggled them across the border into Egypt for local markets and exporting to other countries (Baha El Din 1994, p. 25; CITES uplisting proposal 1995, p. 23). Historically, the species was exported to European and U.S. markets; now the main export destination is Asia (Attum 2020, pers. comm.). Collection pressure is higher in eastern Libya (Cyrenaica), which is considered the heart of the range, than in the western part of the country, although tortoises are collected in western Libya and sold to dealers that smuggle them into Egypt (Baha El Din 2002, p. 2; Baha El Din et al. 2003, p. 653; Schneider and Schneider 2008, p. 150).

It is common to see tens of Egyptian tortoises for sale in multiple pet stores or markets in many parts of Egypt as tortoises continue to be smuggled from Libya (Baha El Din 2020, pers. comm.). The uprising against the Libyan Government in 2011 temporarily brought smuggling operations to a halt (McGrath 2011, unpaginated). However, trade of Egyptian tortoises has returned to levels prior to 2011 (Baha El Din 2020; pers. comm.). Some level of enforcement in Egypt affects smuggling of Egyptian tortoises from Libya into Egypt (Attum 2020, pers. comm.; Baha El Din 2020, pers. comm.). Collection of Egyptian tortoises for the pet trade is minimal in Israel, although some poaching by agricultural workers does occur.

Climate Change

In our analysis of potential climate-change impacts to the Egyptian tortoise, we used two scenarios, Representative Concentration Pathway (RCP) 4.5 and 8.5., to account for uncertainty regarding future atmospheric greenhouse-gas concentrations within the next century. RCP 4.5 is at the lower end of the intermediate range of conditions projected while RCP 8.5 is the high end of Intergovernmental Panel on Climate Change (IPCC) projections of atmospheric conditions. By using both a high and a lower emissions scenario in

our projections, we bracketed the likely possibilities for effects from climate change over the next 60 years.

Climate-change projections for the Mediterranean region, which includes the Egyptian tortoise's range, reveal warming in all seasons and likely reduced precipitation projections across subregions and seasons. Confidence in model projections of mean temperature in this region is high; it is very likely that temperatures will continue to increase over the next 60 years in the Mediterranean region (IPCC 2013, p. 1266; Al-Olaimy 2017, unpaginated). The strongest warming is projected to take place close to the Mediterranean coast. Warming by at least 3 °C (5.4 °F) is projected by the end of the century under RCP 4.5. Under RCP 8.5, mean summer temperatures could be up to 8 °C (14.4 °F) warmer, including more heat extreme days during the summer (World Bank 2014, p. 114).

Winter mean temperature will rise moderately, whereas summer warming will likely be more intense. The length, frequency, and intensity of warm spells or heat waves are very likely to increase throughout the whole Mediterranean region (IPCC 2013, p. 1266). The summer months are currently characterized by daily, potentially lethal maximum daytime temperatures of approximately 32 °C (90 °F) along the Mediterranean coast and even hotter in the desert and other interior areas (Weather Channel 2019, unpaginated; Weather and Climate 2019, unpaginated).

Tortoises aestivate under shrubs in the summer when the temperature is highest, food availability is least, and the warming is projected to be the most intense. This decrease in activity of Egyptian tortoises following rising mean ambient temperatures over 30 °C (86 °F) reflects the strong influence of environmental temperature on their activity. Egyptian tortoises are highly sensitive to thermal stress, particularly increased temperature. Therefore, any marginal increase caused by climatic change would have very limiting effects on their survival in the wild (Baha El Din 2020, pers. comm.). This impact has been observed first-hand in captive populations near Cairo, Egypt (only 100 km (62 mi) south of the natural range) (Baha El Din 2020, pers. comm.). Tortoises are more active during the winter and spring when the mean temperatures is approximately 15 to 25 °C (59–77 °F). Although temperature is projected to rise moderately during the winter, the temperature may not reach levels that are detrimental to the tortoise.

Regulatory Mechanisms

The Egyptian tortoise is afforded some protection based on existing regulations in each of the range countries. However, these regulations have had varying success protecting the species' habitat from destruction and the species from collection for the pet trade. Protected areas, national parks, and nature reserves offer some suitable habitat and protection for the Egyptian tortoise, although habitat in protected areas is degraded and is subject to livestock grazing. Additionally, lax enforcement in these areas may provide opportunities for tortoise poaching and smuggling.

In Egypt, Law 4 (enacted in 1994) became the primary legislation for environmental management, creating the Nature Conservation Sector under the Egyptian Environmental Affairs Agency (NCS 2006, p. 4). Law 4 gives protected status to the Egyptian tortoise; it is illegal to collect, possess, or sell protected species or wild animals, dead or alive (Baha El Din et al 2003, p. 653). Though enforcement is sporadic, it is increasing, and implementation and screening at airports for species listed under the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) has resulted in confiscation of some Egyptian tortoises intended for the illegal pet trade (Baha El Din et al 2003, p. 653). Egypt's Law 102 (enacted in 1983) provides the legislative framework for establishing and managing protected areas in Egypt.

Zaranik Protected Area in North Sinai, Egypt, contains Egyptian tortoise. Local Bedouins manage the native tortoise population in Zaranik and protect the species from habitat degradation and collection. A program operated by Bedouin women contributes to raising awareness for the species through the production of handicrafts with tortoise motifs (Baha El Din 2003, p. 654; Attum *et al.* 2007b, p. 399).

In Libya, Law 7 (enacted in 1982), subsequently repealed and replaced by Law 15 (enacted in 2003), prohibits the catching of endangered species, their sale, or export (Baha El Din 2002, p. 2; FAOLEX 2019a, unpaginated). However, lists of species protected in Libya do not include the Egyptian tortoise (Baha El Din 2002, p. 2; McGrath 2011, unpaginated). The Egyptian tortoise is covered by a resolution by the Minister of Agriculture in favor of their protection and to prevent trading and export (Khalifa *in litt.,* to IUCN/SSC Trade Specialist Group 1993, in CITES uplisting proposal 1995, p. 25). However, we have no information to indicate the resolution is enforceable. Accordingly, domestic regulatory mechanisms for the conservation of the species in Libya are either non-existent or potentially lacking enforcement authority.

In Israel, the Wildlife Protection Law (enacted in 1955 and amended in 1999) has proved to be an effective instrument in the protection of wildlife. The law was designed to protect birds, mammals, reptiles, and amphibians. All species of wild animals anywhere in Israel are completely protected, except for designated pest species and declared game species (IMFA 1997, unpaginated; Wildlife Protection Law 5715–1955). The nature reserve Holot Agur in Israel was established in 2010 (Protected Planet 2019, unpaginated). The reserve covers approximately 176 km^2 (68 mi^2) of the Holot Agur sands area in the western Negev Desert and overlaps about one-fifth of the best known and studied population of Egyptian tortoises in Israel (Buskirk 1993, unpaginated).

Libya, Egypt, and Israel are all Parties to CITES, and Egyptian tortoise is a CITES-protected species. The Egyptian tortoise was included in Appendix II of CITES in 1975 under the genus-level listing of *Testudo* spp., and the species subsequently was transferred to Appendix I on February 16, 1995. CITES Appendix I includes species threatened with extinction that are or may be affected by trade, and species included in Appendix I receive the highest level of protection under CITES (CITES Art. II(1), (4), Art. III; 50 CFR part 23). International trade is permitted only under exceptional circumstances, and international trade for primarily commercial purposes is prohibited, with limited exceptions for qualifying specimens bred in captivity for commercial purposes by CITES-registered facilities and pre-Convention specimens (CITES Art. II(1), (4), Art. III, Art. VII(2), (4); 50 CFR part 23). There are currently no CITES-registered breeding facilities for the species.

Including the Egyptian tortoise in Appendix I of CITES in 1995 was an important action for the conservation of the species, considering the decreasing population numbers and the amount of trade occurring up to the 1970s and 1980s. However, despite their status in Appendix I of CITES, the best available information indicates that Egyptian tortoises are illegally traded internationally. The collection pressure from this illegal trade continues to harm the species, though at a reduced level to the collection pressure previously attributed to the legal commercial trade while the species was included in Appendix II (CITES Trade Database

2020; Theile *et al.* 2004, p. iii; Stengel *et al.* 2011, pp. 10–11, 19).

Current Conditions

The Egyptian tortoise's viability is influenced by its resiliency, adaptive capacity (representation), and redundancy. Resiliency for the Egyptian tortoise is measured by population size, distribution, and health throughout its range. Population size, quality of habitat where the species occurs (taking into account anthropogenic effects), whether a population is in a protected area, and the collection pressure of a population all influence the resiliency of the Egyptian tortoise. Representation for the Egyptian tortoise can be measured by the distribution of the species on both sides of the Nile River because of some ecological diversity in habitat west and east of the river. Redundancy can be measured by the distribution of resilient populations across its range.

Under current conditions, the population in Libya has moderate resiliency. The population has the highest abundance of any population throughout the species' range; the population occurs in three regions, consisting of at least 7,500 tortoises. Suitable habitat remains in Libya; overall the habitat is degraded and the species does not reside in any protected areas in Libya. The magnitude of habitat loss because of development is smaller compared to Egypt and Israel. Collection pressure of the species for the pet trade is highest in Libya.

The population in North Sinai, Egypt, has moderate resiliency. This population is very small, made up of 5 even smaller subpopulations, totaling approximately 200–250 tortoises. Grazing of livestock degrades the habitat. The population in Egypt is not collected for the pet trade, and partially resides within Zaranik Protected Area that is managed and protected by the local people in the area.

Similarly, the Egyptian tortoise in Israel is insignificantly collected for the pet trade, and the population partially overlaps the Holot Agur Nature Reserve. This population has moderate resiliency because even though the population may consist of up to 3,000 tortoises (approximated in 2006), it only occurs within an area up to 1,000 km^2 (386 mi^2) in the western Negev Desert, and a suite of human activities, including urban and agricultural development, and grazing of livestock continues to degrade the habitat.

The Egyptian tortoise is represented in areas west and east of the Nile River with some ecological diversity because the substrates where populations occur vary across its range. West of the Nile, the species occurs in three regions in Libya with substrates varying from rocky to soft sand (Schneider and Schneider 2008, p. 145). The Egyptian tortoise was extirpated from the North Coast and has lost variability of all habitat types it historically occupied in this part of its range. In Egypt, the species only occurs east of the Nile in small subpopulations in North Sinai, in and near Zaranik Protected Area. Also east of the Nile, the distribution in Israel has not changed since the species was discovered in 1963, although suitable habitat for the species is likely reduced because of human activities in the western Negev Desert. The habitat where the Egyptian tortoise occurs in North Sinai, Egypt, and in the western Negev Desert in Israel is sandy dunes. Overall, the Egyptian tortoise occurs in each country (though with only five very small subpopulations making up one small population that totals approximately 200–250 specimens in Egypt), west and east of the Nile River, and maintains some ecological diversity across populations. The representative habitat types where the species occurs has declined and is much less than it was historically.

One population in each range country characterizes redundancy for the Egyptian tortoise. There is no connectivity or overlap (across international borders) between the Egyptian tortoise populations from each country. One population occurs in Libya, spread across three regions along the coast. The best available information provides one total population size in the country and does not distinguish the populations within each of the three regions in Libya. The population in Egypt consists of five very small subpopulations in and on the periphery of Zaranik Protected Area in North Sinai, in which the population size is provided as one total population size. One population occurs in Israel in the western Negev Desert. The reduction of the overall population, including the extirpation of the species from North Coast, Egypt, and the fragmentation of the rangewide populations because of land-use changes that caused habitat loss and degradation across the species' range, compromises the species' ability to reoccupy areas within its historical range.

Overall, the Egyptian tortoise occurs in fragmented populations with moderate resiliency because there are multiple populations, some of which are partially in protected areas, and ongoing habitat degradation and collection pressure. The existence of multiple populations distributed throughout the tortoise's range reduces the likelihood that any single catastrophic event could affect one or more of the populations simultaneously. We have not identified any catastrophic events that would affect the Egyptian tortoise across its entire range. Therefore, the species has sufficient redundancy to withstand catastrophic events.

Future Conditions

We projected the resiliency, representation, and redundancy of the Egyptian tortoise under two plausible future scenarios: (1) A status quo scenario in which human-caused impacts and tortoise population responses continue as the current trends indicate; and (2) a reduced-collection scenario in which the collection of Egyptian tortoises for the pet trade from Libya decreases as a result of Libyan authorities enacting regulations that improve enforcement and reduce the collection of the species. Libyan authorities had been seeking to put an end to collection and exportation by enacting legislation that would prevent illegal removal from Libya (Schneider and Schneider 2008, p. 150). Despite efforts by the Environment General Authority, who along with local academics have interest in tortoise conservation and poaching prevention in Libya, the species is still being collected and showing up in Egyptian markets. Thus, implementing conservation measures in Scenario 2 (reducing collection in Libya) is uncertain given the ongoing collection of Egyptian tortoises and geopolitical instability in Libya.

The two scenarios do not include variance or change in the rate of habitat loss caused by human activities such as development, agriculture and grazing, and military activities. The habitat is highly degraded and continues to degrade throughout the range of the species. With continued expansion of these activities resulting from an increasing human population that will increase demand for urban area and agricultural production, we project that suitable habitat for the species will continue to decrease in the future. Additionally, effects from a changing climate are likely to affect the Egyptian tortoise in the future. The temperature is likely to rise moderately in the winter with more intense warming in the summer. These effects would likely be at an earlier date in the future under RCP 8.5 than RCP 4.5 because warming is projected to be higher under RCP 8.5. However, we do not have information with a specific temperature threshold (beyond their preferred temperature range) where Egyptian tortoises would be affected. The best available

information indicates that Egyptian tortoises are highly sensitive to thermal stress, particularly increased temperature. Therefore, any marginal increase because of climatic change under either RCP, combined with the loss of habitat (*i.e.,* shrubs needed for thermal buffering), would likely limit their ability to survive in the wild (Baha El Din 2020, pers. comm.). Furthermore, reduced precipitation is projected in the Mediterranean region that will likely affect the quantity and quality of annual plants and woody shrubs that the Egyptian tortoise uses for food and shelter. We recognize the effects of climate change in the future but do not differentiate between RCP 4.5 and RCP 8.5 in the future scenarios because we could not distinguish between RCPs 4.5 and 8.5 at which temperature or timeframe the Egyptian tortoise would show signs of stress. Factors such as habitat loss and degradation and collection for the pet trade will have a more immediate and pronounced effect on the species and its habitat. Therefore, we focus the future condition on habitat degradation and collection pressure because of human activities.

Scenario 1

Under Scenario 1, we project that rangewide habitat degradation, collection pressure in Libya will continue on the same trajectory as current conditions, and the tortoise population in Libya would be substantially reduced. The habitat in the North Coast of Egypt has been substantially degraded, and coupled with collection of the species for the pet trade, the Egyptian tortoise has been extirpated from the North Coast of Egypt. We recognize that the human population and development pressure are higher in North Coast than in Libya. Thus, we would not expect as much habitat loss from development in Libya. However, collection of the species for the pet trade in Libya would continue on the same trajectory resulting in a decrease in population resiliency from moderate to low.

The population resiliency in North Sinai, Egypt, may decrease from moderate to low-moderate. Even though about half of the total population is within a protected area (Zaranik) that is managed by the local population, and there is no commercial collection pressure, the population is very small and stressors such as grazing, military activities, and climate change will continue to degrade the habitat into the future.

In Israel, the population resiliency would decrease from moderate to low-moderate. The population partially overlaps a protected area (Holot Agur) and commercial collection is insignificant; however, the population only occurs in the western Negev Desert and a suite of human activities, including urban and agricultural development, will continue to degrade the habitat and likely reduce population abundance.

Populations in Libya (one population across three regions), North Sinai, Egypt (one small population made up of five very small subpopulations), and Israel (one population in western Negev Desert) would decrease, be fragmented, and we conclude that the resiliency of the species will decrease from moderate to low-moderate within the foreseeable future because of ongoing habitat degradation and collection pressure. A decreasing population of Egyptian tortoise residing in increasingly degraded habitat reduces the species' ability to sustain populations in the event of stochastic variation. We project that the population in Libya would be substantially reduced because of ongoing collection, but would still occur within the three regions in Libya at much smaller population sizes. The tortoise populations in North Sinai, Egypt, and western Negev Desert in Israel would remain, but would decrease. Therefore, we project the species will continue to occupy the same areas as it currently occupies. The Egyptian tortoise would occur in each country, west and east of the Nile River, and maintain some ecological diversity between the populations, though at decreasing levels in each population. Thus, representation would likely be similar to current conditions. However, representative habitat types in which the species occurs would continue to be much less than it was historically, and continue to decline.

The Egyptian tortoise would occur in multiple populations distributed across its range. We have not identified any catastrophic events that would affect the Egyptian tortoise across its entire range. Therefore, the species would have redundancy to withstand catastrophic events.

Scenario 2

Under Scenario 2, we project that rangewide habitat degradation will continue, but collection pressure in Libya will be reduced. Libyan authorities and local academics had been seeking to end collection and exportation of Egyptian tortoise from Libya. We acknowledge that with the ongoing collection of the species for the pet trade and geopolitical instability in Libya, implementing conservation measures to reduce collection for the pet trade is uncertain. Nonetheless, if collection is reduced, the population in Libya would not decline at the current trajectory, and at a minimum, the Libyan population of Egyptian tortoises would decline at a slower rate compared to current conditions. However, this population would have low to moderate resiliency within the foreseeable future because the habitat will continue to be degraded, the population is not in a protected area, and even if conservation measures are implemented, we conclude some collection for the pet trade will continue. The populations in North Sinai, Egypt, and western Negev Desert in Israel would experience a decrease in resiliency in the foreseeable future as described under Scenario 1.

Because the populations in Libya, North Sinai in Egypt, and the western Negev Desert in Israel would remain, the Egyptian tortoise would occur in each country, west and east of the Nile River, and represent the same ecological diversity and habitats between the populations as current conditions, though at decreasing levels in each population. The species would occupy the same areas as it currently occupies. Human activities will continue to degrade and encroach on the tortoise's habitat. Therefore, representative habitat types in which the species occurs would continue to be much less than it was historically, and continue to decline. Because we have not identified any catastrophic event that would affect the species throughout its range, and the Egyptian tortoise would continue to be distributed from Libya to Israel, the species will have redundancy to withstand catastrophic events.

We note that, by using the SSA framework to guide our analysis of the scientific information documented in the SSA report, we have not only analyzed individual effects on the Egyptian tortoise, but we have also analyzed their potential cumulative effects. We incorporate the cumulative effects into our SSA analysis when we characterize the current and future condition of the species. Our assessment of the current and future conditions encompasses and incorporates the threats individually and cumulatively. Our current- and future-condition assessment is iterative because it accumulates and evaluates the effects of all the factors that may be influencing the species, including threats and conservation efforts. Because the SSA framework considers not just the presence of the factors, but to what degree they collectively influence risk to the entire species, our assessment integrates the cumulative effects of the

factors and replaces a standalone cumulative-effects analysis.

Determination of Egyptian Tortoise Status

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the procedures for determining whether a species meets the definition of an endangered species or a threatened species. The Act defines ''endangered species'' as a species in danger of extinction throughout all or a significant portion of its range, and ''threatened species'' as a species likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The Act requires that we determine whether a species meets the definition of ''endangered species'' or ''threatened species'' because of any of the following 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.

Status Throughout All of Its Range

After evaluating threats to the species and assessing the cumulative effect of the threats under the section 4(a)(1) factors, we found that habitat loss and degradation continues throughout the species' range because of a suite of ongoing human activities, and is the major factor limiting the availability of suitable habitat (Factor A). Collection of the species is ongoing and a significant threat in Libya where the largest remaining population of Egyptian tortoise occurs (Factor B). Collection for the pet trade is not known to be a major factor in the North Sinai in Egypt or in Israel, although minimal poaching likely occurs in Israel. Additionally, the potential exists that commercial collectors may target Egyptian tortoises in Zaranik Protected Area in the future. The Egyptian tortoise is afforded some protection in Egypt and Israel based on existing regulations; however, these regulations have had minimal success protecting the species and its habitat. No enforceable conservation measures for the species are in place in Libya. Including the species in Appendix I of CITES has substantially reduced the international trade in wild specimens for primarily commercial purposes since 1995, though some illegal commercial trade continues despite their status in Appendix I of CITES.

Despite losses in numbers and habitat, approximately 11,000 Egyptian tortoises occur within 7,929–15,857 km^2 (3,061–6,122 mi^2) of suitable habitat across a range that covers the Mediterranean coastal area of Libya, the North Sinai in Egypt, and the western Negev Desert in Israel (Perälä 2005, p. 894; Perälä 2006, p. 61; Rhodin 2020, pers. comm.).

Collection for the pet trade is significant in Libya and ongoing, and the habitat has experienced rangewide degradation because of human activities. However, the total population is estimated to be about the same in 2020 as it was in 2005–2006. Based on best available information, the population over the last 15 years appears to be steady. This appearance could be an artifact of uncertainty in the data. It could reflect the possibility that more tortoises exist in Libya than previously understood or that collection for the pet trade briefly slowed at the start of the uprising against the Libyan Government in 2011. A combination of factors could be responsible for the apparent steadiness of the population. In any case, the species has representation across its historical range even though it has been extirpated from North Coast, Egypt. The two populations east of the Nile River in North Sinai, Egypt, and western Negev Desert, Israel, are partially in protected areas with varying levels of enforcement. Therefore, after assessing the best available information, we conclude the Egyptian tortoise has sufficient resiliency, redundancy, and representation that with its current numbers and distribution it is not in danger of extinction throughout all of its range at this time.

We next considered whether the Egyptian tortoise is likely to become in danger of extinction throughout all of its range within the foreseeable future, which we determined for the species to be three generations of the species (approximately 60 years). Based on projected increases in the human population along the Mediterranean coast within the range of the species, we expect both the species' population and habitat to decline into the future because of ongoing habitat degradation and collection for the pet trade. Additionally, habitat loss and degradation is likely to be intensified by synergistic effects associated with the consequences of climate change (Baha El Din 2020, pers. comm.; IPCC 2013, p. 1266; Al-Olaimy 2017, unpaginated). Projections for the Mediterranean region reveal warming in all seasons and reduced precipitation throughout the year. Egyptian tortoises are highly sensitive to thermal stress, particularly increased temperature. Therefore, any marginal increase resulting from climatic change, combined with the loss of habitat (*i.e.,* shrubs needed for thermal buffering), would limit the species' ability to survive in the wild (Baha El Din 2020, pers. comm.).

The Egyptian tortoise population appears steady and maintains sufficient redundancy and representation to maintain viability throughout its range. Two of the three populations are partially protected with varying levels of enforcement, though one of these populations is very small (200–250 specimens) and consists of 5 smaller subpopulations. However, the species is restricted to the Mediterranean coast and multiple threats to the species and its habitat that will cause the population to decline are ongoing. These threats will reduce the species' population and quality of habitat that remains, thereby decreasing the resilience of the population into the future. Existing regulatory measures have had minimal success conserving the species' habitat and reducing the number of tortoises collected for the pet trade. Although the species is not in danger of extinction throughout all of its range now, the factors identified above continue to negatively affect the Egyptian tortoise and its habitat such that it is likely to become in danger of extinction within the foreseeable future throughout all of its range. Based on the best available scientific studies and information assessing land-use trends, collection pressure, adequacy of enforcement of laws, projections of temperature increases because of climate change, and predictions about how those threats may affect the Egyptian tortoise, we conclude that the Egyptian tortoise will lack sufficient resiliency, redundancy, and representation for its continued existence to be secure within the foreseeable future. We therefore determine that the Egyptian tortoise is likely to be in danger of extinction within the foreseeable future throughout all of its range.

Status Throughout a Significant Portion of Its Range

Under the Act and our implementing regulations, a species may warrant listing if it is in danger of extinction or likely to become so in the foreseeable future throughout all or a significant portion of its range. The court in *Center for Biological Diversity* v. *Everson,* 2020 WL 437289 (D.D.C. Jan. 28, 2020) (*Center for Biological Diversity*), vacated the aspect of the Final Policy on Interpretation of the Phrase ''Significant Portion of Its Range'' in the Endangered Species Act's Definitions of

''Endangered Species'' and ''Threatened Species'' (79 FR 37578; July 1, 2014) that provided that the Service does not undertake an analysis of significant portions of a species' range if the species warrants listing as threatened throughout all of its range. Therefore, we proceed to evaluating whether the species is endangered in a significant portion of its range—that is, whether there is any portion of the species' range for which both (1) the portion is significant; and (2) the species is in danger of extinction in that portion. Depending on the case, it might be more efficient for us to address the ''significance'' question or the ''status'' question first. We can choose to address either question first. Regardless of which question we address first, if we reach a negative answer with respect to the first question that we address, we do not need to evaluate the other question for that portion of the species' range.

Following the court's holding in *Center for Biological Diversity,* we now consider whether there are any significant portions of the species' range where the species is in danger of extinction now (*i.e.,* endangered). In undertaking this analysis for Egyptian tortoise, we choose to address the status question first—we consider information pertaining to the geographic distribution of both the species and the threats that the species faces to identify any portions of the range where the species may be endangered.

For the Egyptian tortoise, we considered whether the threats are geographically concentrated in any portion of the species' range at a biologically meaningful scale. We examined the following threats: Habitat loss and degradation, collection for the pet trade, and small population size, including cumulative effects. The suite of activities that has caused and continues to cause the loss and degradation of habitat such as urban development, agricultural conversion, grazing, and military exercises occurs throughout the species range and across all populations throughout the species range. The available data do not suggest that the threats to the species habitat are concentrated at a biologically meaningful scale. Therefore, those threats do not themselves result in the species being in danger of extinction in any significant portion of its range, although we did consider the cumulative impacts of habitat threats in the context of the other threats discussed below.

Collection for the pet trade is the most significant threat to the species in Libya and concentrated in this part of the species' range currently. Collection has historically been a significant threat across Egypt, particularly in the North Coast, which combined with loss of habitat led to the extirpation of the species from this part of its range. Collection for the pet trade is not known to be a factor in North Sinai in Egypt or in the western Negev Desert in Israel, although minimal poaching likely occurs in Israel, and there is concern that commercial collectors will target Egyptian tortoises in Zaranik Protected Area (McGrath 2011, unpaginated). Libya contains the majority of the entire population of Egyptian tortoises. While the threat of collection for the pet trade is currently concentrated in Libya, which is the only population on the west side of the Nile River, the effect of collection does not place the species in danger of extinction in this portion of its range, even in combination with other threats to the species there. In other words, the concentrated collection pressure in Libya is not severe enough to make the species currently endangered in this portion of its range.

Additionally, we considered whether the small population of Egyptian tortoises in North Sinai in Egypt and the moderately sized population in a small area in the western Negev Desert in Israel may each be more vulnerable to a loss of genetic diversity and stochastic environmental events because of their small sizes. However, we have no information that the species is affected by inbreeding depression, and we are not aware of likely stochastic environmental events that would make the species currently in danger of extinction in these portions of its range.

Thus, there is no portion of the species' range where it may be in danger of extinction, and we determine that the species is likely to become in danger of extinction within the foreseeable future throughout all of its range. Our approach to analyzing significant is consistent with the courts' holdings in *Desert Survivors* v. *Department of the Interior,* No. 16–cv–01165–JCS, 2018 WL 4053447 (N.D. Cal. Aug. 24, 2018), and *Center for Biological Diversity* v. *Jewell,* 248 F. Supp. 3d, 946, 959 (D. Ariz. 2017).

Determination of Status

Our review of the best available scientific and commercial information indicates that the Egyptian tortoise meets the definition of a threatened species. Therefore, we propose to list the Egyptian tortoise as a threatened species in accordance with sections 3(20) and 4(a)(1) of the Act.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened species under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing results in public awareness, and encourages and results in conservation actions by Federal, State, Tribal, and local agencies, foreign governments, private organizations, and individuals. The Act encourages cooperation with the States and other countries and calls for recovery actions to be carried out for listed species. The protection required by Federal agencies and the prohibitions against certain activities are discussed, in part, below.

Our regulations at 50 CFR part 402 implement the interagency cooperation provisions found under section 7 of the Act. Under section 7(a)(1) of the Act, Federal agencies are to use, in consultation with and with the assistance of the Service, their authorities in furtherance of the purposes of the Act. Section 7(a)(2) of the Act, as amended, requires Federal agencies to ensure, in consultation with the Service, that any action authorized, funded, or carried out by such agency is not likely to jeopardize the continued existence of a listed species or result in destruction or adverse modification of its critical habitat. An action that is subject to the consultation provisions of section 7(a)(2) is defined in our implementing regulations at 50 CFR 402.02 as all activities or programs of any kind authorized, funded, or carried out, in whole or in part, by Federal agencies in the United States or upon the high seas. With respect to this species, there are no actions known to require consultation under section 7(a)(2) of the Act. Given the regulatory definition of ''action,'' which clarifies that it applies to activities or program ''in the United States or upon the high seas,'' the Egyptian tortoise is unlikely to be the subject of section 7 consultations, because the entire life cycle of the species occurs in terrestrial areas outside of the United States unlikely to be affected by U.S. Federal actions. Additionally, no critical habitat will be designated for this species because, under 50 CFR 424.12(g), we will not designate critical habitat within foreign countries or in other areas outside of the jurisdiction of the United States.

Section 8(a) of the Act (16 U.S.C. 1537(a)) authorizes the provision of limited financial assistance for the development and management of

programs that the Secretary of the Interior determines to be necessary or useful for the conservation of endangered or threatened species in foreign countries. Sections 8(b) and 8(c) of the Act (16 U.S.C. 1537(b) and (c)) authorize the Secretary to encourage conservation programs for foreign listed species, and to provide assistance for such programs, in the form of personnel and the training of personnel.

As explained below, the proposed 4(d) rule for the Egyptian tortoise would, in part, make it illegal for any person subject to the jurisdiction of the United States to import or export; deliver, receive, carry, transport, or ship in interstate or foreign commerce, by any means whatsoever and in the course of commercial activity; or sell or offer for sale in interstate or foreign commerce any Egyptian tortoise. It would also be illegal to take (which includes harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or to attempt any of these) any Egyptian tortoise within the United States or on the high seas; or possess, sell, deliver, carry, transport, or ship, by any means whatsoever any Egyptian tortoise that has been taken in violation of the Act. It would also be unlawful to attempt to commit, to solicit another to commit or to cause to be committed, any of these acts. Certain exceptions apply to agents of the Service and State conservation agencies. An exception is also provided in the proposed 4(d) rule for interstate commerce from public institutions to other public institutions, specifically museums, zoological parks, and scientific institutions that meet the definition of ''public'' at 50 CFR 10.12.

We may issue permits to carry out otherwise prohibited activities involving endangered and threatened wildlife species under certain circumstances. Regulations governing permits for threatened species are codified at 50 CFR 17.32, and general Service permitting regulations are codified at 50 CFR part 13. With regard to threatened wildlife, a permit may be issued for scientific purposes, to enhance the propagation or survival of the species, for incidental take in connection with otherwise lawful activities, as well as for zoological exhibition, education, and special purposes consistent with the Act. The Service may also register persons subject to the jurisdiction of the United States through its captive-bred-wildlife (CBW) program if certain established requirements are met under the CBW regulations (50 CFR 17.21(g)). Through a CBW registration, the Service may allow a registrant to conduct certain otherwise prohibited activities under certain circumstances to enhance the propagation or survival of the affected species: Take; export or re-import; deliver, receive, carry, transport, or ship in interstate or foreign commerce, in the course of a commercial activity; or sell or offer for sale in interstate or foreign commerce. A CBW registration may authorize interstate purchase and sale only between entities that both hold a registration for the taxon concerned. The CBW program is available for species having a natural geographic distribution not including any part of the United States and other species that the Director has determined to be eligible by regulation. The individual specimens must have been born in captivity in the United States. There are also certain statutory exemptions from the prohibitions, which are found in sections 9 and 10 of the Act.

It is our policy, as published in the **Federal Register** on July 1, 1994 (59 FR 34272), to identify to the maximum extent practicable at the time a species is listed, those activities that would or would not constitute a violation of section 9 of the Act. The intent of this policy is to increase public awareness of the effect of a proposed listing on proposed and ongoing activities within the range of the species proposed for listing. The discussion below regarding protective regulations under section 4(d) of the Act complies with our policy.

II. Proposed Rule Issued Under Section 4(d) of the Act

Background

Section 4(d) of the Act contains two sentences. The first sentence states that the ''Secretary shall issue such regulations as he [or she] deems necessary and advisable to provide for the conservation'' of species listed as threatened. The U.S. Supreme Court has noted that statutory language like ''necessary and advisable'' demonstrates a large degree of deference to the agency (see *Webster* v. *Doe,* 486 U.S. 592 (1988)). Conservation is defined in the Act to mean ''the use of all methods and procedures which are necessary to bring any endangered species or threatened species to the point at which the measures provided pursuant to [the Act] are no longer necessary.'' Additionally, the second sentence of section 4(d) of the Act states that the Secretary ''may by regulation prohibit with respect to any threatened species any act prohibited under section 9(a)(1), in the case of fish or wildlife, or section 9(a)(2), in the case of plants.'' Thus, the combination of the two sentences of section 4(d) provides the Secretary with broad discretion to select and promulgate appropriate regulations tailored to the specific conservation needs of the threatened species. The second sentence grants particularly broad discretion to the Service when adopting the prohibitions under section 9.

The courts have recognized the extent of the Secretary's discretion under this standard to develop rules that are appropriate for the conservation of a species. For example, courts have upheld rules developed under section 4(d) as a valid exercise of agency authority where they prohibited take of threatened wildlife, or include a limited taking prohibition (see *Alsea Valley Alliance* v. *Lautenbacher,* 2007 U.S. Dist. Lexis 60203 (D. Or. 2007); *Washington Environmental Council* v. *National Marine Fisheries Service,* 2002 U.S. Dist. Lexis 5432 (W.D. Wash. 2002)). Courts have also upheld 4(d) rules that do not address all of the threats a species faces (see *State of Louisiana* v. *Verity,* 853 F.2d 322 (5th Cir. 1988)). As noted in the legislative history when the Act was initially enacted, ''once an animal is on the threatened list, the Secretary has an almost infinite number of options available to him with regard to the permitted activities for those species. He [or she] may, for example, permit taking, but not importation of such species, or he [or she] may choose to forbid both taking and importation but allow the transportation of such species'' (H.R. Rep. No. 412, 93rd Cong., 1st Sess. 1973).

Exercising this authority under section 4(d), we have developed a proposed rule that is designed to address the Egyptian tortoise's specific threats and conservation needs. Although the statute does not require us to make a ''necessary and advisable'' finding with respect to the adoption of specific prohibitions under section 9, we find that this proposed rule as a whole satisfies the requirement in section 4(d) of the Act to issue regulations deemed necessary and advisable to provide for the conservation of the Egyptian tortoise.

As discussed above under Summary of Biological Status and Threats, we have concluded that the Egyptian tortoise is likely to become in danger of extinction within the foreseeable future primarily because of habitat loss and degradation and collection for the pet trade, in concert with climate change. Under this proposed 4(d) rule, certain prohibitions and provisions that apply to endangered wildlife under section 9(a)(1) prohibitions will help minimize threats that could cause further declines in the species' status. The provisions of this proposed 4(d) rule would promote

conservation of the Egyptian tortoise by ensuring that activities undertaken with the species by any person under the jurisdiction of the United States are also supportive of the conservation efforts undertaken for the species in Libya, Egypt, and Israel, and the Appendix-I listing under CITES. The provisions of this proposed rule are one of many tools that we would use to promote the conservation of the Egyptian tortoise. This proposed 4(d) rule would apply only if and when we make final the proposed listing of the Egyptian tortoise as a threatened species.

Provisions of the Proposed 4(d) Rule

In the SSA report and this proposed rule, we identified factors such as habitat loss and degradation and collection for the pet trade, in concert with climate change, that have negative effects on this species and its habitat. Additionally, we have identified existing regulatory mechanisms in the tortoise's range countries of Libya, Egypt, and Israel to conserve the Egyptian tortoise, as well as the international measures of CITES for Appendix-I species. While we have found these regulatory mechanisms are not sufficient to prevent the species from likely becoming in danger of extinction within the foreseeable future throughout all of its range, we recognize the benefits of these regulations in helping to conserve the species.

This proposed 4(d) rule would provide for the conservation of the Egyptian tortoise by prohibiting the following activities, except as otherwise authorized or permitted: Importing or exporting; take; possession and other acts with unlawfully taken specimens; delivering, receiving, transporting, or shipping in interstate or foreign commerce in the course of commercial activity; or selling or offering for sale in interstate or foreign commerce such unlawfully taken specimens or offspring of unlawfully taken specimens.

As discussed above under Summary of Biological Status and Threats, habitat loss and degradation and collection for the pet trade are affecting the status of the Egyptian tortoise. A suite of activities has the potential to affect the Egyptian tortoise in its range countries, including urban development, agricultural conversion, grazing, military exercises, and collection for the pet trade. Habitat degradation will continue in the species' range countries. Prohibiting take (which applies to take within the United States, within the territorial sea of the United States, or upon the high seas) would indirectly contribute to conservation of the species in its range countries of Libya, Egypt, and Israel by helping prevent any captive-held Egyptian tortoises in the United States being used to establish a domestic market for trade of Egyptian tortoise parts or for the commercial pet trade. For the same reason, regulating interstate commerce in the species in the course of commercial activity by persons subject to the jurisdiction of the United States can benefit the species in the wild by limiting demand in the United States to non-commercial activities and permitted commercial activities for scientific purposes or to enhance the propagation or survival of the species in the wild, such as activities associated with bona fide conservation breeding. The United States is not a primary destination for Egyptian tortoises. However, collection of the species for the illegal international pet trade is ongoing. Further regulating import and export to, from, and through the United States and foreign commerce by persons subject to the jurisdiction of the United States could deter breeding and demand for the species, and help conserve the species by eliminating the United States as a potential market for illegally collected and traded Egyptian tortoises.

The proposed 4(d) rule also provides an exception for interstate commerce from public institutions to other public institutions, specifically museums, zoological parks, and scientific institutions, meeting the definition of ''public'' at 50 CFR 10.12. Demand for Egyptian tortoises held at or captive-bred by these types of institutions in the United States is not substantial nor is it likely to pose a significant threat to the wild population in the species' range countries. As defined in our regulations, ''public'' museums, public zoological parks, and scientific institutions, refers to such as are open to the general public and are either established, maintained, and operated as a governmental service or are privately endowed and organized but not operated for profit. This exception would apply unless prohibited by CITES regulation, for example if use after import is restricted under 50 CFR 23.55.

We may issue permits to carry out otherwise prohibited activities, including those described above, involving threatened wildlife under certain circumstances. Regulations governing permits are codified at 50 CFR 17.32. With regard to threatened wildlife, a permit may be issued for the following purposes: For scientific purposes, to enhance propagation or survival, for economic hardship, for zoological exhibition, for educational purposes, for incidental taking, or for special purposes consistent with the purposes of the Act. As noted above, we may also authorize certain activities associated with conservation breeding under CBW registrations. We recognize that captive breeding of wildlife can support conservation, for example by producing animals that could be used for reintroductions. We are not aware of any captive-breeding programs for the Egyptian tortoise for this purpose. There are also certain statutory exemptions from the prohibitions, which are found in sections 9 and 10 of the Act. This proposed 4(d) rule, if finalized, would apply to all live and dead Egyptian tortoise parts and products, and support conservation management efforts for Egyptian tortoise in the wild in Libya, Egypt, and Israel.

Required Determinations

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(1) Be logically organized;

(2) Use the active voice to address readers directly;

(3) Use clear language rather than jargon;

(4) Be divided into short sections and sentences; and

(5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in **ADDRESSES**. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

We have determined that environmental assessments and environmental impact statements, as defined under the authority of the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) need not be prepared in connection with listing a species as an endangered or threatened species under the Endangered Species Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

References Cited

A complete list of references cited in this rulemaking is available on the

internet at *http://www.regulations.gov* and upon request from the Branch of Delisting and Foreign Species (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this proposed rule are the staff members of the U.S. Fish and Wildlife Service's Species Assessment Team and the Branch of Delisting and Foreign Species.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

■ 2. Amend § 17.11(h) by adding an entry for ''Tortoise, Egyptian'' to the List of Endangered and Threatened Wildlife in alphabetical order under Reptiles to read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
*	*	*	*	*
REPTILES				
*	*	*	*	*
Tortoise, Egyptian	*Testudo kleinmanni*	Wherever found	T	[**Federal Register** citation when published as a final rule]; 50 CFR 17.42(l).[4d]
*	*	*	*	*

■ 3. Amend § 17.42 by adding paragraph (l) to read as follows:

§ 17.42 Special rules—reptiles.

* * * * *

(l) Egyptian tortoise *(Testudo kleinmanni)*—(1) *Prohibitions.* The following prohibitions that apply to endangered wildlife also apply to the Egyptian tortoise. Except as provided under paragraph (l)(2) of this section and §§ 17.4 and 17.5, it is unlawful for any person subject to the jurisdiction of the United States to commit, to attempt to commit, to solicit another to commit, or cause to be committed, any of the following acts in regard to this species:

(i) Import or export, as set forth for endangered wildlife at § 17.21(b).

(ii) Take, as set forth for endangered wildlife at § 17.21(c)(1).

(iii) Possession and other acts with unlawfully taken specimens, as set forth for endangered wildlife at § 17.21(d)(1).

(iv) Interstate or foreign commerce in the course of commercial activity, as set forth for endangered wildlife at § 17.21(e).

(v) Sale or offer for sale in interstate or foreign commerce, as set forth for endangered wildlife at § 17.21(f).

(2) *Exceptions from prohibitions.* In regard to this species, you may:

(i) Conduct activities as authorized by a permit under § 17.32.

(ii) Sell, offer for sale, deliver, receive, carry, transport, or ship in interstate commerce live Egyptian tortoises from one public institution to another public institution, if such activity is in accordance with 50 CFR part 23. For the purposes of this paragraph, ''public institution'' means a museum, zoological park, and scientific institution that meets the definition of ''public'' at 50 CFR 10.12.

(iii) Take, as set forth at § 17.21(c)(2) through (4) for endangered wildlife.

(iv) Possess and engage in other acts, as set forth at § 17.21(d)(2) for endangered wildlife.

(v) Conduct activities as authorized by a captive-bred wildlife registration under § 17.21(g) for endangered wildlife.

* * * * *

Martha Williams,

Principal Deputy Director, Exercising the Delegated Authority of the Director, U.S. Fish and Wildlife Service.

[FR Doc. 2021–23839 Filed 11–8–21; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 211104–0226]

RIN 0648–BK70

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Reef Fish Resources of the Gulf of Mexico; Requirement for a Descending Device or Venting Tool

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes regulations to clarify terms used in the Direct Enhancement of Snapper Conservation and the Economy through Novel Devices Act of 2020 (Descend Act). Section 3 of the Descend Act requires commercial and recreational fishermen to have a descending device or a venting tool on the vessel and ready for use when fishing for federally managed reef fish species in Gulf of Mexico (Gulf) Federal waters. The purpose of this proposed rule is to clarify the statutory definitions of descending device and venting tool.

DATES: Written comments on the proposed rule must be received by December 9, 2021.

ADDRESSES: You may submit comments on the proposed rule, identified by ''NOAA–NMFS–2021–0100,'' by either of the following methods:

- *Electronic submission:* Submit all electronic comments via the Federal e-Rulemaking Portal. Go to *http://www.regulations.gov* and enter ''NOAA–NMFS–2021–0100'' in the Search box. Click the ''Comment'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit all written comments to Peter Hood, NMFS Southeast Regional Office, 263 13th Avenue South, St. Petersburg, FL 33701.

Instructions: Comments sent by any other method, to any other address or

individual, or received after the end of the comment period may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, *etc.*), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments—enter ''N/A'' in required fields if you wish to remain anonymous.

Electronic copies of the Descend Act and the Regulatory Flexibility Act (RFA) analysis for this proposed rule may be obtained from *www.regulations.gov* or the NMFS Southeast Regional Office website at *https://www.fisheries.noaa.gov/action/descending-device-and-venting-tool-direct-enhancement-snapper-conservation-and-economy.*

FOR FURTHER INFORMATION CONTACT: Peter Hood, NMFS Southeast Regional Office, telephone: 727–824–5305, or email: *peter.hood@noaa.gov.*

SUPPLEMENTARY INFORMATION: On January 13, 2021, the majority of the Descend Act became effective with the exception of section 3, which becomes effective on January 13, 2022. Section 3 of the Descend Act amends the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by adding section 321, titled ''Required possession of descending devices.'' Section 321 of the Magnuson-Stevens Act requires fishermen on commercial vessels, charter vessels and headboats (for-hire vessels), and private recreational vessels to have a descending device or venting tool rigged and ready to use when fishing for Gulf reef fish in Federal waters. This proposed rule would clarify the statutory definitions of descending device and venting tool, which are devices designed to help reduce post-release mortality of fish from the effects of barotrauma.

Gulf reef fish are those fish included in the Fishery Management Plan for the Reef Fish Resources of the Gulf of Mexico (FMP). A list of Gulf reef fish can be found in Table 3 of Appendix A to 50 CFR part 622—Species Tables; Gulf Reef Fish, *https://www.ecfr.gov/current/title-50/chapter-VI/part-622/appendix-Appendix%20A%20to%20Part%20622.* For purposes of management of under the FMP, Federal waters in the Gulf begin seaward of 9 nautical miles (16.7 km) from the coast off all the Gulf States (Pub. L. 114–113, December 18, 2015, and Pub. L. 115–31, May 5, 2017).

Barotrauma in fish is an injury caused by the expansion of gas inside a fish from the rapid pressure decrease that may occur when a fish is retrieved from depth. Barotrauma generally occurs when retrieving fish from depths of 90 ft (27.4 m) or greater, though it can occur in waters as shallow as approximately 33 ft (10 m) deep. The internal gases fill the abdomen and the fish may be unable to swim back down to the catch depth. Signs of barotrauma in fish include a distended abdomen, bulging eyes, an everted stomach, and bubbling under the scales. Fish experiencing barotrauma often have difficulty returning to deeper water or float on the surface, which makes them more vulnerable to predation from dolphins, sharks and other fish, and seabirds. Fishermen can help reduce mortality to fish they release by using a descending device or a venting tool when barotrauma is affecting a fish that has been caught. A descending device lowers the fish back to depth where internal gases recompress and the fish can be released. A venting tool can release gases in a fish's abdomen at the surface allowing the fish to swim unaided back to depth.

The Descend Act states that the term ''venting tool'' has the meaning given to it by the Gulf Council. The Gulf Council defines the term venting tool in its Policy on the Use of Venting Tools and Descending Devices as a sharpened, hollow instrument capable of penetrating the abdomen of a fish to release the excess gases accumulated in body cavity. The definition also indicates a device that is not hollow, such as a knife or ice pick, is not a venting tool and will cause additional damage to a fish.

The Gulf Council previously required the use of a venting tool for Gulf reef fish in Amendment 27 to the FMP and the final rule implementing the amendment added a definition of ''venting device'' to the regulations (73 FR 5117, January 29, 2008). The term ''venting device'' means, ''a device intended to deflate the abdominal cavity of a fish to release the fish with minimum damage.'' 50 CFR 622.2. The Gulf Council and NMFS subsequently removed the requirement to use a ''venting tool,'' the term used in the August 2, 2013, final rule, for several reasons (78 FR 46820), but the regulations at 50 CFR 622.2 retain the definition of venting device. This proposed rule would clarify that the applicable Gulf Council definition is the definition in its Policy on the Use of Venting Tools and Descending Devices.

The Descend Act defines the term descending device as an instrument that will release fish at a depth sufficient for the fish to be able to recover from the effects of barotrauma; it is a weighted hook, lip clamp, or box that will hold the fish while it is lowered to depth, or another device determined to be appropriate by the Secretary of Commerce (Secretary); and is capable of releasing the fish automatically, releasing the fish by actions of the operator of the device, or allowing the fish to escape on its own. This proposed rule would clarify that the depth sufficient for a fish to be able to recover from the effects of barotrauma is the depth at which the fish was caught and specify the minimum weight and minimum length of line required to be consistent with the current regulatory definition of ''descending device'' at 50 CFR 622.188(a)(4). The regulations in section 622.188(a)(4) were put in place by NMFS in 2020 to implement the South Atlantic Fishery Management Council's Regulatory Amendment 29 to the Fishery Management Plan for the Snapper-Grouper Fishery of the South Atlantic (85 FR 36166, June 15, 2020). Those regulations require a descending device be on board a vessel and be ready for use while fishing for or possessing South Atlantic snapper-grouper.

Management Measures Contained in This Proposed Rule

Consistent with the requirement in the Descend Act, this proposed rule would require a descending device or a venting tool on the vessel that is rigged and ready for use while fishing is occurring. This proposed rule would also clarify the statutory definitions of descending device and venting tool to assist Gulf reef fish fishermen in complying with the statutory requirement.

Descending Device

This proposed rule would define a descending device as a device capable of releasing the fish at the depth from which the fish was caught, and would specify that the device must use a minimum of a 16-ounce (454-gram) weight and a minimum of a 60-ft (15.2-m) length of line. A 16-ounce weight is available at many tackle shops and is heavy enough to descend a majority of Gulf reef fish subject to barotrauma. However, using more weight would help to descend a large fish or where currents are strong. NMFS proposes the 60-ft (18.3-m) minimum length for the line attached to a descending device to ensure fish are released at a minimum depth of 50 ft (15.2 m) while someone using the descending device is standing

on the deck of a vessel, and to account for possible ocean currents or swells. Using a line long enough to release a fish at the depth from which it was caught will best ensure that the fish can recover from the effects of barotrauma.

These proposed minimum specifications are currently required for commercial and recreational fishermen in the South Atlantic snapper-grouper fishery. NMFS proposes the same specifications for a descending device in the Gulf reef fish fishery to increase the likelihood of compliance by fishermen who may fish in both the Gulf and South Atlantic, and to aid with enforcement.

As specified in the Descend Act, a descending device may attach to the fish's mouth, through the fish's mouth and gill plate, or it may be a container that will retain the fish while it is lowered to depth. Operating a descending device can vary between types but the device must be capable of releasing the fish at depth automatically, by actions of the device operator, or by allowing the fish to escape on its own when at depth.

Venting Tool

This proposed rule would define a venting tool consistent with the Gulf Council's policy and remove the term ''venting device'' from the regulations. A venting tool must be capable of penetrating the abdomen of a fish to release the excess gases accumulated in body cavity when a fish is retrieved from depth. Further, a venting tool must be a sharpened, hollow instrument that allows air to escape, such as a hypodermic syringe with the plunger removed. A 16–gauge needle, which has an outside diameter of 0.065 inches (1.65 mm), is the minimum diameter hollow tube that must be used. Gulf reef fish fishermen may also choose to use a larger diameter hollow needle because it will allow more air to escape from a fish rapidly. Fishermen must not use a tool that is not hollow, such as a knife or an ice pick, to vent a fish. A knife or other non-hollow tube is not a venting tool and its use would cause further injury to a fish.

While the Descend Act and this proposed rule would allow Gulf reef fish fishermen to choose whether to carry a descending device or venting tool on a vessel, there is nothing that would prevent fishermen from carrying both types of devices. Fishermen may find that they favor a certain device for individual situations.

Expiration of Requirements

The requirement in section 3 of Descend Act expires 5 years after its enactment. Therefore, the provisions contained in this proposed rule would also end after January 13, 2026, unless the Gulf Council or NMFS take further action to retain any of the regulatory provisions.

Classification

NMFS is issuing this proposed rule pursuant to section 305(d) of the Magnuson-Stevens Act. Pursuant to section 305(d), this action is necessary to clarify the statutory definitions in section 3 of the Descend Act, which adds new section 321 to the Magnuson-Stevens Act that affects persons fishing for Gulf reef fish species. The NMFS Assistant Administrator has determined that this proposed rule is consistent with the Descend Act, other provisions of the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

The Chief Counsel for Regulation of the Department of Commerce has certified to the Chief Counsel for Advocacy of the Small Business Administration (SBA) that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. The factual basis for this determination follows.

A description of this proposed rule, why it is being considered, and the objectives of this proposed rule are contained in the **SUPPLEMENTARY INFORMATION** section of the preamble. The Magnuson-Stevens Act provides the statutory basis for this proposed rule.

This proposed rule would apply to all federally permitted commercial vessels and for-hire vessels, as well as private or rental recreational vessels that are fishing for Gulf reef fish in Gulf Federal waters. The RFA does not consider recreational anglers to be small entities, so they are outside the scope of this analysis and only the impacts on commercial and for-hire fishing businesses will be discussed.

As of February 23, 2021, there were 831 valid or renewable limited-access permits for Gulf reef fish. On average from 2015 through 2019, there were 543 federally permitted commercial vessels each year with reported landings of Gulf reef fish. Their average annual vessel-level gross revenue from all species harvested for 2015 through 2019 was approximately $121,500 (2020 dollars) and Gulf reef fish accounted for approximately 94 percent of this revenue. The maximum annual revenue from all species reported by a single one of the commercial vessels that landed Gulf reef fish from 2015 through 2019 was approximately $2.4 million (2020 dollars).

On February 23, 2021, there were 1,306 vessels with a valid or renewable charter vessel/headboat permit for Gulf reef fish (including historical captain permits). Although the charter vessel/headboat permit application collects information on the primary method of operation, the permit itself does not identify the permitted vessel as either a charter vessel or a headboat and vessels may operate in both capacities. The average charter vessel is estimated to receive approximately $91,000 (2020 dollars) in annual revenue; the average headboat is estimated to receive approximately $275,000 in annual revenue.

For RFA purposes only, NMFS has established a small business size standard for businesses, including their affiliates, whose primary industry is commercial fishing (see 50 CFR 200.2). A business primarily engaged in commercial fishing (NAICS code 11411) is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual receipts not in excess of $11 million for all its affiliated operations worldwide. All of the commercial fishing businesses directly regulated by this proposed rule are believed to be small entities based on the NMFS size standard.

The SBA has established size standards for all major industry sectors in the U.S. including for-hire businesses (NAICS code 487210). A business primarily involved in the for-hire fishing industry is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual receipts not in excess of $8 million for all its affiliated operations worldwide. All of the for-hire fishing businesses directly regulated by this proposed rule are believed to be small entities based on the SBA size criteria.

No other small entities that would be directly affected by this proposed rule have been identified.

This proposed rule would not establish any new reporting or record-keeping requirements. It would, however, reiterate the requirements of the Descend Act and add clarity to the definitions of a descending device or venting tool. Per the requirements of the Descend Act, for a person on a vessel used to fish for Gulf reef fish in the Gulf Federal waters, a descending device or a venting tool that is rigged and ready for use while fishing is occurring must

be on the vessel. This statutory requirement will remain in effect regardless of the outcome of this proposed rule. No special professional skills would be necessary for compliance with this proposed rule.

Data on how many commercial and for-hire vessels currently own a suitable descending device or venting tool are not available. Again, all regulated small entities would need to have or obtain such descending devices or venting tools regardless of the outcome of this proposed rule. The estimated cost per vessel of purchasing a compliant descending device, based on the lowest price retail option for descending devices, plus the cost of a qualifying weight and line, would be approximately $19 (2020 dollars). The estimated cost to purchase a compliant venting tool would be $7 (2020 dollars). Either option would represent well less than one percent of average annual per vessel revenue for affected small entities. Because there is no requirement for these tools to be put into use, only for them to be on board and rigged for use while fishing for Gulf reef fish, there are no additional implicit or explicit costs associated with this proposed rule. In summary, this proposed rule would not be expected to have a significant economic impact on a substantial number of small entities.

The information provided above supports a determination that this proposed rule would not have a significant economic impact on a substantial number of small entities. As a result, an initial regulatory flexibility analysis is not required and none has been prepared.

No duplicative, overlapping, or conflicting Federal rules have been identified. In addition, this proposed rule contains no information collection requirements under the Paperwork Reduction Act of 1995.

List of Subjects in 50 CFR Part 622

Charter vessel, Commercial, Fisheries, Fishing, Gulf of Mexico, Headboat, Recreational, Reef fish.

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

Dated: November 4, 2021.

Carrie Robinson,

Acting Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 622 is proposed to be amended as follows:

PART 622—FISHERIES OF THE CARIBBEAN, GULF OF MEXICO, AND SOUTH ATLANTIC

■ 1. The authority citation for part 622 continues to read as follows:

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

§ 622.2 Definitions and acronyms. [Amended]

■ 2. In § 622.2, remove the definition of *venting device.*

■ 3. In § 622.30, revise the introductory text and add paragraph (c) to read as follows:

§ 622.30 Required fishing gear.

For a person on board a vessel to fish for Gulf reef fish in the Gulf EEZ, the following fishing gear must be on the vessel and such person must use the gear as specified in paragraphs (a) and (b) of this section.

* * * * *

(c) *Gear required by the DESCEND Act of 2020.* For a person on a vessel to fish for Gulf reef fish in the Gulf EEZ, a descending device or a venting tool that is rigged and ready for use while fishing is occurring must be on the vessel. The requirements in this paragraph (c) are effective until January 14, 2026.

(1) *Descending device.* A descending device is an instrument capable of releasing a fish at the depth from which the fish was caught.

(i) The descending device must be a weighted hook, lip clamp, or container that will hold the fish while it is lowered to depth. The device must be capable of releasing the fish automatically, by actions of the operator of the device, or by allowing the fish to escape on its own when at depth.

(ii) The descending device must use a minimum of a 16-ounce (454-gram) weight and a minimum of a 60-ft (15.2-m) length of line.

(2) *Venting tool.* A venting tool is a device capable of penetrating the abdomen of a fish to release the excess gases accumulated in body cavity when a fish is retrieved from depth. A venting tool must be a sharpened, hollow instrument that allows air to escape, such as a hypodermic syringe with the plunger removed. A 16-gauge needle, which has an outside diameter of 0.065 inches (1.65 mm), is the minimum diameter hollow tube that must be used. A larger diameter hollow needle is preferred to allow more air to escape from a fish rapidly. A device that is not hollow, such as a knife or an ice pick, is not a venting tool and will cause additional damage to a fish.

[FR Doc. 2021–24513 Filed 11–8–21; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 86, No. 214
Tuesday, November 9, 2021

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

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

November 4, 2021.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding: Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by December 9, 2021 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

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

Rural Business-Cooperative Service

Title: 7 CFR part 1980–E, Business and Industry Loan Program.

OMB Control Number: 0570–0014.

Summary of Collection: The Business and Industry (B&I) program was legislated in 1972, under Section 310B of the Consolidated Farm and Rural Development Act, as amended. The purpose of the program is to improve, develop, or finance businesses, industries, and employment and improve the economic and environmental climate in rural communities, including pollution abatement and control. This purpose is achieved through bolstering the existing private credit structure by making direct loans, thereby providing lasting community benefits. The B&I program is administered by the Agency through Rural Development State and sub-State Offices serving the State.

7 CFR 1980–E, in conjunction with 7 CFR 1942–A, and other regulations, is currently used only for making B&I Direct Loans. 7 CFR 1951–E is used for servicing B&I Direct and Community Facility loans. All reporting and recordkeeping burden estimates for making and servicing B&I Guaranteed Loans have been moved to the B&I Guaranteed Loan Program regulations, 7 CFR 4279–A and B and 4287–B. Consequently, only a fraction of the total reporting and recordkeeping burden for making and servicing B&I Direct Loans is reflected in this document.

Need and Use of the Information: The collected information is submitted to the B&I loan official by loan applicants and commercial lenders for use in making program eligibility, financial feasibility determinations and loan security determinations as required by the Con Act.

Description of Respondents: Individuals or Households; Business or Other for Profit, State, Local or Tribal Governments, public bodies, cooperatives.

Number of Respondents: 16.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 228.

Levi S. Harrell,
Departmental Information Collection Clearance Officer.

[FR Doc. 2021–24492 Filed 11–8–21; 8:45 am]
BILLING CODE 3410–XY–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

November 3, 2021.

The Department of Agriculture will submit the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13 on or after the date of publication of this notice. Comments are requested regarding: (1) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding these information collections are best assured of having their full effect if received by December 9, 2021. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

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

displays a currently valid OMB control number.

National Agricultural Statistics Service (NASS)

Title: Conservation Practice Adoption Motivations Survey.

OMB Control Number: 0535–NEW.

Summary of Collection: The primary objective of the National Agricultural Statistics Service (NASS) is to collect, prepare and issue State and national estimates of crop and livestock production, prices, and disposition; as well as economic statistics, environmental statistics related to agriculture and also to conduct the Census of Agriculture.

Need and Use of the Information: NASS will collect information about these types of operations to understand conservation practices within the United States in terms of the following: (1) How often are specific conservation practices adopted without assistance, with technical assistance and/or financial assistance. (2) How does adoption evolve over time? What proportion of producers who ''try'' a given practice continue or expand use over time? How many discontinue the practice? (3) What motivates farmers to initially try a practice and then continue, expand, or discontinue use? The questions reflect a range of factors including conservation need(s), experience(s) of neighbors, financial benefits or costs, producer's time and effort, availability of technical and financial assistance, regulation or conservation compliance, and concern about the environmental quality. The United States Department of Agriculture's Natural Resources Conservation Service has entered into an interagency agreement with NASS to conduct this survey.

Description of Respondents: The 2022 survey will target operations who own or operate cropland as well as confined livestock feeding operations. Operators who have grazing land or forestry land will be done at a later date.

Number of Respondents: 35,200.

Frequency of Responses: Once.

Total Burden Hours: 35,614.

Levi S. Harrell,

Departmental Information Collection Clearance Officer.

[FR Doc. 2021–24375 Filed 11–8–21; 8:45 am]

BILLING CODE 3410–20–P

DEPARTMENT OF AGRICULTURE

Privacy Act of 1974; System of Records

AGENCY: Office of Secretary, USDA.

ACTION: Notice of a new system of records.

SUMMARY: As required by the Privacy Act of 1974, and Office of Management and Budget (OMB) Circular No. A–108, this notice is a new Privacy Act System of Records titled USDA/OSEC–02 Contractor and Visitor Public Health Emergency Records, which include information on contractor employees who work in, as well as visitors to, Department of Agriculture (USDA) facilities during declared public health emergencies. The system contains information provided by the contractor's employees including such information as their applicable vaccination or medical countermeasure status and whether they are experiencing symptoms associated with the public health emergency. Each contractor with employees who will work in USDA facilities (regardless of whether the contract is with USDA or another Federal agency) will be asked to confirm if its employees have been vaccinated or have received appropriate medical countermeasures, in addition, the contractor will be required to ensure that its employees follow the guidelines specified for working in USDA facilities, for example, to mitigate the spread of COVID–19, not fully vaccinated employees are required to wear masks and maintain physical distancing. Visitors to USDA facilities will also be asked to provide information about their vaccination or medical countermeasure status and may be asked to provide proof of their status and information about whether they are experiencing any symptoms associated with the public health emergency.

DATES: This notice is applicable upon publication, subject to a 30-day review and comment period for the routine uses. We will consider comments received on or before November 29, 2021.

ADDRESSES: The public, OMB, and Congress are invited to submit any comments by mail to the United States Department of Agriculture, Privacy Office, ATTN: Privacy Analyst, 1400 Independence Ave. SW, Washington, DC 20250; by telephone at 202–384–5026; or by email at SM.OCIO.CIO.UsdaPrivacy

FOR FURTHER INFORMATION CONTACT: Sullie Coleman, Chief Privacy Officer, 1400 Independence Ave. SW, Washington, DC 20250, 202–604–0467.

SUPPLEMENTARY INFORMATION: USDA is establishing a system of records, USDA/OSEC–02, subject to the Privacy Act of 1974, 5 U.S.C. 552a. The purpose of this new system of records is to house information provided by contractors, subcontractors, their employees, and visitors needed for USDA to take appropriate actions during a public health emergency. The information collected includes medical countermeasures, such as vaccinations, diagnostic test results, whether the individual is experiencing relevant symptoms, and any other information necessary to assist USDA with determining appropriate mitigation measures to take with respect to contractor employees and visitors in USDA facilities or in the performance of duties associated with the Department. In general, the information will be used to confirm that contractors, their employees, and visitors to USDA facilities are aware of and complying with requirements necessitated by the public health emergency, such as those to wear masks and maintain physical distancing while working onsite or visiting a USDA facility. For onsite contractor employees, the information will be used to make decisions such as office space planning and assigning office space, assigning tasks that require individuals to work in close physical proximity, as well for operational staffing requirements for carrying out work in field operations.

As required by the Privacy Act (specifically 5 U.S.C. 552a(r)) and implemented by the Office of Management and Budget (OMB) Circular A108, USDA has provided a report of this system of records to the Office of Information and Regulatory Affairs, Office of Management and Budget; the Chairman, Committee on Government Reform and Oversight, House of Representatives; and the Chairman, Committee on Governmental Affairs, United States Senate.

SYSTEM NAME AND NUMBER:

USDA/OSEC–02 Contractor and Visitor Public Health Emergency Records

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Micro-Soft (MS) 365 Multi-Tenant (MT) provides Exchange and SharePoint Access for USDA/OSEC–02 Contractor and Visitor Public Health Emergency Records. Tenant locations are defaulted to Geo based on the country. In the United States, these records may be maintained electronically at one or more of Microsoft Data Centers, including, but not limited to, Boydton, Virginia, and Cheyenne, Wyoming. The agency, U.S. Department of Agriculture, address is 1400 Independence Ave. SW,

Washington, DC 20250 and the address of the third-party service provider is Microsoft, 1 Microsoft Way, Redmond, Washington 98052–6399.

SYSTEM MANAGER(S):

Contact information of the agency official who is responsible for this system is USDA OCIO–CEC MS 365 Program Manager, 2312 E Bannister Road, Mail Stop 9198, Kansas City, MO 64114, 816–926–6860.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

National Emergencies Act (50 U.S.C. 1601–1651); the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121, 5192(1)); 5 U.S.C. 301, 7901, 7902, and 7903; the Occupational Safety and Health Act (29 U.S.C. 668), Executive Order 12196, Occupational safety, and health programs for Federal employees; Executive Order 14042, Ensuring Adequate COVID Safety Protocols for Federal Contractors; Workforce Innovation and Opportunity Act (WIOA) WIOA 159(g) ((29 U.S.C. 3209(g)) and WIOA 147(a)(3)(J) ((29 U.S.C. 3197(a)(3)(J)).

PURPOSE(S) OF THE SYSTEM:

To capture and report health and safety-related information during public health emergencies. Such reporting will be provided to USDA contracting officers and other authorized officials in USDA to enable the agency to use the data from the system to review submissions for compliance with applicable mitigation requirements, and, in the case of contractor employees, with contractual terms and conditions for contracts for which they are responsible.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

USDA/OSEC–02 Contractor and Visitor Public Health Emergency Records System contains records related to employees of prime and subcontractors who are performing work on federal contract awards at any USDA facility, or in shared operations. An owner, agent, or employee of a prime or subcontractor may enter or certify information, as applicable.

USDA/OSEC–02 Contractor and Visitor Public Health Emergency Records System may also contain records related to visitors to USDA facilities, such as, but not limited to, volunteers, individuals from outside the USDA workforce on detail to USDA, experts/consultants, and grantees.

CATEGORIES OF RECORDS IN THE SYSTEM:

The information in the system of records consists of electronic records, including records of vaccination status or other medical countermeasures (such as diagnostic test results), status of employees or visitors, and other health and safety information related to the public health emergency. The information in the system of records includes the name of the person entering, and as applicable, certifying, information on behalf of the prime or subcontractor, their position within the company, phone number, and email address.

Categories of records include, but are not limited to: Name, unique identifier assigned by the prime or subcontractor, medical countermeasure (vaccination or diagnostic test) status, symptom questionnaires and other information relevant and necessary for mitigation purposes. Optional records that may be required for certain contracts or in certain geographic areas include: Name, position, work phone number, email address, USDA facility, lands, or shared operations at which the employee will be working on-site, and other similar records related to their official responsibilities.

RECORD SOURCE CATEGORIES:

Contract employee records are created, reviewed and, as appropriate, certified by the prime or subcontractor. Records pertaining to the individual entering and certifying data in the system may be created by the individual, by a contracting officer, or in the case of a subcontractor by the prime contractor or another subcontractor. Visitor records are created, reviewed and, as appropriate, certified by the appropriate Agency Official receiving the visitor to the USDA facility.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b), all or a portion of the records or information contained in this system of records may be disclosed as a routine use pursuant to 5 U.S.C. 552a(b)(3) under the circumstances or for the purposes described below, to the extent such disclosures are compatible with the purposes for which the information was collected:

A. To appropriate medical facilities, or federal, state, local, tribal, territorial, or foreign government agencies, to the extent permitted by law, for the purpose of protecting the vital interests of individual(s), including to assist the United States Government in responding to or mitigating high consequence public health threats, or diseases and illnesses relating to a public health emergency.

B. Where a record, either alone or in conjunction with other information, indicates a violation or potential violation of law—criminal, civil, or regulatory in nature—the relevant records may be referred to the appropriate federal, state, local, territorial, tribal, or foreign law enforcement authority or other appropriate entity charged with the responsibility for investigating or prosecuting such violation or charged with enforcing or implementing such law.

C. In an appropriate proceeding before a court, grand jury, or administrative or adjudicative body, when the Department determines that the records are arguably relevant to the proceeding; or in an appropriate proceeding before an administrative or adjudicative body when the adjudicator determines the records to be relevant to the proceeding.

D. To contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for the Federal Government, when necessary to accomplish an agency function related to this system of records.

E. To a former employee of the Department for purposes of: Responding to an official inquiry by a federal, state, or local government entity or professional licensing authority, in accordance with applicable Department regulations; or facilitating communications with a former employee that may be necessary for personnel-related or other official purposes where the Department requires information and/or consultation assistance from the former employee regarding a matter within that person's former area of responsibility.

F. To Federal, state, local, territorial, tribal, foreign, or international licensing agencies or associations which require information concerning the suitability or eligibility of an individual for a license or permit.

G. To a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of, and at the request of, the individual who is the subject of the record.

H. To the National Archives and Records Administration for purposes of records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906.

I. To appropriate agencies, entities, and persons when

(1) the Department suspects or has confirmed that there has been a breach of the system of records;

(2) the Department has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the Department (including its information systems, programs, and operations), the Federal Government, or national security; and

(3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Department's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

J. To another Federal agency or Federal entity, when the Department determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in

(1) responding to a suspected or confirmed breach, or

(2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

K. To any agency, organization, or individual for the purpose of performing authorized audit or oversight operations of the Department and meeting related reporting requirements.

L. To such recipients and under such circumstances and procedures as are mandated by Federal statute or treaty.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

All records in this system of records are maintained electronically and in paper and are in compliance with applicable executive orders, statutes, and agency implementing recommendations. Electronic records are stored in databases and/or on hard disks, removable storage devices, or other electronic media.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

The Department will retrieve records by the individual's name, unique identifier assigned by the prime or subcontractor, vaccination status, position, or facility at which the employee will be working on-site.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

To the extent applicable, to ensure compliance with Americans with Disabilities Act (ADA) and the Rehabilitation Act, medical information must be ''maintained on separate forms and in separate medical files and be treated as a confidential medical record.'' 42 U.S.C. 12112(d)(3)(B). This means that medical information and documents must be stored separately from other personnel records. As such, the Department must keep medical records for at least one year from creation date. 29 CFR 1602.14. Further, records compiled under this SORN will be maintained in accordance with NARA General Records Schedule (GRS) 2.7, Items 010, 070 or 080, and NARA records retention schedules DAA–GRS2017–0010–0001, DAA–GRS2017–0010–0012, and DAA–GRS2017–0010–0013, to the extent applicable.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

The Department safeguards records in this system according to applicable rules and polices, including all applicable USDA automated systems security and access policies. The Department has imposed strict controls to minimize the risk of compromising the information that is being stored. Users of individual computers can only gain access to the data by a valid user identification and password. Paper records are maintained in a secure, access-controlled room, with access limited to authorized personnel.

RECORD ACCESS PROCEDURES:

All requests for access to records must be in writing and should be addressed to the USDA Departmental FOIA Office, ATTN: Departmental FOIA Officer, 1400 Independence Avenue SW South Building, Room 4104, Washington, DC 20250–0706, Email: *USDAFOIA@ocio.usda.gov.* The envelope and letter should be clearly marked ''Privacy Act Access Request.'' The request must describe the records sought in sufficient detail to enable Department personnel to locate them with a reasonable amount of effort. The request must include a general description of the records sought and must include the requester's full name, current address, and date and place of birth. The request must be signed and either notarized or submitted under penalty of perjury. Additional details on procedures for access under the Privacy Act can be found in USDA Department Regulation 3515–002 Privacy Policy and Compliance for Personally Identifiable Information (PII) or at Privacy Policy and Compliance for Personally Identifiable Information (PII) (*usda.gov*).

CONTESTING RECORD PROCEDURES:

Individuals seeking to contest or amend records maintained in this system of records must direct their requests to the address indicated in the ''RECORD ACCESS PROCEDURES'' paragraph, above. All requests to contest or amend records must be in writing and the envelope and letter should be clearly marked ''Privacy Act Amendment Request.'' All requests must state clearly and concisely what record is being contested, the reasons for contesting it, and the proposed amendment to the record. Additional details on procedures for contesting or amending records under the Privacy Act can be found in USDA Department Regulation 3515–002 Privacy Policy and Compliance for Personally Identifiable Information (PII) or at Privacy Policy and Compliance for Personally Identifiable Information (PII) (*usda.gov*).

NOTIFICATION PROCEDURES:

Individuals may be notified if a record in this system of records pertains to them when the individuals request information utilizing the same procedures as those identified in the ''RECORD ACCESS PROCEDURES'' paragraph, above.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

Sullie Coleman,

Chief Privacy Officer, United States Department of Agriculture.

[FR Doc. 2021–24402 Filed 11–8–21; 8:45 am]

BILLING CODE 3410–90–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

November 4, 2021.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding; whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological

collection techniques or other forms of information technology.

Comments regarding this information collection received by December 9, 2021 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

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

Animal and Plant Health Inspection Service

Title: Movement of Plants and Plant Products from Hawaii and the Territories.

OMB Control Number: 0579–0346.

Summary of Collection: Under the Plant Protection Act (7 U.S.C 7701), the Secretary of Agriculture is authorized to prohibit or restrict the importation, entry, or movement of fruits, vegetables, plants, and plant pests to prevent the introduction of pests or diseases into the United States, or dissemination of pests and diseases within the United States. The Animal and Plant Health Inspection Service (APHIS), Plant Protection and Quarantine (PPQ), is responsible for implementing this Act and does so through the enforcement of its Hawaiian and territorial quarantine regulations contained in Part 318 of Title 7, Code of Federal Regulations.

Need and Use of the Information: APHIS will use the following forms and activities to collect information: PPQ 530, PPQ 586, PPQ 519, PPQ 540, Labeling of Boxes for Pest Free Areas, Inspection and Certification, Trapping and Surveillance, Contingency Plans approved by APHIS, Updated Mapping Identifying Places Where Horticultural or Other Crops are Grown, Written Request for Treatment Facility Approval—and Recertification, Recordkeeping, Decertification of Pest Free Areas—and Reinstatement, Notification of Emergency Conveyance, Aircraft/Ship Inspections of Departure, Production Site Registration, Packing House Registration; Labeling From Pest Free Areas, Labeling of Boxes for Pest Free Areas; Packing, Markings and Identify. If APHIS did not collect this information or if APHIS collected this information less frequently, the spread of dangerous plant diseases and pests could cause millions of dollars in damage to U.S. agriculture.

Description of Respondents: Business or other for-profits; State, Local or Tribal Government.

Number of Respondents: 283.

Frequency of Responses: Recordkeeping; Reporting: On occasion.

Total Burden Hours: 3,286.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2021–24470 Filed 11–8–21; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

National Agricultural Statistics Service

Notice of Intent To Request a Revision and Extension of a Currently Approved Information Collection

AGENCY: National Agricultural Statistics Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of the National Agricultural Statistics Service (NASS) to request revision and extension of a currently approved information collection for surveys funded by NASS's many cooperators (Federal agencies, State governments, land grant universities, and other organizations). Results from these surveys are important for the cooperators in carrying out their missions, as well as of general interest to the agricultural community. This generic clearance will allow NASS to conduct surveys in a timely manner for the cooperating institutions providing funding for the surveys.

DATES: Comments on this notice must be received by January 10, 2022 to be assured of consideration.

ADDRESSES: You may submit comments, identified by docket number 0535–NEW, by any of the following methods:

- *Email: ombofficer@nass.usda.gov.* Include docket number above in the subject line of the message.
- *E-fax:* 855–838–6382.
- *Mail:* Mail any paper, disk, or CD–ROM submissions to: David Hancock, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW, Washington, DC 20250–2024.
- *Hand Delivery/Courier:* Hand deliver to: David Hancock, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW, Washington, DC 20250–2024.

FOR FURTHER INFORMATION CONTACT: Kevin L. Barnes, Associate Administrator, National Agricultural Statistics Service, U.S. Department of Agriculture, 202–720–4333. Copies of this information collection and related instructions can be obtained without charge from David Hancock, NASS—OMB Clearance Officer, at 202–690–2388 or at *ombofficer@nass.usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: Quick Response for Cooperator-Funded Surveys Generic Clearance.

OMB Control Number: 0535–0264.

Type of Request: To revise and extend a currently approved information collection for a period of three years.

Abstract: The primary objective of the National Agricultural Statistics Service (NASS) is to collect, prepare, and issue state and national estimates of crop and livestock production, prices, and disposition; as well as economic statistics, environmental statistics related to agriculture; and also to conduct the Census of Agriculture. In addition, NASS has many cooperators from other Federal agencies, State governments, land grant universities, and other organizations that seek NASS's assistance in collecting agricultural data through surveys. Results from these surveys are important for the cooperators in carrying out their missions, as well as of general interest to the agricultural community. Results from these surveys will be made available to the public by NASS or the cooperators who fund them. This generic clearance seeks approval for NASS to conduct a variety of agricultural surveys which will be paid for entirely by cooperators. NASS anticipates the cooperator-funded surveys will cover topics such as: (1) Farm management practices, (2) food safety, (3) workplace safety, (4) conservation and land use practices, (5) chemical use management practices, (6) crop quality, (7) agri-tourism, (8) local foods, and (9) other agricultural-related topics. This generic clearance is subject to the regular clearance process at OMB with a 60-day notice and a 30-day notice as part of the 120-day review period. Each individual cooperator-funded survey is then subject to a clearance process with an abbreviated clearance package which justifies the particular content of the survey, describes the

sample design, provides the timeline for the survey activities, and the questionnaire. The review period for each individual survey is approximately 45 days, including a 30-day **Federal Register** notice period.

Authority: These data will be collected under authority of 7 U.S.C. 2204(a). Individually identifiable data collected under this authority are governed by Section 1770 of the Food Security Act of 1985 as amended, 7 U.S.C. 2276, which requires USDA to afford strict confidentiality to non-aggregated data provided by respondents. This Notice is submitted in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–113, 44 U.S.C. 3501, *et seq.*) and Office of Management and Budget regulations at 5 CFR part 1320.

All NASS employees and NASS contractors must also fully comply with all provisions of the Confidential Information Protection and Statistical Efficiency Act of 2018, Title III of Pubic Law 115–435, codified in 44 U.S.C. ch. 35.

Estimate of Burden: Public reporting burden for this information collection is estimated to average 30 minutes per response. Up to 10 individual surveys are included in this generic clearance to be conducted annually (total of 30). The estimated sample size for each of the 30 surveys is approximately 7,500. Each of the 30 surveys are expected to be conducted once annually. This is an increase from the previous approval due as the previous burden request submitted was intended to be a one year burden request.

The estimated number of responses per respondent is 1. Publicity materials and instruction sheets will account for approximately 5 minutes of additional burden per respondent. Respondents who refuse to complete a survey will be allotted 2 minutes of burden per attempt to collect the data. NASS will conduct the surveys initially by mail and/or internet with phone follow-up for non-response. Face-to-face interviews may also be used in limited situations.

Respondents: Farmers and ranchers, and others associated with the agricultural industry.

Estimated Number of Respondents: 225,000.

Frequency of Responses: Once annually for each individual survey.

Estimated Total Burden on Respondents: The total estimated burden is 112,000 hours.

Comments: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, through the use of appropriate automated, electronic, mechanical, technological, or other forms of information technology collection methods.

All responses to this notice will become a matter of public record and be summarized in the request for OMB approval.

Signed at Washington, DC, November 3, 2021.

Kevin L. Barnes,

Associate Administrator.

[FR Doc. 2021–24401 Filed 11–8–21; 8:45 am]

BILLING CODE 3410–20–P

DEPARTMENT OF AGRICULTURE

National Agricultural Statistics Service

Notice of Intent To Request Revision and Extension of a Currently Approved Information Collection

AGENCY: National Agricultural Statistics Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of the National Agricultural Statistics Service (NASS) to request revision and extension of a currently approved information collection, the Generic Clearance for Survey Research Studies. Burden hours and number of contacts will be increased to accommodate the proposed testing for the upcoming three year period.

DATES: Comments on this notice must be received by January 10, 2022 to be assured of consideration.

ADDRESSES: You may submit comments, identified by docket number 0535–0248, by any of the following methods:

- *Email: omboffi cer@nass.usda.gov.* Include docket number above in the subject line of the message.
- *E-fax:* (855) 838–6382.
- *Mail:* Mail any paper, disk, or CD–ROM submissions to: David Hancock, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW, Washington, DC 20250–2024.
- *Hand Delivery/Courier:* Hand deliver to: David Hancock, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW, Washington, DC 20250–2024.

FOR FURTHER INFORMATION CONTACT: Kevin L. Barnes, Associate Administrator, National Agricultural Statistics Service, U.S. Department of Agriculture, (202) 720–2707. Copies of this information collection and related instructions can be obtained without charge from David Hancock, NASS—OMB Clearance Officer, at (202) 690–2388 or at *omboffi cer@nass.usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: Generic Clearance To Conduct Survey Research Studies.

OMB Control Number: 0535–0248.

Type of Request: To revise and extend a currently approved information collection for a period of three years.

Abstract: The National Agricultural Statistics Service (NASS) of the United States Department of Agriculture (USDA) will request approval from the Office of Management and Budget (OMB) for a generic clearance that will allow NASS to rigorously develop, test, and evaluate its survey instruments and methodologies. The primary objectives of the National Agricultural Statistics Service are to prepare and issue State and national estimates of crop production, livestock production, economic statistics, and environmental statistics related to agriculture and to conduct the Census of Agriculture. This request is part of an on-going initiative to improve NASS surveys, as recommended by both its own guidelines and those of OMB.

In the last decade, state-of-the art techniques have been increasingly instituted by NASS and other Federal agencies and are now routinely used to improve the quality and timeliness of survey data and analyses, while simultaneously reducing respondents' cognitive workload and burden. The purpose of this generic clearance is to allow NASS to continue to adopt and use these state-of-the-art techniques to improve its current data collections efforts. These tests will also be used to aid in the development of new surveys.

NASS envisions using a variety of survey improvement techniques, as appropriate to the individual project under investigation. These include focus groups, cognitive and usability laboratory and field techniques, exploratory interviews, behavior coding, respondent debriefing, pilot surveys, and split-panel tests. After obtaining participants' permission, NASS plans to audio-record some cognitive interviews

and usability interviews, in order to allow for more complete and accurate summaries of these qualitative interviews. This is a standard procedure for cognitive interviews and usability interviews at many other survey organizations, including Federal agencies. The consent form would be used for audio recording some cognitive interviews and usability interviews for research purposes. For these types of interviews, there will be no collection of Personally Identifiable Information (PII) or any identifying information about the operator or operation.

In addition to the testing techniques listed above NASS will be including parallel testing with this renewal request. NASS is investigating methodologies using additional sources of farm operators (including web scraping). These methodologies will be tested against the NASS's current multi-frame methodology.

Following standard OMB requirements NASS will submit a change request to OMB individually for each survey improvement project it undertakes under this generic clearance and provide OMB with a copy of the questionnaire (if one is used), and all other materials describing the project.

Authority: These data will be collected under the authority of 7 U.S.C. 2204(a). Individually identifiable data collected under this authority are governed by Section 1770 of the Food Security Act of 1985, 7 U.S.C. 2276, which requires USDA to afford strict confidentiality to non-aggregated data provided by respondents. This Notice is submitted in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13) and Office of Management and Budget regulations at 5 CFR part 1320. Participation in all surveys and studies conducted under this approval will be voluntary.

NASS also complies with OMB Implementation Guidance, ''Implementation Guidance for Title V of the E-Government Act, Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA),'' **Federal Register,** Vol. 72, No. 115, June 15, 2007, p. 33362.

Estimate of Burden: Public reporting burden for these collections of information is estimated to average from 15 minutes to 1.5 hours per respondent, dependent upon the survey and the technique used to test for that particular survey. The overall average is estimated to be 0.60 hours per response.

Respondents: Farmers, ranchers, farm managers, farm contractors, agri-businesses, and households.

Estimated Number of Respondents: 25,000.

Frequency of Responses: On occasion.

Estimated Total Annual Burden: 15,000 hours.

Comments: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, through the use of appropriate automated, electronic, mechanical, technological or other forms of information technology collection methods.

All responses to this notice will become a matter of public record and be summarized in the request for OMB approval.

Signed at Washington, DC, November 3, 2021.

Kevin L. Barnes,

Associate Administrator.

[FR Doc. 2021–24394 Filed 11–8–21; 8:45 am]

BILLING CODE 3410–20–P

COMMISSION ON CIVIL RIGHTS

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

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of virtual business 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 Florida Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a virtual business meeting via Webex at 10:00 a.m. ET on Monday, November 29, 2021.

DATES: The meeting will take place on Monday, November 29, 2021, at 10:00 a.m. ET.

Online Regisration (Audio/Visual): https://bit.ly/3nVNJgV.

Telephone (Audio Only): Dial 800–360–9505 USA Toll Free; Access code: 2763 894 1640.

FOR FURTHER INFORMATION CONTACT: Melissa Wojnaroski, DFO, at *mwojnaroski@usccr.gov* or (202) 618–4158.

SUPPLEMENTARY INFORMATION: Committee meetings are available to the public through the conference link above. Any interested member of the public may listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. If joining via phone, 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. Individuals who are deaf, deafblind, and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference details found through registering at the web link above. To request additional accommodations, please email *mwojnaroski@usccr.gov* at least ten (10) days prior to the meeting.

Members of the public are also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to Liliana Schiller at *lschiller@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (312) 353–8311.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Coordination Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Florida 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 Coordination Unit at the above email or street address.

Agenda

I. Welcome & Roll Call

II. Voting Rights Review

III. Public Comment

IV. Next Steps

V. Adjournment

Dated: Thursday, November 4, 2021.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2021–24484 Filed 11–8–21; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

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

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of virtual business meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act, that the Georgia Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a virtual business meeting via Webex at 2:00 p.m. ET on Wednesday, December 8, 2021. The Committee will review testimony from the web briefings on Civil Asset Forfeiture and its Impact on Communities of Color.

DATES: The meeting will take place on Wednesday, December 8, 2021, at 2:00 p.m. ET.

Online Regisration (Audio/Visual): *https://bit.ly/3z6neJb.*

Telephone (Audio Only): Dial 800–360–9505 USA Toll Free; Access code: 2762 558 0334.

FOR FURTHER INFORMATION CONTACT: Melissa Wojnaroski, DFO, at *mwojnaroski@usccr.gov* or (202) 618–4158.

SUPPLEMENTARY INFORMATION: Committee meetings are available to the public through the conference link above. Any interested member of the public may listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. If joining via phone, 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. Individuals who are deaf, deafblind, and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference details found through registering at the web link above. To request additional accommodations, please email *mwojnaroski@usccr.gov* at least ten (10) days prior to the meeting.

Members of the public are also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to Liliana Schiller at *lschiller@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (312) 353–8311.

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

Agenda

I. Welcome & Roll Call
II. Review Testimony & Prepare for Report
III. Public Comment
IV. Next Steps
V. Adjournment

Dated: Thursday, November 4, 2021.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2021–24486 Filed 11–8–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Census Bureau

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; National Survey of Children's Health

AGENCY: Census Bureau, Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act (PRA) of 1995, invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment on the proposed revision of the National Survey of Children's Health, prior to the submission of the information collection request (ICR) to OMB for approval.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before January 10, 2022.

ADDRESSES: Interested persons are invited to submit written comments by email to *ADDP.NSCH.List@census.gov.* Please reference National Survey of Children's Health in the subject line of your comments. You may also submit comments, identified by Docket Number USBC–2021–0026, to the Federal e-Rulemaking Portal: *http://www.regulations.gov.* All comments received are part of the public record. No comments will be posted to *http://www.regulations.gov* for public viewing until after the comment period has closed. Comments will generally be posted without change. All Personally Identifiable Information (for example, name and address) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information. You may submit attachments to electronic comments in Microsoft Word, Excel, or Adobe PDF file formats.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Carolyn Pickering, Survey Director, by way of phone (301–763–3873) or email (*Carolyn.M.Pickering@census.gov*).

SUPPLEMENTARY INFORMATION:

I. Abstract

Sponsored primarily by the U.S. Department of Health and Human Services' Health Resources Services Administration's Maternal and Child Health Bureau (HRSA MCHB), the National Survey of Children's Health (NSCH) is designed to produce data on the physical and emotional health of children under 18 years of age who live in the United States. The United States Department of Agriculture (USDA) and the United States Department of Health and Human Services' Center for Disease Control and Prevention, National Center on Birth Defects and Developmental Disabilities (CDC–NCBDDD) sponsor supplemental content on the NSCH. Additionally, the upcoming cycle of the NSCH plans to include five returning age-based or state-based oversamples and one new region-based oversample. The age-based oversample would be funded by the United States Department of Health and Human Services' Center for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion (CDC–NCCDPHP). The state- or region-based oversamples would be sponsored by Children's Health Care of Atlanta, the State of Colorado, the State of Nebraska, the Ohio Department of Health, the Oregon Center for Children and Youth

with Special Health Care Needs, and the State of Tennessee.

The NSCH collects information on factors related to the well-being of children, including access to health care, in-home medical care, family interactions, parental health, school and after-school experiences, and neighborhood characteristics. The goal of the 2022 NSCH is to provide HRSA MCHB, the supplemental sponsoring agencies, states, regions, and other data users with the necessary data to support the production of national estimates yearly and state- or region-based estimates with pooled samples on the health and well-being of children, their families, and their communities as well as estimates of the prevalence and impact of children with special health care needs.

NSCH is seeking clearance to make the following changes:

• *Increased sample size*—The MCHB sponsored NSCH sample plus the separately sponsored age-, state-, or region-based oversamples will be approximately 360,000 addresses for the 2022 NSCH, compared with 300,000 in 2021. The increased sample will allow individual states and agencies to produce statistically sound child health estimates in a fewer number of pooled years than if the sample were to remain the same annually, thereby resulting in more timely age-, state- and region-based health estimates of children.

• *Revised questionnaire content*—The NSCH questionnaires with newly proposed and revised content from the sponsors at HRSA MCHB are currently undergoing two rounds of cognitive testing. This testing request was submitted under the generic clearance package and approved by OMB.[1] Based on the results, a final set of proposed new and modified content will be included in the full OMB ICR for the 2022 NSCH.

• *Oversamples*[2]—In order to inform various priorities that are otherwise not supported by the NSCH, some stakeholders have shown interest in sponsoring an oversample of particular populations as part of the annual NSCH administration. Currently, there are five states, one region, and one federal partner contributing to an oversample as part of the 2022 NSCH. Four states (Colorado, Nebraska, Ohio, and Oregon) and the Atlanta, GA Metro Area were initially oversampled in 2020 or 2021 and are continuing with the option as part of the 2022 NSCH. One additional state (Tennessee) will be oversampled for the first time in 2022. CDC–NCCDPHP is supporting an oversample of households with young children. Additionally, MCHB is requesting oversamples within the states of California, New York, Pennsylvania, and Wyoming.

Besides the proposed changes listed above, the 2022 NSCH will proceed with the current design outlined in the previous OMB ICR package, including the use of incentives. Response rates for the unconditional monetary incentive group continues to show a statistically significant difference over the control group that did not receive an unconditional monetary incentive. As part of the initial screener mailing, 90% will include $5 and 10% will not receive an incentive. The incentive assignment to each sampled address would still be random as was done in prior cycles and approved by OMB. Additionally, the use of a $5 or $10 incentive with the initial paper topical mailing will be used. We will continue to make modifications to data collection strategies based on modeled information about paper or internet response preference. Results from prior survey cycles will continue to be used to inform the decisions made regarding future cycles of the NSCH.

From prior cycles of the NSCH, using American Association for Public Opinion Research definitions of response, we can expect for the 2022 NSCH an overall screener completion rate to be about 44.5% and an overall topical completion rate to be about 36.0%. This is different from the overall response rate, which we expect to be about 40.3%.

II. Method of Collection

The 2022 NSCH plan for the web push data collection design includes approximately 70% of the production addresses receiving an initial invite with instructions on how to complete an English or Spanish-language screener questionnaire via the web. Households that decide to complete the web-based survey will be taken through the screener questionnaire to determine if they are eligible for one of three topical instruments. Households that list at least one child who is 0 to 17 years old in the screener are directed into a topical questionnaire immediately after the last screener question. If a household in the web push treatment group decides to complete the paper screener, the household may have a chance to receive an additional topical questionnaire incentive. This group will receive two web survey invitation letters requesting their participation in the survey prior to receiving up to two additional paper screener questionnaires in the second and third follow-up mailings.

The 2022 NSCH plan for the mixed-mode data collection design includes up to 30% of the production addresses receiving a paper screener questionnaire in either the initial or the first nonresponse follow-up and instructions on how to complete an English or Spanish language screener questionnaire via the web. Households that decide to complete the web-based survey will follow the same screener and topical selection path as the web push. Households that choose to complete the paper screener questionnaire rather than completing the survey on the internet and that have eligible children will be mailed a paper topical questionnaire upon receipt of their completed paper screener at the Census Bureau's National Processing Center. If a household in the mixed-mode group chooses to complete the paper screener instead of completing the web-based screener via the internet, then the household may receive an additional topical questionnaire incentive. This group will receive both a web survey invitation letter along with a mailed paper screener questionnaire with either the initial invitation or the first follow-up and each additional nonresponse follow-up mailing.

III. Data

OMB Control Number: 0607–0990.

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

Type of Review: Regular submission, Request for a Revision of a Currently Approved Collection.

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

Estimated Number of Respondents: 131,884.

Estimated Time per Response: 5 minutes per screener response and 35–36 minutes per topical response, which in total is approximately 40–41 minutes for households with eligible children.

Estimated Total Annual Burden Hours: 46,587.

[1] Generic Clearance Information Collection Request: *https://www.reginfo.gov/public/do/PRAViewIC?ref_nbr=201909-0607-002&icID=248532.*

[2] State Oversampling in the National Survey of Children's Health: Feasibility, Cost, and Alternative Approaches *https://census.gov/content/dam/Census/programs-surveys/nsch/NSCH_State_Oversample_Summary_Document.pdf.*

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

Respondent's Obligation: Voluntary.

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

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) 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; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include, or summarize, each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–24503 Filed 11–8–21; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Census Bureau

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Business Pulse Survey

AGENCY: Census Bureau, Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act (PRA) of 1995, invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment on the proposed new Business Pulse Survey prior to the submission of the information collection request (ICR) to OMB for approval.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before January 10, 2022.

ADDRESSES: Interested persons are invited to submit written comments by email to *Thomas.J.Smith@census.gov.* Please reference Business Pulse Survey in the subject line of your comments. You may also submit comments, identified by Docket Number USCB–2021–0027, to the Federal e-Rulemaking Portal: *http://www.regulations.gov.* All comments received are part of the public record. No comments will be posted to *http://www.regulations.gov* for public viewing until after the comment period has closed. Comments will generally be posted without change. All Personally Identifiable Information (for example, name and address) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information. You may submit attachments to electronic comments in Microsoft Word, Excel, or Adobe PDF file formats.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Stephanie Studds, Chief, Economic Indicator Division, 301–763–2633, and *stephanie.lee.studds@census.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The U.S. Census Bureau plans to request a 3-year approval from the Office of Management and Budget (OMB) for a new survey, the Business Pulse Survey. During the Coronavirus pandemic, the Census Bureau launched new weekly and monthly programs to measure the pandemic's impact on the economy. The Census Bureau was commended by policy makers, media, academia, and other stakeholders on its timeliness and rapid response to their data needs to understand the impact of the pandemic on the economy. The Census Bureau has a need to collect and publish economic baseline data on a frequent, ongoing basis.

The Business Pulse Survey will be a new experimental survey with bi-weekly data collection and publication. This continuous near real time data publication will provide a baseline of the U.S. economy and will measure change as a result of current and future economic shocks. The ongoing nature of the Business Pulse Survey is in response to stakeholder feedback on the Small Business Pulse Survey (SBPS), which was that economic baseline or 'norms' data would have been helpful to have in comparison to the SBPS data on pandemic impact.

The Business Pulse Survey will evolve and progress to its full desired scope over time, in stages or phases. The Census Bureau plans to learn from the incremental progress of the Business Pulse Survey and make improvements to the survey as it matures. Initially, the Business Pulse Survey will be an expansion of the Small Business Pulse Survey (OMB Number: 0607–1014). The SBPS was restricted to small businesses with 1–499 employees and included only a single island territory, Puerto Rico. The Business Pulse Survey's initial sample criteria will include all single unit employer businesses in the U.S. and U.S. Island Areas. At full scope, the Business Pulse Survey will allow for data collection from businesses across most non-farm sectors of the U.S. economy, while producing statistics on employer and non-employer businesses across all employer size classes, as well as geographically detailed data on the fifty U.S. states, Washington DC, and the U.S. Island Areas.

The Business Pulse Survey will collect the following high-level topics:

- Overall current business performance or business climate
- Change in operating revenues/sales/receipts
- Change in employment
- Change in hours of paid employees

• Expectations: Future performance

Business Pulse Survey data would be collected in near-real time and disseminated as experimental products. Business Pulse Survey data will be experimental with the goal of meeting Census Bureau quality standards for regularly occurring, non-experimental statistics.

II. Method of Collection

The data will be collected by paper or electronic instruments, depending on whether respondent email is available.

III. Data

OMB Control Number: 0607–XXXX.

Form Number(s): None.

Type of Review: Regular submission, new information collection request.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 45,000 responses/bi-weekly.

Estimated Time per Response: 6 minutes.

Estimated Total Annual Burden Hours: 117,000.

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

Respondent's Obligation: Voluntary.

Legal Authority: Title 13 U.S.C., Sections 131 and 182.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) 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; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include, or summarize, each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–24502 Filed 11–8–21; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

International Trade Administration

[Application No. 99–14A05]

Export Trade Certificate of Review

ACTION: Notice of issuance of an amended Export Trade Certificate of Review to California Almond Export Association, LLC (CAEA), Application No. 99–14A05.

SUMMARY: The Secretary of Commerce, through the Office of Trade and Economic Analysis (OTEA), issued an amended Export Trade Certificate of Review (Certificate) to CAEA on October 15, 2021.

FOR FURTHER INFORMATION CONTACT: Joseph Flynn, Director, OTEA, International Trade Administration, (202) 482–5131 (this is not a toll-free number) or email at *etca@trade.gov.*

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (15 U.S.C. 4001–21) (the Act) authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. An Export Trade Certificate of Review protects the holder and the members identified in the Certificate from State and Federal government antitrust actions and from private treble damage antitrust actions for the export conduct specified in the Certificate and carried out in compliance with its terms and conditions. The regulations implementing Title III are found at 15 CFR part 325. OTEA is issuing this notice pursuant to 15 CFR 325.6(b), which requires the Secretary of Commerce to publish a summary of the certification in the **Federal Register**. Under Section 305(a) of the Act and 15 CFR 325.11(a), any person aggrieved by the Secretary's determination may, within 30 days of the date of this notice, bring an action in any appropriate district court of the United States to set aside the determination on the ground that the determination is erroneous.

Description of Certified Conduct

CAEA's Certificate has been amended as follows: The following companies were added as Members of the Certificate within the meaning of section 325.2(1) of the Regulations (15 CFR 325.2(1)):

- Bear Republic Nut, Chico, CA
- JSS Almonds, LLC, Bakersfield, CA
- VF Marking Corporation DBA Vann Family Orchards, Williams, CA

CAEA's amended Certificate Membership is as follows:

Almonds California Pride, Inc., Caruthers, CA
Baldwin-Minkler Farms, Orland, CA
Bear Republic Nut, Chico, CA
Blue Diamond Growers, Sacramento, CA
Campos Brothers, Caruthers, CA
Chico Nut Company, Chico, CA
Del Rio Nut Company, Livingston, CA
Fair Trade Corner, Inc., Chico, CA
Fisher Nut Company, Modesto, CA
Hilltop Ranch, Inc., Ballico, CA
Hughson Nut, Inc., Hughson, CA
JSS Almonds, LLC, Bakersfield, CA
Mariani Nut Company, Winters, CA
Nutco, LLC d.b.a. Spycher Brothers, Turlock, CA
Pearl Crop, Inc., Stockton, CA
P-R Farms, Inc., Clovis, CA
Roche Brothers International Family Nut Co., Escalon, CA
RPAC, LLC, Los Banos, CA
South Valley Almond Company, LLC, Wasco, CA
Stewart & Jasper Marketing, Inc., Newman, CA
SunnyGem, LLC, Wasco, CA
VF Marking Corporation DBA Vann Family Orchards, Williams, CA
Western Nut Company, Chico, CA
Wonderful Pistachios & Almonds, LLC, Los Angeles, CA

The effective date of the amended certificate is June 22, 2021, the date on which CAEA's application to amend was deemed submitted.

Dated: November 3, 2021.

Joseph Flynn,

Director, Office of Trade and Economic Analysis, International Trade Administration, U.S. Department of Commerce.

[FR Doc. 2021–24416 Filed 11–8–21; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

[Application No. 10–5A001]

Export Trade Certificate of Review

ACTION: Notice of issuance of an amended Export Trade Certificate of Review to Alaska Longline Cod Commission (''ALCC''), Application No. 10–5A001.

SUMMARY: The Secretary of Commerce, through the Office of Trade and Economic Analysis (''OTEA''), issued an amended Export Trade Certificate of Review (''Certificate'') to ALCC on October 26, 2021.

FOR FURTHER INFORMATION CONTACT: Joseph Flynn, Director, OTEA, International Trade Administration, by telephone at (202) 482–5131 (this is not a toll-free number) or email at *etca@trade.gov.*

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (15 U.S.C. 4001 21) (''the Act'') authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. An Export Trade Certificate of Review protects the holder and the members identified in the Certificate from State and Federal government antitrust actions and from private treble damage antitrust actions for the export conduct specified in the Certificate and carried out in compliance with its terms and conditions. The regulations implementing Title III are found at 15 CFR part 325. OTEA is issuing this notice pursuant to 15 CFR 325.6(b), which requires the Secretary of Commerce to publish a summary of the certification in the **Federal Register**. Under Section 305(a) of the Act and 15 CFR 325.11(a), any person aggrieved by the Secretary's determination may, within 30 days of the date of this notice, bring an action in any appropriate district court of the United States to set aside the determination on the ground that the determination is erroneous.

Description of Certified Conduct

ALCC's Export Trade Certificate of Review has been amended as follows:

1. Added the following companies as new Members of the Certificate within the meaning of section 325.2(l) of the Regulations (15 CFR 325.2(l)):

a. Aleutian Longline, LLC, Seattle, WA;

b. Bristol Wave Seafoods, LLC, Seattle, WA;

c. Coastal Alaska Premier Seafoods, LLC, Anchorage, AK;

d. Gulf Prowler, LLC, Juneau, AK;

e. Kodiak Leader Fisheries LLC, Lynden, WA; and

f. Starfish Reverse, LLC, Seattle, WA.

2. Changed the address for the following entities:

a. Beauty Bay Washington, LLC, changes address from Edmonds, WA to Bothell, WA.

b. Tatoosh Seafoods, LLC, changes address from Edmonds, WA to Kingston, WA.

3. Removed the following Members of the Certificate:

a. Prowler Fisheries LLC, Seattle, WA;

b. Blue North Fisheries, Inc., Seattle, WA;

c. Blue North Trading Company, LLC, Seattle, WA;

d. Clipper Group, Ltd., Seattle, WA;

e. Clipper Seafoods, Ltd., Seattle, WA;

f. Liberator Fisheries LLC, Seattle, WA; and

g. Siberian Sea Fisheries LLC, Seattle, WA.

4. Retained the names of the following Members, as updated in Application No. 10–4A001:

a. Bristol Leader Fisheries LLC;

b. Bering Leader Fisheries LLC; and

c. Northern Leader Fisheries LLC.

ALCC's Membership, as amended, is below:

1. Akulurak LLC, Seattle, WA;

2. Alaskan Leader Fisheries LLC, Lynden, WA;

3. Alaskan Leader Seafoods LLC, Lynden, WA;

4. Alaskan Leader Vessel LLC, Lynden, WA;

5. Aleutian Longline, LLC, Seattle, WA;

6. Aleutian Spray Fisheries, Inc., Seattle, WA;

7. Beauty Bay Washington, LLC, Bothell, WA;

8. Bering Leader Fisheries LLC, Lynden, WA;

9. Bristol Leader Fisheries LLC, Lynden, WA;

10. Bristol Wave Seafoods, LLC, Seattle, WA

11. Coastal Alaska Premier Seafoods, LLC, Anchorage, AK

12. Coastal Villages Longline LLC, Anchorage, AK;

13. Deep Sea Fisheries, Inc., Everett, WA;

14. Gulf Mist, Inc., Everett, WA;

15. Gulf Prowler, LLC, Juneau, AK;

16. Kodiak Leader Fisheries LLC, Lynden, WA

17. Northern Leader Fisheries LLC, Lynden, WA;

18. Romanzof Fishing Company, L.L.C., Seattle, WA;

19. Shelford's Boat, Ltd., Mill Creek, WA;

20. Siu Alaska Corporation, Anchorage, AK;

21. Starfish Reverse, LLC, Seattle, WA;

22. Tatoosh Seafoods, LLC, Kingston, WA.

The effective date of the amended Certificate is July 28, 2021, the date on which ALCC's application to amend was deemed submitted.

Dated: November 3, 2021.

Joseph Flynn,

Director, Office of Trade and Economic Analysis, International Trade Administration, U.S. Department of Commerce.

[FR Doc. 2021–24415 Filed 11–8–21; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Scientific Research, Exempted Fishing, and Exempted Educational Activity Submissions

The Department of Commerce will submit the following information collection request 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. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on September 1, 2021 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

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

Title: Scientific Research, Exempted Fishing, and Exempted Activity Submissions.

OMB Control Number: 0648–0309.

Form Number(s): None.

Type of Request: Regular submission (extension of a currently approved collection).

Number of Respondents: 123.

Average Hours per Response: Scientific research plans, 13 hours; scientific research reports, 6 hours; exempted fishing permit requests, 10 hours; exempted fishing permit reports, 4.5 hours; exempted educational requests, 5 hours; exempted educational reports, 2.5 hours.

Total Annual Burden Hours: 2,164.

Needs and Uses: This request is for extension of a current information collection.

Fishery regulations do not generally affect scientific research activities conducted by a scientific research vessel. Persons planning to conduct such research are encouraged to submit

a scientific research plan to ensure that the activities are considered research and not fishing. The researchers are requested to submit reports of their scientific research activity after its completion. Eligible researchers on board federally permitted fishing vessels that plan to temporarily possess fish in a manner not compliant with applicable fishing regulations for the purpose of collecting scientific data on catch may submit a request for a temporary possession letter of authorization. The researchers are requested to submit reports of their scientific research activity after its completion. The National Marine Fisheries Service (NMFS) may also grant exemptions from fishery regulations for educational or other activities (*e.g.,* using non-regulation gear). The applications for these exemptions must be submitted, as well as reports on activities.

Affected Public: Businesses or other for-profit organizations and not-for-profit institutions such as educational and research institutions.

Frequency: As needed.

Respondent's Obligation: Mandatory and Voluntary.

Legal Authority: Magnuson Stevens Fishery Conservation and Management Act.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0648–0309.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–24507 Filed 11–8–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; U.S. Fishermen Fishing in Russian Waters

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

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before January 10, 2022.

ADDRESSES: Interested persons are invited to submit written comments to Adrienne Thomas, NOAA PRA Officer, at *Adrienne.thomas@noaa.gov.* Please reference OMB Control Number 0648–0228 in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Elizabethann Mencher, Foreign Affairs Specialist, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910, 301–427–8362, or *Elizabethann.Mencher@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

National Marine Fisheries Service's Office of International Affairs and Seafood Inspection is requesting an extension of a currently approved information collection.

Regulations at 50 CFR part 300, subpart J, govern U.S. fishing in the Economic Zone of the Russian Federation. Russian authorities may permit U.S. fishermen to fish for allocations of surplus stocks in the Russian Economic Zone. U.S. fishermen must submit permit application information to the National Marine Fisheries Service (NMFS) for transmission to Russia. If Russian authorities issue a permit, the vessel owner or operator must submit a permit abstract report to NMFS, and also report 24 hours before leaving the U.S. Exclusive Economic Zone (EEZ) for the Russian Economic Zone and 24 hours before re-entering the U.S. EEZ after being in the Russian Economic Zone.

The permit application information is used by Russian authorities to determine whether to issue a permit. NMFS uses the other information to help ensure compliance with Russian and U.S. fishery management regulations.

II. Method of Collection

Paper or electronic forms are used for applications. Submission of copies of permits, vessel abstract reports, and departure and return messages are provided by fax or email.

III. Data

OMB Control Number: 0648–0228.

Form Number(s): None.

Type of Review: Regular submission (extension of a currently approved information collection).

Affected Public: Business or other for profit organizations.

Estimated Number of Respondents: One or less.

Estimated Time per Response: 30 minutes.

Estimated Total Annual Burden Hours: 1.

Estimated Total Annual Cost to Public: $0 in recordkeeping/reporting costs.

Respondent's Obligation: Required to Obtain or Retain Benefits.

Legal Authority: 50 CFR part 300, subpart J.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) 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; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of

public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–24505 Filed 11–8–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Fishery Products Subject to Trade Restrictions Pursuant to Certification Under the High Seas Driftnet Fishing (HSDF) Moratorium Protection Act

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

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before January 10, 2022.

ADDRESSES: Interested persons are invited to submit written comments to Adrienne Thomas, NOAA PRA Officer, at *Adrienne.thomas@noaa.gov.* Please reference OMB Control Number 0648–0651 in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Christopher Rogers, Fishery Management Specialist, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910, 301–427–8375, or *chistopher.rogers@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

National Marine Fisheries Service's Office of International Affairs and Seafood Inspection is requesting an extension of a currently approved information collection.

The information collection involves certification of admissibility for importation of certain fish and fish products that are subject to requirements of the High Seas Driftnet Fishing Moratorium Protection Act (Moratorium Protection Act) or the Marine Mammal Protection Act (MMPA).

Pursuant to a final rule implementing certain provisions of the Moratorium Protection Act (RIN 0648–BA89), certain fish or fish products of a nation may be subject to import prohibitions. To facilitate enforcement, the National Marine Fisheries Service (NMFS) requires that other fish or fish products from that nation that are not subject to the import prohibitions must be accompanied by documentation of admissibility. A duly authorized official/agent of the applicant's Government must certify that the fish in the shipments being imported into the United States (U.S.) are of a species, or from fisheries, that are not subject to an import restriction. If a nation is identified under the Moratorium Protection Act and fails to receive a positive certification decision from the Secretary of Commerce, products from that nation that are not subject to the import prohibitions must be accompanied by the documentation of admissibility.

Under the Marine Mammal Protection Act, import certification requirements apply in cases where foreign fisheries do not meet U.S. standards for marine mammal bycatch mitigation. A final rule (RIN 0648–AY15) implemented a procedure for making comparability findings for nations that are eligible for exporting fish and fish products to the United States. The nations may receive a comparability finding to export fish and fish products by providing documentation that a nation's bycatch reduction regulatory program is comparable in effectiveness to that of the United States. Fish and fish products from a foreign fishery without a comparability finding are prohibited from entry into U.S. commerce. To facilitate enforcement, NMFS requires that other fish or fish products from that nation that are not subject to the import prohibitions must be accompanied by documentation of admissibility.

The Certification of Admissibility information is used by Customs and Border Protection authorities to determine that inbound seafood shipments are not subject to trade restrictions. NMFS uses the information to ensure compliance with fish product embargoes and to assess compliance with international fishery management regulations.

II. Method of Collection

The information is collected electronically at the time of entry filing in the Automated Commercial Environment (ACE) of U.S. Customs and Border Protection. The exporter completes information on the contents/origin of the fish products contained in the export shipment and obtains export government certification that the fish meet the U.S. admissibility criteria. Entry filers (importers or customs brokers) obtain the completed Certification of Admissibility from the exporter (attached to the shipment packaging or via email or fax) and upload the image file of the document to ACE via the Document Image System. Customs and Border Protection will also accept paper submission at the port of entry.

III. Data

OMB Control Number: 0648–0651.

Form Number(s): None.

Type of Review: Regular submission (extension of a currently approved information collection).

Affected Public: Business or other for profit organizations.

Estimated Number of Respondents: 90 respondents annually filing 10 responses each.

Estimated Time per Response: 10 minutes.

Estimated Total Annual Burden Hours: 150 hours.

Estimated Total Annual Cost to Public: $9,000.

Respondent's Obligation: Required to Obtain or Retain Benefits.

Legal Authority: 50 CFR part 216; 50 CFR part 300, subpart N.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a)

Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) 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; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–24504 Filed 11–8–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

Negotiation of a Reciprocal Defense Procurement Agreement With the Ministry of National Defence of the Republic of Lithuania

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

ACTION: Notice and request for public comments.

SUMMARY: On behalf of the U.S. Government, DoD is contemplating negotiating and concluding a Reciprocal Defense Procurement Agreement with the Ministry of National Defence of the Republic of Lithuania. DoD is requesting industry feedback regarding its experience in public defense procurements conducted by or on behalf of the Lithuanian Ministry of National Defence or Armed Forces.

DATES: Comments must be received by December 6, 2021.

ADDRESSES: Submit comments to Contract Policy, Attn: Mr. Jeff Grover, 3060 Defense Pentagon, Room 3B938, Washington, DC 20301–3060; or by email to *jeffrey.c.grover.civ@mail.mil.*

FOR FURTHER INFORMATION CONTACT: Mr. Jeff Grover, telephone 703–697–9352.

SUPPLEMENTARY INFORMATION: DoD has concluded Reciprocal Defense Procurement (RDP) Agreements with 27 qualifying countries, as defined in the Defense Federal Acquisition Regulation Supplement (DFARS) 225.003, at the level of the Secretary of Defense and his counterpart. The purpose of an RDP Agreement is to promote rationalization, standardization, and interoperability of conventional defense equipment with allies and other friendly governments. These Agreements provide a framework for ongoing communication regarding market access and procurement matters that enhance effective defense cooperation.

RDP Agreements generally include language by which the Parties agree that their defense procurements will be conducted in accordance with certain implementing procedures. These procedures relate to—

- Publication of notices of proposed purchases;
- The content and availability of solicitations for proposed purchases;
- Notification to each unsuccessful offeror;
- Feedback, upon request, to unsuccessful offerors concerning the reasons they were not allowed to participate in a procurement or were not awarded a contract; and
- Provision for the hearing and review of complaints arising in connection with any phase of the procurement process to ensure that, to the extent possible, complaints are equitably and expeditiously resolved.

Based on the Agreement, each country affords the other country certain benefits on a reciprocal basis consistent with national laws and regulations. The benefits that the United States accords to the products of qualifying countries include the following:

- Offers of qualifying country end products are evaluated without applying the price differentials otherwise required by the Buy American statute and the Balance of Payments Program.
- The chemical warfare protection clothing restrictions in 10 U.S.C. 2533a and the specialty metals restriction in 10 U.S.C. 2533b do not apply to products manufactured in a qualifying country.
- Customs, taxes, and duties are waived for qualifying country end products and components of defense procurements.

If DoD (for the U.S. Government) concludes an RDP Agreement with the Ministry of National Defence of Lithuania, then Lithuania would be listed as one of the qualifying countries in the definition of ''qualifying country'' at DFARS 225.003, and offers of products of Lithuania or that contain components from Lithuania would be afforded the benefits available to all qualifying countries. This also means that U.S. products would be exempt from any analogous ''Buy Lithuania'' and ''Buy European Union'' laws or policies applicable to procurements by the Lithuanian Ministry of National Defence or Armed Forces.

While DoD is evaluating Lithuania's laws and regulations in this area, DoD would benefit from U.S. industry's experience in participating in Lithuania's public defense procurements. DoD is, therefore, asking U.S. firms that have participated or attempted to participate in procurements by or on behalf of Lithuania's Ministry of National Defence or Armed Forces to let us know if the procurements were conducted with transparency, integrity, fairness, and due process in accordance with published procedures, and if not, the nature of the problems encountered.

DoD is also interested in comments relating to the degree of reciprocity that exists between the United States and Lithuania when it comes to the openness of defense procurements to offers of products from the other country.

Authority: DoD Instruction 5000.35, Defense Acquisition Regulations (DAR) System.

Jennifer Johnson,

Editor/Publisher, Defense Acquisition Regulations System.

[FR Doc. 2021–24558 Filed 11–5–21; 4:15 pm]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2021–SCC–0157]

Agency Information Collection Activities; Comment Request; International Computer and Information Literacy Study (ICILS 2023) Main Study Sampling, Recruitment, and Data Collection

AGENCY: Institute of Education Sciences (IES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is

proposing a reinstatement with change of a previously approved collection.

DATES: Interested persons are invited to submit comments on or before January 10, 2022.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2021–SCC–0157. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the PRA Coordinator of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W208B, Washington, DC 20202–8240.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Carrie Clarady, (202) 245–6347.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: International Computer and Information Literacy Study (ICILS 2023) Main Study Sampling, Recruitment, and Data Collection.

OMB Control Number: 1850–0929.

Type of Review: Reinstatement with change of a previously approved collection.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 9,860.

Total Estimated Number of Annual Burden Hours: 4,817.

Abstract: The International Computer and Information Literacy Study (ICILS) is a computer-based international assessment of eighth-grade students' computer and information literacy (CIL) skills. ICILS was first administered internationally in 2013 in 21 education systems and again in 2018, when the United States participated for the first time. Our participation in this study has provided data on students' skills and experience using technology to investigate, create, and communicate, and provided a comparison of U.S. student performance and technology access and use with those of the international peers. The next administration of ICILS will be in 2023. The 2023 study will allow the U.S. to begin monitoring the progress of its students compared to that of other nations and to provide data on factors that may influence student computer and information literacy skills. The data collected through ICILS will provide valuable information with which to understand the nature and extent of the ''digital divide'' and has the potential to inform understanding of the relationship between technology skills and experience and student performance in other core subject areas.

ICILS is conducted by the International Association for the Evaluation of Educational Achievement (IEA), an international collective of research organizations and government agencies that create the assessment framework, assessment, and background questionnaires. The IEA decides and agrees upon a common set of standards and procedures for collecting and reporting ICILS data, and defines the study timeline, all of which must be followed by all participating countries. As a result, ICILS is able to provide a reliable and comparable measure of student skills in participating countries. In the U.S., the National Center for Education Statistics (NCES) conducts this study and works with the IEA and RTI International to ensure proper implementation of the study and adoption of practices in adherence to the IEA's standards. Participation in ICILS will allow NCES to meet its mandate of acquiring and disseminating data on educational activities and student achievement in the United States compared with foreign nations [The Educational Sciences Reform Act of 2002 (ESRA 2002) 20 U.S.C. 9543].

In preparation for the ICILS 2023 main study, all countries are asked to implement a field test between March 1 and April 15, 2022. The purpose of the ICILS field test is to evaluate new assessment items and background questions, to ensure practices that promote low exclusion rates, and to ensure that classroom and student sampling procedures proposed for the main study are successful. In October 2021 NCES submitted and OMB approved a separate package for the ICILS 2023 Pilot Field Test (OMB# 1850–0803 v.304). The U.S. ICILS main study will be conducted from March through May 2023 and will involve a nationally-representative sample of at least 3,000 eighth-grade students from a minimum of 150 schools. This request is to conduct the ICILS 2023 main study data recruitment and collection. The materials to be used in the main study are based upon those that were proposed most recently in October 2021. This submission describes the overarching plan for all phases of the data collection for the 2023 main study.

Dated: November 3, 2021.

Stephanie Valentine,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2021–24430 Filed 11–8–21; 8:45 am]

BILLING CODE 4000–01–P

ELECTION ASSISTANCE COMMISSION

Notice and Request for Public Comment on VVSG Lifecycle Policy

AGENCY: Election Assistance Commission.

ACTION: Notice for public comment.

SUMMARY: The U.S. Election Assistance Commission (EAC) is publishing the Voluntary Voting System Guidelines (VVSG) Lifecycle Policy 1.0 for public comment. The intent of the VVSG

Lifecycle Policy is to help facilitate migration to the new VVSG 2.0 standard by providing guidance on the types of version changes, Voting System Test Laboratory (VSTL) accreditation, deprecation of obsolete major standards, and establishing a periodic review and update timeline for new standards going forward. The policy defines changes that may be made to systems certified to deprecated standards and describes the process for updating the standards.

DATES: Comments must be received no later than 5 p.m. Eastern Standard Time on December 7, 2021.

ADDRESSES: Submission of Comments: Comments on the proposed VVSG Lifecycle Policy 1.0 should be submitted electronically via *https://www.regulations.gov* (docket ID: EAC–2021–0001). Written comments on the proposed information collection can also be sent to the U.S. Election Assistance Commission, 633 3rd Street NW, Suite 200, Washington, DC 20001, Attn: Testing & Certification.

Obtaining a copy of the VVSG Lifecycle Policy 1.0: To obtain a copy of the draft VVSG Lifecycle Policy 1.0 (1) Download a copy at *https://www.regulations.gov* (docket ID: EAC–2021–0001); or (2) write to the EAC (including your address and phone number) at U.S. Election Assistance Commission, 633 3rd Street NW, Suite 200, Washington, DC 20001, Attn: Testing & Certification.

FOR FURTHER INFORMATION CONTACT: Jon Panek, phone (301) 960–1216, email *jpanek@eac.gov;* U.S. Election Assistance Commission, 633 3rd Street NW, Suite 200, Washington, DC 20001.

Kevin Rayburn,

General Counsel, U.S. Election Assistance Commission.

[FR Doc. 2021–24501 Filed 11–8–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF ENERGY

[OE Docket No. EA–492]

Application To Export Electric Energy; Heartland Generation Ltd.

AGENCY: Office of Electricity, Department of Energy.

ACTION: Notice of application.

SUMMARY: Heartland Generation Ltd. (Applicant or Heartland Generation) has applied for authorization to transmit electric energy from the United States to Canada pursuant to the Federal Power Act.

DATES: Comments, protests, or motions to intervene must be submitted on or before December 9, 2021.

ADDRESSES: Comments, protests, motions to intervene, or requests for more information should be addressed by electronic mail to *Electricity.Exports@hq.doe.gov.*

FOR FURTHER INFORMATION CONTACT: Matt Aronoff, 202–586–5863, *matthew.aronoff@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: The Department of Energy (DOE) regulates exports of electricity from the United States to a foreign country, pursuant to sections 301(b) and 402(f) of the Department of Energy Organization Act (42 U.S.C. 7151(b) and 42 U.S.C. 7172(f)). Such exports require authorization under section 202(e) of the Federal Power Act (16 U.S.C. 824a(e)).

On October 7, 2021, Heartland Generation filed an application with DOE (Application or App.) to ''transmit electric energy from the United States to Canada for a period of five years.'' App. at 1. Heartland Generation states that it ''is a corporation organized under the Business Corporations Act of Canada, with its principal place of business [in] Calgary, Alberta, [Canada].'' *Id.* Heartland Generation adds that it ''is an indirect subsidiary of ECP ControlCo, LLC.'' *Id.* at 2.

Heartland Generation represents that it ''does not own any electric generation or transmission facilities in the United States and, as a power marketer in the United States, does not hold a franchise or service territory or native load obligation in the United States.'' App. at 3. Heartland Generation states that it would ''purchase surplus electric energy from electric utilities and other suppliers within the United States and [would] export this energy to Canada over the international electric transmission facilities . . . listed in Exhibit C.'' *Id.* at 4. Heartland Generation contends that ''[b]ecause this electric energy [would] be purchased from others voluntarily, it [would] be surplus to the needs of the selling entities,'' and that the proposed ''export of power therefore will not impair the sufficiency of electric power supply in the [United States].'' *Id.*

Heartland Generation further states that ''[t]he controls that are inherent in any transaction that complies with all NERC requirements and the export limits imposed by DOE on the referenced transmission facilities are sufficient to ensure that exports by Heartland Generation will not impede, or tend to impede, the coordinated use of transmission facilities within the meaning of Section 202(e) of the [Federal Power Act].'' App. at 5.

Procedural Matters: Any person desiring to be heard in this proceeding should file a comment or protest to the Application at the address provided above. Protests should be filed in accordance with Rule 211 of the Federal Energy Regulatory Commission's (FERC) Rules of Practice and Procedure (18 CFR 385.211). Any person desiring to become a party to this proceeding should file a motion to intervene at the above address in accordance with FERC Rule 214 (18 CFR 385.214).

Comments and other filings concerning Heartland Generation's application to export electric energy to Canada should be clearly marked with OE Docket No. EA–492. Additional copies are to be provided directly to Natasha Gianvecchio, 555 Eleventh Street NW, Suite 1000, Washington, DC 20004, *natasha.gianvecchio@lw.com;* and James B. Blackburn, 555 Eleventh Street NW, Suite 1000, Washington, DC 20004, *james.blackburn@lw.com.*

A final decision will be made on the requested authorization after the environmental impacts have been evaluated pursuant to DOE's National Environmental Policy Act Implementing Procedures (10 CFR part 1021) and after DOE evaluates whether the proposed action will have an adverse impact on the sufficiency of supply or reliability of the U.S. electric power supply system.

Copies of the Application will be made available, upon request, by accessing the program website at *https://energy.gov/node/11845,* or by emailing Matt Aronoff at *matthew.aronoff@hq.doe.gov.*

Signed in Washington, DC, on November 4, 2021.

Christopher Lawrence,

Management and Program Analyst, Electricity Delivery Division, Office of Electricity.

[FR Doc. 2021–24466 Filed 11–8–21; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[OE Docket No. EA–315–C]

Application To Export Electric Energy; BP Energy Company

AGENCY: Office of Electricity, Department of Energy.

ACTION: Notice of application.

SUMMARY: BP Energy Company (Applicant or BP Energy) has applied for authorization to transmit electric energy from the United States to Canada pursuant to the Federal Power Act.

DATES: Comments, protests, or motions to intervene must be submitted on or before December 9, 2021.

ADDRESSES: Comments, protests, motions to intervene, or requests for more information should be addressed by electronic mail to *Electricity.Exports@hq.doe.gov,* or by facsimile to (202) 586–8008.

FOR FURTHER INFORMATION CONTACT: Matt Aronoff, 202–586–5863, *matthew.aronoff@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: The Department of Energy (DOE) regulates exports of electricity from the United States to a foreign country, pursuant to sections 301(b) and 402(f) of the Department of Energy Organization Act (42 U.S.C. 7151(b) and 42 U.S.C. 7172(f)). Such exports require authorization under section 202(e) of the Federal Power Act (16 U.S.C. 824a(e)).

On September 29, 2021, BP Energy filed an application with DOE (Application or App.) to transmit electric energy from the United States to Canada ''for a term of five (5) years, or the maximum period allowed.'' App. at 1. BP Energy states that it ''is a Delaware corporation and a wholly-owned indirect subsidiary of BP America Inc.'' which ''is an indirect, wholly-owned subsidiary of BP p.l.c. (''BP''), a company organized under the laws of England and Wales with its international headquarters in London, UK and its U.S. headquarters in Houston, Texas.'' *Id.* at 2. BP Energy represents that ''[n]either [it] nor any of its affiliates own or control electric transmission facilities except for those facilities that are necessary to connect generating facilities owned by affiliates to the transmission grid.'' *Id.* at 5.

BP Energy further claims that its proposed purchases will derive from ''electric utilities, power marketers, federal power marketing agencies, and affiliated suppliers pursuant to voluntary agreements.'' App. at 5. BP Energy contends that its proposed exports ''do not and will not impair the sufficiency of the electric power supply within the United States.'' *Id.* at 5–6. BP Energy adds that its exports ''will not impede or tend to impede the regional coordination of electric utility planning or operations, but will instead conform to system requirements as they may change over time.'' *Id.* at 6.

The existing international transmission facilities to be utilized by the Applicant have previously been authorized by Presidential permits issued pursuant to Executive Order 10485, as amended, and are appropriate for open access transmission by third parties.

Procedural Matters: Any person desiring to be heard in this proceeding should file a comment or protest to the Application at the address provided above. Protests should be filed in accordance with Rule 211 of the Federal Energy Regulatory Commission's (FERC) Rules of Practice and Procedure (18 CFR 385.211). Any person desiring to become a party to this proceeding should file a motion to intervene at the above address in accordance with FERC Rule 214 (18 CFR 385.214).

Comments and other filings concerning BP Energy's application to export electric energy to Canada should be clearly marked with OE Docket No. EA–315–C. Additional copies are to be provided directly to Betsy Carr, 201 Helios Way, Houston, TX 77079, *betsy.carr@bp.com* and Judy Briscoe, 201 Helios Way, Houston, TX 77079, *judy.briscoe@bp.com.*

A final decision will be made on the requested authorization after the environmental impacts have been evaluated pursuant to DOE's National Environmental Policy Act Implementing Procedures (10 CFR part 1021) and after DOE evaluates whether the proposed action will have an adverse impact on the sufficiency of supply or reliability of the U.S. electric power supply system.

Copies of the Application will be made available, upon request, by accessing the program website at *http://energy.gov/node/11845,* or by emailing Matt Aronoff at *matthew.aronoff@hq.doe.gov.*

Signed in Washington, DC, on November 4, 2021.

Christopher Lawrence,

Management and Program Analyst, Electricity Delivery Division, Office of Electricity.

[FR Doc. 2021–24464 Filed 11–8–21; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[OE Docket No. EA–434–A]

Application To Export Electric Energy; Southwest Power Pool, Inc.

AGENCY: Office of Electricity, Department of Energy.

ACTION: Notice of application.

SUMMARY: Southwest Power Pool, Inc. (Applicant or SPP) has applied for authorization to transmit electric energy from the United States to Canada pursuant to the Federal Power Act.

DATES: Comments, protests, or motions to intervene must be submitted on or before December 9, 2021.

ADDRESSES: Comments, protests, motions to intervene, or requests for more information should be addressed by electronic mail to *Electricity.Exports@hq.doe.gov,* or by facsimile to (202) 586–8008.

FOR FURTHER INFORMATION CONTACT: Matt Aronoff, 202–586–5863, *matthew.aronoff@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: The Department of Energy (DOE) regulates exports of electricity from the United States to a foreign country, pursuant to sections 301(b) and 402(f) of the Department of Energy Organization Act (42 U.S.C. 7151(b) and 42 U.S.C. 7172(f)). Such exports require authorization under section 202(e) of the Federal Power Act (16 U.S.C. 824a(e)).

On September 30, 2021, SPP filed an application with DOE (Application or App.) to transmit electric energy from the United States to Canada ''for an additional five-year term beginning on February 7, 2022, the date its current export authorization is set to expire.'' App. at 1. SPP states that it ''is an Arkansas non-profit corporation with its principal place of business in Little Rock, Arkansas.'' *Id.* at 3. SPP represents that, ''[a]lthough [it] administers the Integrated Marketplace for wholesale sales of electricity and transmission service across the transmission lines of its member utilities, . . . [it] does not own electric transmission or generation facilities and does not have a retail service area for the sale of electricity.'' *Id.* at 4.

SPP explains that it ''seeks authorization to continue to export electric energy to Canada on an emergency basis via facilities owned by its member Basin Electric.'' App. at 9. SPP adds that before it applied initially for authorization in 2016, it ''entered into a Joint Operating Agreement with Saskatchewan Power Corporation (''SaskPower'') . . . that allows SPP to make emergency sales at the United States-Canada border to SaskPower over the Tioga-Sask Intertie, which . . . is an authorized export facility under Presidential Permit No. PP–64.'' *Id.* SPP contends that its proposed exports ''will not impair the sufficiency of electric supply within the United States or impede or tend to impede the coordination in the public interest of facilities subject to the jurisdiction of FERC [*sic*].'' *Id.* at 11–12.

The existing international transmission facilities to be utilized by the Applicant have previously been authorized by Presidential permits issued pursuant to Executive Order 10485, as amended, and are appropriate

for open access transmission by third parties.

Procedural Matters: Any person desiring to be heard in this proceeding should file a comment or protest to the Application at the address provided above. Protests should be filed in accordance with Rule 211 of the Federal Energy Regulatory Commission's (FERC) Rules of Practice and Procedure (18 CFR 385.211). Any person desiring to become a party to this proceeding should file a motion to intervene at the above address in accordance with FERC Rule 214 (18 CFR 385.214).

Comments and other filings concerning SPP's application to export electric energy to Canada should be clearly marked with OE Docket No. EA–434–A. Additional copies are to be provided directly to Joseph W. Ghormley, 201 Worthen Drive, Little Rock, AR 72223, *jghormley@spp.org;* Matthew J. Binette, 1200 G Street NW, Suite 600, Washington, DC 20005, *binette@wrightlaw.com;* Victoria M. Lauterbach, 1200 G Street NW, Suite 600, Washington, DC 20005, *lauterbach@wrightlaw.com;* and Uju Okasi, 1200 G Street NW, Suite 600, Washington, DC 20005, *okasi@wrightlaw.com.*

A final decision will be made on the requested authorization after the environmental impacts have been evaluated pursuant to DOE's National Environmental Policy Act Implementing Procedures (10 CFR part 1021) and after DOE evaluates whether the proposed action will have an adverse impact on the sufficiency of supply or the reliability of the U.S. electric power supply system.

Copies of the Application will be made available, upon request, by accessing the program website at *http://energy.gov/node/11845,* or by emailing Matt Aronoff at *matthew.aronoff@hq.doe.gov.*

Signed in Washington, DC, on November 4, 2021.

Christopher Lawrence,

Management and Program Analyst, Electricity Delivery Division, Office of Electricity.

[FR Doc. 2021–24465 Filed 11–8–21; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ID–9320–000]

Starheim, Gregory J.; Notice of Filing

Take notice that on November 2, 2021, Gregory J. Starheim submitted for filing, application for authority to hold interlocking positions, pursuant to section 305(b) of the Federal Power Act, 16 U.S.C. 825d (b) and Part 45.8 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR part 45.8.

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.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Comment Date: 5:00 p.m. Eastern Time on November 23, 2021.

Dated: November 2, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–24399 Filed 11–8–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC21–26–000]

Commission Information Collection Activities (FERC–725b) Comment Request; Errata Notice

AGENCY: Federal Energy Regulatory Commission, Department of Energy.

ACTION: Errata and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved information collection, FERC–725B, (Mandatory Reliability Standards, Critical Infrastructure Protection (CIP). This notice corrects the 30-day notice published on September 14, 2021 (86 FR 51131) adjusting the estimates in the burden table.

DATES: Comments on the collection of information are due December 9, 2021.

ADDRESSES: Send written comments on FERC–725B to OMB through *www.reginfo.gov/public/do/PRAMain.* Attention: Federal Energy Regulatory Commission Desk Officer. Please identify the OMB Control Number (1902–0248) in the subject line of your comments. Comments should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.*

Please submit copies of your comments to the Commission. You may submit copies of your comments (identified by Docket No. IC21–26–000) by one of the following methods:

Electronic filing through *http://www.ferc.gov,* is preferred.

- *Electronic Filing:* Documents must be filed in acceptable native applications and print-to-PDF, but not in scanned or picture format.
- For those unable to file electronically, comments may be filed by USPS mail or by hand (including courier) delivery.

○ *Mail via U.S. Postal Service Only:* Addressed to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

○ *Hand (including courier) delivery:* Deliver to: Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852.

Instructions: OMB submissions must be formatted and filed in accordance with submission guidelines at *www.reginfo.gov/public/do/PRAMain.* Using the search function under the ''Currently Under Review'' field, select Federal Energy Regulatory Commission; click ''submit,'' and select ''comment'' to the right of the subject collection.

FERC submissions must be formatted and filed in accordance with submission guidelines at: *http://www.ferc.gov.* For user assistance, contact FERC Online Support by email at *ferconlinesupport@ferc.gov,* or by phone at: (866) 208–3676 (toll-free).

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at *https://www.ferc.gov/ferc-online/overview.*

FOR FURTHER INFORMATION CONTACT: Ellen Brown may be reached by email at *DataClearance@FERC.gov,* telephone at (202) 502–8663.

SUPPLEMENTARY INFORMATION:

Title: FERC–725B (Mandatory Reliability Standards, Critical Infrastructure Protection (CIP)).

OMB Control No.: 1902–0248.

Type of Request: Three-year extension of the FERC–725B information collection requirements with no changes to the reporting requirements.

Abstract: On August 8, 2005, Congress enacted the Energy Policy Act of 2005.[1] The Energy Policy Act of 2005 added a new section 215 to the FPA,[2] which requires a Commission-certified Electric Reliability Organization to develop mandatory and enforceable Reliability Standards,[3] including requirements for cybersecurity protection, which are subject to Commission review and approval. Once approved, the Reliability Standards may be enforced by the Electric Reliability Organization subject to Commission oversight, or the Commission can independently enforce Reliability Standards.

On February 3, 2006, the Commission issued Order No. 672,[4] implementing FPA section 215. The Commission subsequently certified NERC as the Electric Reliability Organization. The Reliability Standards developed by NERC become mandatory and enforceable after Commission approval and apply to users, owners, and operators of the Bulk-Power System, as set forth in each Reliability Standard.[5] The CIP Reliability Standards require entities to comply with specific requirements to safeguard critical cyber assets. These standards are results-based and do not specify a technology or method to achieve compliance, instead leaving it up to the entity to decide how best to comply.

On January 18, 2008, the Commission issued Order No. 706,[6] approving the initial eight CIP Reliability Standards, CIP version 1 Standards, submitted by NERC. Subsequently, the Commission has approved multiple versions of the CIP Reliability Standards submitted by NERC, partly to address the evolving nature of cyber-related threats to the Bulk-Power System. On November 22, 2013, the Commission issued Order No. 791,[7] approving CIP version 5 Standards, the last major revision to the CIP Reliability Standards. The CIP version 5 Standards implement a tiered approach to categorize assets, identifying them as high, medium, or low risk to the operation of the Bulk Electric System (BES)[8] if compromised. High impact systems include large control centers. Medium impact systems include smaller control centers, ultra-high voltage transmission, and large substations and generating facilities. The remainder of the BES Cyber Systems[9] are categorized as low impact systems. Most requirements in the CIP Reliability Standards apply to high and medium impact systems; however, a technical controls requirement in Reliability standard CIP–003, described below, applies only to low impact systems. Since 2013, the Commission has approved new and modified CIP Reliability Standards that address specific issues such as supply chain risk management, cyber incident reporting, communications between control centers, and the physical security of critical transmission facilities.[10]

[1] Energy Policy Act of 2005, Public Law 109–58, sec. 1261 *et seq.,* 119 Stat. 594 (2005).

[2] 16 U.S.C. 824o.

[3] FPA section 215 defines Reliability Standard as a requirement, approved by the Commission, to provide for reliable operation of existing bulk-power system facilities, including cybersecurity protection, and the design of planned additions or modifications to such facilities to the extent necessary to provide for reliable operation of the Bulk-Power System. However, the term does not include any requirement to enlarge such facilities or to construct new transmission capacity or generation capacity. *Id.* at 824o(a)(3).

[4] *Rules Concerning Certification of the Elec. Reliability Org.; and Procedures for the Establishment, Approval, and Enf't of Elec. Reliability Standards,* Order No. 672, 71 FR 8661 (Feb. 17, 2006), 114 FERC ¶ 61,104, *order on reh'g,* Order No. 672–A, 71 FR 19814 (Apr. 28, 2006), 114 FERC ¶ 61,328 (2006).

[5] NERC uses the term ''registered entity'' to identify users, owners, and operators of the Bulk-Power System responsible for performing specified reliability functions with respect to NERC Reliability Standards. *See, e.g., Version 4 Critical Infrastructure Protection Reliability Standards,* Order No. 761, 77 FR 24594 (Apr. 25, 2012), 139 FERC ¶ 61,058, at P 46, *order denying clarification and reh'g,* 140 FERC ¶ 61,109 (2012). Within the NERC Reliability Standards are various subsets of entities responsible for performing various specified reliability functions. We collectively refer to these as ''entities.''

[6] Order No. 706, 122 FERC ¶ 61,040 at P 1.

[7] *Version 5 Critical Infrastructure Protection Reliability Standards,* Order No. 791, 78 FR 72755 (Dec. 13, 2013), 145 FERC ¶ 61,160 (2013), *order on reh'g,* Order No. 791–A, 146 FERC ¶ 61,188 (2014).

[8] In general, NERC defines BES to include all Transmission Elements operated at 100 kV or higher and Real Power and Reactive Power resources connected at 100 kV or higher. This does not include facilities used in the local distribution of electric energy. *See* NERC, *Bulk Electric System Definition Reference Document,* Version 3, at page iii (August 2018). In Order No. 693, the Commission found that NERC's definition of BES is narrower than the statutory definition of Bulk-Power System. The Commission decided to rely on the NERC definition of BES to provide certainty regarding the applicability of Reliability Standards to specific entities. *See Mandatory Reliability Standards for the Bulk-Power System,* Order No. 693, 72 FR 16415 (Apr. 4, 2007), 118 FERC ¶ 61,218, at PP 75, 79, 491, *order on reh'g,* Order No. 693–A, 72 FR 49717 (July 25, 2007), 120 FERC ¶ 61,053 (2007).

[9] NERC defines BES Cyber System as ''[o]ne or more BES Cyber Assets logically grouped by a responsible entity to perform one or more reliability tasks for a functional entity.'' NERC, Glossary of Terms Used in NERC Reliability Standards, at 5 (2020), *https://www.nerc.com/files/glossary_of_terms.pdf* (NERC Glossary of Terms). NERC defines BES Cyber Asset as

> A Cyber Asset that if rendered unavailable, degraded, or misused would, within 15 minutes of its required operation, mis-operation, or non-operation, adversely impact one or more Facilities, systems, or equipment, which, if destroyed, degraded, or otherwise rendered unavailable when needed, would affect the reliable operation of the Bulk Electric System. Redundancy of affected Facilities, systems, and equipment shall not be considered when determining adverse impact. Each BES Cyber Asset is included in one or more BED Cyber Systems.

Id. at 4.

[10] *See, e.g.,* Order No. 791, 78 FR 72755; *Revised Critical Infrastructure Protection Reliability Standards,* Order No. 822, 81 FR 4177 (Jan. 26, 2016), 154 FERC ¶ 61,037, *reh'g denied,* Order No. 822–A, 156 FERC ¶ 61,052 (2016); *Revised Critical Infrastructure Protection Reliability Standard CIP–003–7—Cyber Security—Security Management Controls,* Order No. 843, 163 FERC ¶ 61,032 (2018).

The CIP Reliability Standards currently consist of 13 standards specifying a set of requirements that entities must follow to ensure the cyber and physical security of the Bulk-Power System.

- *CIP–002–5.1a Bulk Electric System Cyber System Categorization:* Requires entities to identify and categorize BES Cyber Assets for the application of cyber security requirements commensurate with the adverse impact that loss, compromise, or misuse of those BES Cyber Systems could have on the reliable operation of the BES.
- *CIP–003–8 Security Management Controls:* Requires entities to specify consistent and sustainable security management controls that establish responsibility and accountability to protect BES Cyber Systems against compromise that could lead to mis-operation or instability in the BES.
- *CIP–004–6 Personnel and Training:* Requires entities to minimize the risk against compromise that could lead to mis-operation or instability in the BES from individuals accessing BES Cyber Systems by requiring an appropriate level of personnel risk assessment, training, and security awareness in support of protecting BES Cyber Systems.
- *CIP–005–6 Electronic Security Perimeter(s):* Requires entities to manage electronic access to BES Cyber Systems by specifying a controlled Electronic Security Perimeter in support of protecting BES Cyber Systems against compromise that could lead to mis-operation or instability in the BES.
- *CIP–006–6 Physical Security of Bulk Electric System Cyber Systems:* Requires entities to manage physical access to BES Cyber Systems by specifying a physical security plan in support of protecting BES Cyber Systems against compromise that could lead to mis-operation or instability in the BES.
- *CIP–007–6 System Security Management:* Requires entities to manage system security by specifying select technical, operational, and procedural requirements in support of protecting BES Cyber Systems against compromise that could lead to mis-operation or instability in the BES.
- *CIP–008–6 Incident Reporting and Response Planning:* Requires entities to mitigate the risk to the reliable operation of the BES as the result of a cybersecurity incident by specifying incident response requirements.
- *CIP–009–6 Recovery Plans for Bulk Electric System Cyber Systems:* Requires entities to recover reliability functions performed by BES Cyber Systems by specifying recovery plan requirements in support of the continued stability, operability, and reliability of the BES.
- *CIP–010–3 Configuration Change Management and Vulnerability Assessments:* Requires entities to prevent and detect unauthorized changes to BES Cyber Systems by specifying configuration change management and vulnerability assessment requirements in support of protecting BES Cyber Systems from compromise that could lead to mis-operation or instability in the BES.
- *CIP–011–2 Information Protection:* Requires entities to prevent unauthorized access to BES Cyber System Information by specifying information protection requirements in support of protecting BES Cyber Systems against compromise that could lead to mis-operation or instability in the BES.
- *CIP–012–1 Communications between Control Centers:*[11] Requires entities to protect the confidentiality and integrity of Real-time Assessment and Real-time monitoring data transmitted between Control Centers.
- *CIP–013–1 Supply Chain Risk Management:* Requires entities to mitigate cybersecurity risks to the reliable operation of the BES by implementing security controls for supply chain risk management of BES Cyber Systems.
- *CIP–014–2 Physical Security:* Requires the Transmission Owner to perform a risk assessment, consisting of a transmission analysis, to determine which of those Transmission stations and Transmission Substations and conduct an assessment of potential threats and vulnerabilities to those Transmission stations, Transmission substations, and primary control centers using a tailored evaluation process.

The CIP Reliability Standards, viewed as a whole, implement a defense-in-depth approach to protecting the security of BES Cyber Systems at all impact levels.[12] The CIP Reliability Standards are objective-based and allow entities to choose compliance approaches best tailored to their systems.[13]

FERC–725B—(Mandatory Reliability Standards for Critical Infrastructure Protection [CIP] Reliability Standards) After Adding Filers From Cybersecurity Incentives Investment Activity

[Submitted as a separate IC within FERC–725B]

	Number and type of respondent[14] (1)	Annual number of responses per respondent (2)	Total number of responses (1) * (2) = (3)	Average burden per response (hours)[15] and cost per response (4)	Total annual burden (hours) and total annual cost[16] ($) (3) * (4) = (5)
CIP–002–5.1	1,492	1	1,492	20 hrs.; $1,700.40	29,840 hrs.; $2,536,996.8.
CIP–003–8	[17] 1,492	156.149	232,974.387	1.56 hrs.; $132.63	363,440.04 hrs.; $30,899,672.20.
CIP–004–6	343	1	343	565 hrs.; $48,036.30	193,795 hrs.; $16,476,450.90.
CIP–005–7	343	1	343	525 hrs.; $44,635.50	180,075 hrs.; $15,309,976.50.
CIP–006–6	343	1	343	232 hrs.; $19,724.64	79,576 hrs.; $6,765,551.52.
CIP–007–6	343	1	343	2,080 hrs.; $176,841.60	713,440 hrs.; $60,656,668.80.
CIP–008–6	343	8	2744	13.225 hrs.; $1,124.39	36,288 hrs.; $3,085,205.76.
CIP–009–6	343	1	343	162 hrs.; $13,773.24	55,566 hrs.; $4,724,221.32.
CIP–010–3	343	1	343	1,172 hrs.; $99,643.44	401,996 hrs.; $34,177,699.92.
CIP–011–2	343	1	343	86 hrs.; $7,311.72	29,498 hrs.; $2,507,919.96.
CIP–012–1	[18] 724	1	724	85.67 hrs.; $7,283.66	62,025.08 hrs.; $5,273,372.30.

[11] CIP–012–1: Communications between Control Centers will be subject to enforcement by July 1, 2022.

[12] Order No. 822, 154 FERC ¶ 61,037 at 32.

[13] Order No. 706, 122 FERC ¶ 61,040 at 72.

FERC–725B—(MANDATORY RELIABILITY STANDARDS FOR CRITICAL INFRASTRUCTURE PROTECTION [CIP] RELIABILITY STANDARDS) AFTER ADDING FILERS FROM CYBERSECURITY INCENTIVES INVESTMENT ACTIVITY—Continued

[Submitted as a separate IC within FERC–725B]

	Number and type of respondent [14] (1)	Annual number of responses per respondent (2)	Total number of responses (1) * (2) = (3)	Average burden per response (hours) [15] and cost per response (4)	Total annual burden (hours) and total annual cost [16] ($) (3) * (4) = (5)
CIP–013–1	343	1	343	20 hrs.; $1,700.40	6,860 hrs.; $583,237.20.
CIP–014–2	[19] 321	1	321	32.71 hrs.; $2,781	10,449.91 hrs.; $888,451.35.
Total Burden of FERC–725B.			240,099.387		2,162,849.03 hrs.; $183,885,424.53.

Comments: Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: November 3, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–24475 Filed 11–8–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC22–13–000.

Applicants: Howard Wind LLC.

Description: Application for Authorization Under Section 203 of the Federal Power Act of Howard Wind LLC.

Filed Date: 11/3/21.

Accession Number: 20211103–5027.

Comment Date: 5 p.m. ET 11/24/21.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG22–19–000.

Applicants: Cottontail Solar 2, LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generators Status of Cottontail Solar 2, LLC.

Filed Date: 11/3/21.

Accession Number: 20211103–5061.

Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: EG22–20–000.

Applicants: Cottontail Solar 8, LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Cottontail Solar 8, LLC.

Filed Date: 11/3/21.

Accession Number: 20211103–5062.

Comment Date: 5 p.m. ET 11/24/21.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER21–2455–001.

Applicants: California Independent System Operator Corporation.

Description: Tariff Amendment: 2021–11–02 FERC Order No. 2222—Response to Letter to be effective 12/31/9998.

Filed Date: 11/2/21.

Accession Number: 20211102–5180.

Comment Date: 5 p.m. ET 11/23/21.

Docket Numbers: ER22–327–000.

Applicants: Nine Mile Point Nuclear Station, LLC.

Description: § 205(d) Rate Filing: Certificate of Concurrence for Nuclear Operating Services Agreement to be effective 12/31/9998.

Filed Date: 11/2/21.

Accession Number: 20211102–5177.

Comment Date: 5 p.m. ET 11/23/21.

Docket Numbers: ER22–328–000.

Applicants: Portland General Electric Company.

Description: § 205(d) Rate Filing: NorthernGrid Funding Agreement Concurrence to be effective 1/1/2022.

Filed Date: 11/2/21.

Accession Number: 20211102–5185.

Comment Date: 5 p.m. ET 11/23/21.

Docket Numbers: ER22–329–000.

Applicants: R.E. Ginna Nuclear Power Plant, LLC.

Description: § 205(d) Rate Filing: Certificate of Concurrence for Nuclear Operating Services Agreement to be effective 12/31/9998.

Filed Date: 11/2/21.

Accession Number: 20211102–5186.

Comment Date: 5 p.m. ET 11/23/21.

Docket Numbers: ER22–330–000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Amendment: Notice of Cancellation of Service Agreement Nos. 4955 (PJM & AEP NITSA) to be effective 1/1/2022.

Filed Date: 11/2/21.

Accession Number: 20211102–5187.

Comment Date: 5 p.m. ET 11/23/21.

Docket Numbers: ER22–331–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: Revisions to Modify the Review of Base Plan Allocation Methodology to be effective 1/3/2022.

Filed Date: 11/3/21.

Accession Number: 20211103–5068.

Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: ER22–333–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: NorthWestern Corporation (South Dakota) Formula Rate Revision to be effective 1/3/2022.

Filed Date: 11/3/21.

Accession Number: 20211103–5111.

[14] The number of respondents is based on the NERC Compliance Registry as of June 22, 2021. Currently there are 1,508 unique NERC Registered, subtracting 16 Canadians Entities yields 1492 U.S. entities.

[15] Of the average estimated 295.702 hours per response, 210 hours are for recordkeeping, and 85.702 hours are for reporting.

[16] The estimates for cost per hour are $85.02/hour (averaged based on the following occupations):

[17] We estimate that 1,161 entities will face an increased paperwork burden under Reliability Standard CIP 003–8, estimating that a majority of these entities will have one or more low impact BES Cyber Systems.

[18] The number of entities and the number of hours required are based on FERC Order No. 802 which approved CIP–012–1.

[19] 321 U.S. Transmission Owners in NERC Compliance Registry as of June 22, 2021.

Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: ER22–334–000.

Applicants: Alabama Power Company.

Description: § 205(d) Rate Filing: Solarpack Development (Black Prairie Solar) LGIA Filing to be effective 10/20/2021.

Filed Date: 11/3/21.

Accession Number: 20211103–5113.

Comment Date: 5 p.m. ET 11/24/21.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by 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 3, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–24477 Filed 11–8–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP22–179–000.

Applicants: Rover Pipeline LLC.

Description: § 4(d) Rate Filing: Summary of Negotiated Rate Capacity Release Agreements on 11–2–21 to be effective 11/1/2021.

Filed Date: 11/2/21.

Accession Number: 20211102–5140.

Comment Date: 5 p.m. ET 11/15/21.

Docket Numbers: RP22–180–000.

Applicants: Portland Natural Gas Transmission System.

Description: § 4(d) Rate Filing: NS Power to NS Mktg—Neg Rate Amendment to be effective 11/1/2021.

Filed Date: 11/2/21.

Accession Number: 20211102–5159.

Comment Date: 5 p.m. ET 11/15/21.

Docket Numbers: RP22–181–000.

Applicants: Northern Border Pipeline Company.

Description: Compliance filing: Request for Waiver—Reservation of Capacity to be effective N/A.

Filed Date: 11/2/21.

Accession Number: 20211102–5169.

Comment Date: 5 p.m. ET 11/15/21.

Docket Numbers: RP22–182–000.

Applicants: Discovery Gas Transmission LLC.

Description: Compliance filing: NAESB Version 3.2 Compliance Filing (Order 587–Z) to be effective 6/1/2022.

Filed Date: 11/3/21.

Accession Number: 20211103–5030.

Comment Date: 5 p.m. ET 11/15/21.

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.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

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 3, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–24478 Filed 11–8–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP14–517–001]

Golden Pass LNG Terminal LLC, Golden Pass Products LLC; Notice of Amendment of Authorizations and Establishing Intervention Deadline

Take notice that on February 25, 2021 and May 19, 2021, Golden Pass Products LLC, (Golden Pass LNG), 811 Louisiana Street Suite 1400, Houston, TX 77002, filed its Golden Pass LNG Export Project Variance Request No. 15 (Variance No. 15).[1] On June 3, 2021, Golden Pass LNG received a data request regarding the information provided in Variance Request No. 15, responding on June 8 with all of the information requested. Variance No. 15 describes Golden Pass LNG's identified need for traffic volume and work week/hour limits in excess of what was originally authorized under Section 3 of the Natural Gas Act (NGA) for construction of the Golden Pass LNG Export Project Docket No. CP14–517–001 which the Commission authorized on December 21, 2016.[2] If authorized, Variance No. 15 which would modify their original authorizations to such an extent that it is appropriate to treat these plans as amendments to the Section 3 approvals for issued for the projects. The plan and subsequent filings are on file with the Commission and open for public inspection.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Any questions regarding the proposed project should be directed to Kevin M. Sweeney, Legal Counsel, Golden Pass Products, LLC, Law Office of Kevin M. Sweeney 1625 K Street NW, Suite 1100 Washington, DC 20006, or by phone at

[1] We note that in the February 25, 2021, May 19, 2021 and June 8, 2021 filings references were made to Golden Pass LNG Terminal LLC holding the Section 3 authorization for the LNG Terminal.

[2] In 2016, the Commission authorized Golden Pass Products, LLC to site, construct, and operate facilities for the export of LNG under section 3 of the NGA. Specifically, the 2016 Authorization Order authorized the construction and operation of three liquefaction trains with a total LNG production capacity of 15.6 mtpa, plus feed gas treatment facilities consisting of a mercury removal system, amine system, and heavy hydrocarbon removal system. These facilities, known as the Golden Pass Export Terminal Project, will be constructed adjacent to and integrated with the existing Golden Pass Terminal in Sabine Pass, Texas. Golden Pass LNG has commenced construction of the Golden Pass Export Terminal Project facilities and anticipates commencing service in 2024.

202–609–7709, or email at *ksweeney@kmsenergylaw.com.*

Golden Pass LNG is directed to provide this notice to all affected landowners and towns, communities, and local, state, and federal governments and agencies involved in the project within 10 business days of its publication in the **Federal Register**.

Pursuant to Section 157.9 of the Commission's Rules of Practice and Procedure,[3] within 90 days of this Notice the Commission staff will either: Complete its environmental review and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or environmental assessment (EA) for this proposal. The filing of an EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Public Participation

There are two ways to become involved in the Commission's review of the companies' proposals: You can file comments on the proposals, and you can file a motion to intervene in the proceeding. There is no fee or cost for filing comments or intervening. The deadline for filing a motion to intervene is 5:00 p.m. Eastern Time November 24, 2021.

Comments

Any person wishing to comment on the proposals may do so. Comments may include statements of support or objections to the proposals as a whole or specific aspects of the proposal. The more specific your comments, the more useful they will be. To ensure that your comments are timely and properly recorded, please submit your comments on or before November 24, 2021.

There are three methods you can use to submit your comments to the Commission. In all instances, please reference the Project docket number CP14–517–001 in your submission. Identify your comments separately with regard to one or more of these proposals.

(1) You may file your comments electronically by using the eComment feature, which is located on the Commission's website at *www.ferc.gov* under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project.

(2) You may 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; first select ''General'' and then select ''Comment on a Filing''; or

(3) You can file a paper copy of your comments by mailing them to the following address below. Your written comments must reference the Project docket CP14–517–001.

To mail via USPS, use the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To mail via any other courier, use the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of comments (options 1 and 2 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

Persons who comment on the environmental review of this project, and provide their mailing address, will be placed on the Commission's environmental mailing list, and will receive notification when the environmental documents (EA or EIS) are issued for this project and will be notified of meetings associated with the Commission's environmental review process.

The Commission considers all comments received about the project in determining the appropriate action to be taken. However, the filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding. For instructions on how to intervene, see below.

Interventions

All intervenors in the previous proceedings for the projects CP14–517–001, will be considered intervenors in this amendment proceeding and do not need to file a new motion to intervene.

Any other person, which includes individuals, organizations, businesses, municipalities, and other entities,[4] has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure [5] and the regulations under the NGA [6] by the intervention deadline for the project, which is November 24, 2021. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. [For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene.] For more information about motions to intervene, refer to the FERC website at *https://www.ferc.gov/resources/guides/how-to/intervene.asp.*

There are two ways to submit your motion to intervene. In both instances, please reference the Project docket number CP14–517–001 in your submission.

(1) You may file your motion to intervene by using the Commission's eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. 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; first select ''General'' and then select ''Intervention.'' The eFiling feature includes a document-less intervention option; for more information, visit *https://www.ferc.gov/docs-filing/efiling/document-less-intervention.pdf;* or

(2) You can file a paper copy of your motion to intervene, along with three copies, by mailing the documents to the address below. Your motion to intervene must reference the Project docket number CP14–517–001.

To mail via USPS, use the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To mail via any other courier, use the following address: Kimberly D. Bose,

[3] 18 CFR 157.9.

[4] 18 CFR 385.102(d).

[5] 18 CFR 385.214.

[6] 18 CFR 157.10.

Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of motions to intervene (option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

Motions to intervene must be served on the applicant either by mail or email at: Kevin M. Sweeney, Legal Counsel, Golden Pass Products, LLC, Law Office of Kevin M. Sweeney, 1625 K Street NW, Suite 1100, Washington, DC 20006, or by phone at 202–609–7709, or email at *ksweeney@kmsenergylaw.com.* Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online. Service can be via email with a link to the document.

All timely, unopposed [7] motions to intervene are automatically granted by operation of Rule 214(c)(1).[8] Motions to intervene that are filed after the intervention deadline are untimely and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations.[9] A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be 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 as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to *www.ferc.gov/docs-filing/esubscription.asp.*

Intervention and Scoping Comments Deadline: 5:00 p.m. Eastern Time on November 24, 2021.

Dated: November 3, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–24479 Filed 11–8–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM21–17–000]

Building for the Future Through Electric Regional Transmission Planning and Cost Allocation and Generator Interconnection; Supplemental Notice of Technical Conference

As first announced in the Notice of Technical Conference issued in this proceeding on September 16, 2021, the Federal Energy Regulatory Commission (Commission) will convene a staff-led technical conference in the above-referenced proceeding on Monday, November 15, 2021, from 10:00 a.m. to 4:30 p.m. Eastern Time. The conference will be held electronically. Attached to this Supplemental Notice is an agenda for the technical conference.

Discussions at the conference may involve issues raised in proceedings that are currently pending before the Commission. These proceedings include, but are not limited to:

	Docket Nos.
Duke Energy Florida v. Florida Power and Light, et al	EL21–93–000
NYISO	ER21–1647–002, EL21–66–001
Neptune Regional Transmission System, LLC and Long Island Power Authority v. PJM	ER21–39–000
PPL Electric Utilities Corporation & PJM Interconnection, LLC	ER21–2282–001
SOO Green HVDC Link Project Co, LLC v. PJM Interconnection, LLC	EL21–85–000
California Independent System Operator Corporation	ER21–2530–000
NECEC Transmission LLC and Avangrid, Inc. v. NextEra Energy Resources, LLC	EL21–6–000
ISO New England Inc	EL21–94–000

The conference will be open for the public to attend electronically. There is no fee for attendance. Registration for the conference is not required. Information on this technical conference, including a link to the webcast, will be posted on the conference's event page on the Commission's website, *https://www.ferc.gov/news-events/events/technical-conference-building-future-through-electric-regional-transmission,* prior to the event.

The conference will be transcribed. Transcripts of the conference will be available for a fee from Ace-Federal Reporters, Inc. (202) 347–3700.

Commission conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations, please send an email to *accessibility@ferc.gov,* call toll free (866) 208–3372 (voice) or (202) 208–8659 (TTY), or send a fax to (202) 208–2106 with the required accommodations.

For more information about this technical conference, please contact:

David Tobenkin (Technical Information), Office of Energy Policy and Innovation, (202) 502–6445, *david.tobenkin@ferc.gov*

Lina Naik (Legal Information), Office of General Counsel, (202) 502–8882, *Lina.Naik@ferc.gov*

Sarah McKinley (Logistical Information), Office of External Affairs, (202) 502–8004, *Sarah.Mckinley@ferc.gov*

Dated: November 3, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–24476 Filed 11–8–21; 8:45 am]

BILLING CODE 6717–01–P

[7] The applicant has 15 days from the submittal of a motion to intervene to file a written objection to the intervention.

[8] 18 CFR 385.214(c)(1).

[9] 18 CFR 385.214(b)(3) and (d).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2305–129]

Sabine River Authority of Texas; Sabine River Authority, State of Louisiana; Notice of Application for Amendment of License and Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Non-capacity amendment of license.

b. *Project No.:* 2305–129.

c. *Date Filed:* August 30, 2021.

d. *Applicant:* Sabine River Authority of Texas and Sabine River Authority, State of Louisiana.

e. *Name of Project:* Toledo Bend Hydroelectric Project.

f. *Location:* On the Sabine River, in the Towns of Burkeville, Newton County, TX and Anacoco, Sabine Parish, Louisiana.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Jim Brown, P.O. Box 579, Orange, TX 77631, (409) 746–2192.

i. *FERC Contact:* Jeffrey V. Ojala, (202) 502–8206, *Jeffrey.Ojala@ferc.gov*.

j. *Deadline for filing comments, motions to intervene, and protests:* 30 days from the issuance date of this notice, or December 2, 2021.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp*. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp*. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P–2305–129. Comments emailed to Commission staff are not considered part of the Commission record.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Request:* The Sabine River Authority of Texas and the Sabine River Authority, State of Louisiana (Sabine RA), filed an application for a non-capacity amendment of the license. The existing project license, issued August 29, 2014, authorizes the Sabine RA to construct a 1.3 megawatt minimum flow generating facility within the project's spillway. The Sabine RA conducted a feasibility analysis and determined that it is not financially viable to construct this facility. The Sabine RA therefore request to amend the license and related plans, to remove references to the minimum flow generating facility.

l. *Locations of the Application:* This filing may be viewed on the Commission's website at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. Agencies may obtain copies of the application directly from the applicant.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, and .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Documents:* Any filing must (1) bear in all capital letters the title ''COMMENTS'', ''PROTEST'', or ''MOTION TO INTERVENE'' as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

Dated: November 2, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–24400 Filed 11–8–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP18–46–000]

Adelphia Gateway, LLC; Notice of Request for Extension of Time

Take notice that on November 1, 2021, Adelphia Gateway, LLC (Adelphia) requested that the Federal Energy Regulatory Commission (Commission) grant an extension of time, until June 20, 2023, in order to construct and place into service the facilities authorized by the Federal Energy Regulatory Commission in the above-referenced proceeding into service, in Delaware and Pennsylvania, as authorized as part of Adelphia's Project in the December 20, 2019 Order Issuing Certificate [1] (December 20 Order). The December 20 Order required Adelphia to complete construction and make the facilities available for service within two years of the order date.

While Adelphia has already constructed a significant number of the Project facilities and made substantial progress towards the completion of others, Adelphia states that it has been delayed in completing construction due

[1] *Adelphia Gateway, LLC,* 169 FERC ¶ 61,220 (2019).

to circumstances outside of its control. Shortly after Adelphia's receipt of its Certificate Order, Adelphia states that the COVID–19 pandemic had immediate and substantial impacts on its ability to timely obtain its remaining state environmental permits and progress construction of the Adelphia Project. Adelphia's requests for notices to proceed with construction were directly delayed as a result. Adelphia also had to cease construction activities on numerous occasions as a result of pandemic-related protocols. Furthermore, Adelphia states that the continuing impacts on the supply chain resulting from the COVID–19 pandemic have caused and continue to cause delays in the procurement and delivery of essential equipment and material. Thus, Adelphia requests an extension to construct and place into service the Adelphia Project until June 20, 2023.

This notice establishes a 15-calendar day intervention and comment period deadline. Any person wishing to comment on Adelphia's request for an extension of time may do so. No reply comments or answers will be considered. If you wish to obtain legal status by becoming a party to the proceedings for this request, you should, on or before the comment date stated below, file a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR 157.10).[2]

As a matter of practice, the Commission itself generally acts on requests for extensions of time to complete construction for Natural Gas Act facilities when such requests are contested before order issuance. For those extension requests that are contested,[3] the Commission will aim to issue an order acting on the request within 45 days.[4] The Commission will address all arguments relating to whether the applicant has demonstrated there is good cause to grant the extension.[5] The Commission will not consider arguments that re-litigate the issuance of the certificate order, including whether the Commission properly found the project to be in the public convenience and necessity and whether the Commission's environmental analysis for the certificate complied with the National Environmental Policy Act.[6] At the time a pipeline requests an extension of time, orders on certificates of public convenience and necessity are final and the Commission will not re-litigate their issuance.[7] The OEP Director, or his or her designee, will act on all of those extension requests that are uncontested.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFile'' link at *http://www.ferc.gov.* Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Comment Date: 5:00 p.m. Eastern Time on November 18, 2021.

Dated: November 3, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–24474 Filed 11–8–21; 8:45 am]

BILLING CODE 6717–01–P

[2] Only motions to intervene from entities that were party to the underlying proceeding will be accepted. *Algonquin Gas Transmission, LLC,* 170 FERC ¶ 61,144, at P 39 (2020).

[3] Contested proceedings are those where an intervenor disputes any material issue of the filing. 18 CFR 385.2201(c)(1) (2019).

[4] *Algonquin Gas Transmission, LLC,* 170 FERC ¶ 61,144, at P 40 (2020).

[5] *Id.* at P 40.

[6] Similarly, the Commission will not re-litigate the issuance of an NGA section 3 authorization, including whether a proposed project is not inconsistent with the public interest and whether the Commission's environmental analysis for the permit order complied with NEPA.

[7] *Algonquin Gas Transmission, LLC,* 170 FERC ¶ 61,144, at P 40 (2020).

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9221–01–R6]

Clean Air Act Operating Permit Program; Petitions for Objection to State Operating Permit for Oak Grove Management Company, Oak Grove Steam Electric Station, Robertson County, Texas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of final order on petition for objection to Clean Air Act Title V operating permit.

SUMMARY: The Environmental Protection Agency (EPA) Administrator signed an Order dated October 15, 2021, granting a Petition dated July 25, 2017 from the Environmental Integrity Project and Sierra Club. The Petition requested that the EPA object to a Clean Air Act (CAA) title V operating permit issued by the Texas Commission on Environmental Quality (TCEQ) to Oak Grove Management Company (Oak Grove) for its Oak Grove Steam Electric Station located in Robertson County, Texas.

ADDRESSES: The EPA requests that you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view copies of the final Order, the Petition, and other supporting information. Out of an abundance of caution for members of the public and our staff, the EPA Region 6 office is currently closed to the public to reduce the risk of transmitting COVID–19. Please call or email the contact listed below if you need alternative access to the final Order and Petition, which are available electronically at: *https://www.epa.gov/title-v-operating-permits/title-v-petition-database.*

FOR FURTHER INFORMATION CONTACT: Jonathan Ehrhart, EPA Region 6 Office, Air Permits Section, (214) 665–2295, *ehrhart.jonathan@epa.gov.*

SUPPLEMENTARY INFORMATION: The CAA affords EPA a 45-day period to review and object to, as appropriate, operating permits proposed by state permitting authorities under title V of the CAA. Section 505(b)(2) of the CAA authorizes any person to petition the EPA Administrator to object to a title V operating permit within 60 days after the expiration of the EPA's 45-day review period if the EPA has not objected on its own initiative. Petitions must be based only on objections to the permit that were raised with reasonable specificity during the public comment period provided by the state, unless the petitioner demonstrates that it was impracticable to raise these issues

during the comment period or unless the grounds for the issue arose after this period.

The EPA received the Petition from the Environmental Integrity Project and Sierra Club dated July 25, 2017, requesting that the EPA object to the issuance of operating permit no. O2942, issued by TCEQ to the Oak Grove Steam Electric Station in Robertson County, Texas. The Petition claims the proposed permit omitted enforceable requirements in Oak Grove's written Maintenance, Startup, and Shutdown Plan, omitted limits and representations in Oak Grove's certified Permit by Rule registrations, and failed to assure compliance with emission limits and operating requirements established by Oak Grove's New Source Review permits, including Permits by Rule.

On October 15, 2021, the EPA Administrator issued an Order granting the Petition. The Order explains the basis for EPA's decision.

Dated: November 2, 2021.

Kim Ngo,

Acting Director, Air and Radiation Division, Region 6.

[FR Doc. 2021–24417 Filed 11–8–21; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL FINANCIAL INSTITUTIONS EXAMINATION COUNCIL

[Docket No. AS21–07]

Appraisal Subcommittee; Notice of Meeting

AGENCY: Appraisal Subcommittee of the Federal Financial Institutions Examination Council.

ACTION: Notice of meeting.

Description: In accordance with Section 1104 (b) of Title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, as amended, notice is hereby given that the Appraisal Subcommittee (ASC) will meet in open session for its regular meeting:

Location: Due to the COVID–19 Pandemic, the meeting will be open to the public via live webcast only. Visit the agency's homepage (*www.asc.gov*) and access the provided registration link in the What's New box. You MUST register in advance to attend this Meeting.

Date: November 17, 2021.

Time: 10:00 a.m. ET.

Status: Open.

Reports

Chairman

Executive Director

Grants Director

Financial Manager

Action and Discussion Items

Approval of Minutes: September 15, 2021 Open Session Quarterly Meeting

Notice of Proposed Rulemaking on Temporary Waiver

How To Attend and Observe an ASC Meeting

Due to the COVID–19 Pandemic, the meeting will be open to the public via live webcast only. Visit the agency's homepage (*www.asc.gov*) and access the provided registration link in the What's New box. The meeting space is intended to accommodate public attendees. However, if the space will not accommodate all requests, the ASC may refuse attendance on that reasonable basis. The use of any video or audio tape recording device, photographing device, or any other electronic or mechanical device designed for similar purposes is prohibited at ASC Meetings.

James R. Park,

Executive Director.

[FR Doc. 2021–24483 Filed 11–8–21; 8:45 am]

BILLING CODE 6700–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than November 24, 2021.

A. Federal Reserve Bank of Minneapolis (Chris P. Wangen, Assistant Vice President), 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291. Comments can also be sent electronically to *MA@mpls.frb.org:*

1. *The Paul K. Martinson Irrevocable Trust (in formation), Kari A.M. Nelson, as trustee, the Anna K. Martin Irrevocable Trust (in formation), Paul K. Martinson, as trustee, and Anna K. Martinson, all of Glenwood, Minnesota; and the Eric W. Nelson Irrevocable Trust (in formation), Kirsten R.M. Nelson, as trustee, both of Alexandria, Minnesota;* to join the Nelson-Martinson Family Shareholder Group, a group acting in concert, to acquire voting shares of Financial Services of Lowry, Inc., Lowry, Minnesota, and thereby indirectly acquire voting shares of Lowry State Bank, Lowry, Minnesota, and First National Bank of Osakis, Osakis, Minnesota.

2. *Gene R. Mottes, Iron River, Michigan;* to acquire voting shares of MSB Bankshares, Inc., and thereby indirectly acquire voting shares of The Miners State Bank, both of Iron River, Michigan.

B. Federal Reserve Bank of Kansas City (Jeffrey Imgarten, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *Kyle Heckman, Lafayette, Colorado, individually, and as trustee of the Flatirons Bank Employee Stock Ownership Plan and Trust, Boulder, Colorado;* to acquire voting shares of FBHC Holding Company, Boulder, Colorado, and thereby indirectly acquire voting shares of Flatirons Bank, Boulder, Colorado.

Board of Governors of the Federal Reserve System, November 4, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–24480 Filed 11–8–21; 8:45 am]

BILLING CODE P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–0317; Docket No. 2021–0001; Sequence No. 7]

Submission for OMB Review; Notarized Document Submittal for System for Award Management Registration

AGENCY: Office of Acquisition Policy, General Services Administration (GSA).

ACTION: Notice of request for comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an existing OMB clearance regarding a notarized document submittal for System for Award Management (SAM) Registration.

DATES: Submit comments on or before December 9, 2021.

ADDRESSES: Written comments and recommendations for this information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Nancy Goode, Integrated Award Environment, GSA, 703–605–2175, or via email at *nancy.goode@gsa.gov.*

SUPPLEMENTARY INFORMATION: The Federal Acquisition Regulation and Code of Federal Regulation prescribe the policies and procedures requiring registration in the System for Award Management database. Federal Acquisition Regulation (FAR) Subpart 4.11 prescribes policies and procedures for requiring registration in the System for Award Management (SAM) database to: (1) Increase visibility of vendor sources (including their geographical locations) for specific supplies and services; and (2) establish a common source of vendor data for the Government. The Code of Federal Regulations (CFR) at 2 CFR 25.200 prescribes policies and procedures for requiring recipient registration in the System for Award Management (SAM) database.

In the past, the GSA Office of Inspector General (OIG) conducted an investigation into fraudulent activities discovered within SAM. Certain bad actors have, through electronic means, used public information to impersonate legitimate entities and established new entity registrations for those entities in SAM. By establishing fraudulent entity registrations, bad actors submitted bids in certain U.S. Government procurement systems or shipped deficient or counterfeit goods to the U.S. Government.

GSA established an Information Collection Request (ICR) to collect additional information to support increased validation of entities registered in the System for Award Management (SAM). This additional information is contained in a notarized letter in which an officer or other signatory authority of the entity formally appoints the administrator for the entity when an administrator is not available to perform that function for that entity. The original, signed letter is submitted electronically to the Federal Service Desk (FSD) for SAM when an administrator needs to be appointed for an existing entity.

The new ICR expires December 31, 2021. GSA is actively pursuing technical alternatives to the collection of this information for all non-federal entities. GSA seeks to refine the requirement and adopt a risk-based approach. This notice for an extension of the ICR lays the groundwork for the authority to continue collection of the information provided GSA is still pursuing the technical alternative beyond the ICR expiration date. In the interim, the collection of the notarized letter information is essential to GSA's acquisition mission to meet the needs of all federal agencies, as well as the needs of the grant community. A key element of GSA's mission is to provide efficient and effective acquisition solutions across the Federal Government. SAM is essential to the accomplishment of that mission. In addition to federal contracts, federal assistance programs also rely upon the integrity and security of the information in SAM. Without assurances that the information in SAM is protected and is at minimal risk of compromise, GSA would risk losing the confidence of the federal acquisition and assistance communities which it serves. As a result, some entities may prefer not to do business with the Federal Government.

B. Annual Reporting Burden

Respondents: 686,400.
Responses per Respondent: 1.
Total Annual Responses: 686,400.
Hours per Response: 2.25.
Total Burden Hours: 1,544,400.

The information collection allows GSA to request the notarized letter and apply this approach to new registrants (an average of 7,200 per month) and to existing SAM registrants (an average of 50,000 re-register per month).

Entities registered and registering in SAM are provided the template for the requirements of the notarized letter. It is estimated that the Entity Administrator will take on average 0.5 hour to create the letter and 0.25 hour to submit an electronic copy of the letter to FSD. GSA proposes that an Entity Administrator equivalent to a GS–5, Step 5 Administrative Support person within the Government would perform these tasks. The estimated hourly rate of $24.70 (Base + Locality + Fringe) was used for the calculation.

Based on historical data of the ratio of small entities to other than small entities registering in SAM, GSA approximates 32,200 of the 57,200 new and existing entities (re-registrants) will have in-house resources to notarize documents. GSA proposes that the entities with in-house notaries will typically be large businesses where the projected salary of the executive or officer responsible for signing the notarized letter is on average approximately $150 per hour. The projected time for signature and notarizing the letter internally is 0.5 hour.

The other remaining 25,000 new and existing entities (re-registrants) per month are estimated to be small entities where the projected salary of the executive or officer responsible signing the notarized letter is on average approximately $100 per hour. These entities will more than likely have to obtain notary services from an outside source. The projected time for signature and notarizing the letter externally is 1 hour. The estimate includes a nominal fee ($5.00) usually charged by third-party notaries.

C. Public Comments

A notice was published in the **Federal Register** at 86 FR 47110 on August 23, 2021. No comments were received.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the Regulatory Secretariat Division by calling 202–501–4755 or emailing *GSARegSec@gsa.gov.* Please cite OMB Control No. 3090–0317, Notarized Document Submittal for System for Award Management Registration, in all correspondence.

Beth Anne Killoran,

Deputy Chief Information Officer.

[FR Doc. 2021–24485 Filed 11–8–21; 8:45 am]

BILLING CODE 6820–WY–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Partial Breast Irradiation for Breast Cancer

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for supplemental evidence and data submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *Partial Breast Irradiation for Breast Cancer,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before December 9, 2021.

ADDRESSES:

Email submissions: epc@ahrq.hhs.gov.

Print submissions:

Mailing address: Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E53A, Rockville, MD 20857.

Shipping address (FedEx, UPS, etc.): Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E77D, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Jenae Benns, Telephone: 301–427–1496 or Email: *epc@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Partial Breast Irradiation for Breast Cancer.* AHRQ is conducting this technical brief pursuant to Section 902 of the Public Health Service Act, 42 U.S.C. 299a.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (*e.g.,* details of studies conducted). We are looking for studies that report on *Partial Breast Irradiation for Breast Cancer,* including those that describe adverse events. The entire research protocol is available online at: *https://effectivehealthcare.ahrq.gov/products/accelerated-partial-breast-irradiation/protocol.*

This is to notify the public that the EPC Program would find the following information on *Partial Breast Irradiation for Breast Cancer* helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*
- *For completed studies that do not have results on ClinicalTrials.gov,* a summary, including the following elements: Study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.
- *A list of ongoing studies that your organization has sponsored for this indication.* In the list, please provide the *ClinicalTrials.gov* trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: *https://www.effectivehealthcare.ahrq.gov/email-updates.*

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

Key Questions (KQ)

KQ 1. In adult women with early stage breast cancer, what are the comparative effectiveness, adverse events, and cosmetic outcomes of partial breast irradiation compared to whole breast irradiation?

KQ1a. How does effectiveness of partial breast irradiation vary by clinical-pathologic characteristics?

KQ1b. How do the effectiveness, adverse events, and cosmetic outcomes of partial breast irradiation vary by target volumes, dose-fractionation schemes, motion management, and planning parameters?

KQ 2. In adult women with early stage breast cancer, what are the comparative effectiveness, adverse events, and cosmetic outcomes of different partial breast irradiation modalities (including multicatheter interstitial brachytherapy, single-entry catheter brachytherapy, 3-dimensional conformal external beam radiation therapy, intensity modulated radiation therapy, proton radiation therapy, and intraoperative radiotherapy)?

KQ 2a. When there are no eligible comparative studies to address KQ2 for a particular PBI modality, what are the rates of adverse events in noncomparative series of such modality?

KQ 2b. When there are no eligible comparative studies to address KQ2 for a particular PBI modality, what are the rates of long-term (>5 years) effectiveness outcomes and cosmesis in noncomparative series of such modality?

Contextual Question (CQ)

CQ 1. In adult women with early stage breast cancer, to what extent does financial toxicity differ between partial and whole breast irradiation?

PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, and Settings)

PICOTS elements	Inclusion criteria	Exclusion criteria
Population	• Adult women (*i.e.,* 18 years and older) with early stage breast cancer (*i.e.,* a small tumor less than or equal to 3 cm that has minimal or no lymph node involvement (N0/1)).	• Animals. • Children (*i.e.,* age <18 years). • Men. • Recurrent breast cancer.
Interventions	For all KQs and CQ1, PBI includes the following modalities: • Multicatheter interstitial brachytherapy.	• Combination of PBI and WBI.

PICOTS elements	Inclusion criteria	Exclusion criteria
	• Single-entry catheter brachytherapy. • 3-dimensional conformal external beam radiation therapy. • Intensity modulated radiation therapy. • Proton radiation therapy. • Intraoperative radiotherapy.	
Comparators	KQ 1, CQ 1: WBI KQ 2: A different PBI modality. • Multicatheter interstitial brachytherapy. • Single-entry catheter brachytherapy. • 3-dimensional conformal external beam radiation therapy. • Intensity modulated radiation therapy. • Proton radiation therapy. • Intraoperative radiotherapy. KQ 2a and 2b: No comparator.	None.
Outcomes	KQ 1 and 2: • Ipsilateral breast cancer recurrence (*i.e.,* tumor bed ipsilateral breast cancer recurrence, elsewhere ipsilateral breast cancer recurrence). • Mastectomy-free survival. • Overall survival. • Cancer-free survival. • Contralateral breast cancer recurrence. • Distant breast cancer recurrence. • Regional breast cancer recurrence. • Any breast cancer recurrence. • Breast conservation. • Quality of life (*e.g.,* BCTOS, FACT–B, SF–36, Breast Q scale). • Patient-reported and physician-assessed cosmesis (*e.g.,* including Harvard Breast Cosmesis Scale, Global Cosmesis Scale, or the EORTC breast cancer cosmetic rating system). • Sexual health. • Adverse events, including scales measuring radiation toxicity: ○ RTOG/EORTC scores. ○ LENT–SOMA scales. ○ CTCAE scores. CQ 1: Contextual information about the construct of financial toxicity (*i.e.,* financial distress and hardship).	None.
Timing	At the following intervals: For effectiveness and cosmetic outcomes: • >=1 year to 5 years. • >5 years to 10 years. • >10 years. For adverse events: • <3 months. • >=3 months.	None.
Settings	Any	None.
Study design	KQ1: • RCTs. KQ 2: • RCTs. • Comparative observational studies. KQ 2a: • Single-arm observational studies (>=50 patients). KQ 2b: • Single-arm observational studies (>=50 patients and >=5 year followup). CQ 1: • RCTs. • Comparative observational studies. • Qualitative studies. • Cost-benefit analyses. • Surveys. All KQs and CQ 1: • Relevant systematic reviews or meta-analyses (used for identifying additional studies).	• In vitro studies. • Nonoriginal studies (*e.g.,* narrative reviews, editorials, letters, or erratum). • Cross-sectional (*i.e.,* non-longitudinal) studies.
Subgroup analysis	KQ 1 and 2: • Age. • Treatment schedule (*i.e.,* accelerated, nonaccelerated). • Race/ethnicity. • Socioeconomic status. • Area Deprivation Index. • DCIS vs. invasive disease. • Breast size. • BMI. • Cup size. • Breast implants.	None.

PICOTS elements	Inclusion criteria	Exclusion criteria
	• Mental health comorbidities. • Menopausal status. • Receipt of systemic therapy (*i.e.,* none, endocrine therapy, and/or chemotherapy, both). • Histologic subtype (*e.g.,* invasive ductal carcinoma, invasive lobular carcinoma, DCIS, other). • Nodal status (*i.e.,* N0, N1, NX, number of positive nodes). • Nodal assessment (*i.e.,* sentinel lymph node biopsy, axillary lymph node dissection, none). • Tumor grade. • Tumor size (*i.e.,* <1 cm, 1–2 cm, 2–3 cm, >3 cm). • Focality (unifocal vs multifocal). • Margin status (*i.e.,* positive, <2 mm, 2–3 mm, >3 mm). • Extensive intraductal component. • Ki-67 (<20% vs. >= 20%). • ASTRO or ESTRO risk category (*i.e.,* suitable, cautionary, unsuitable; low, intermediate, high). • Germline genetic mutation (*e.g., BRCA1, BRCA2, CHEK2, PALB2, ATM,* etc.). • Cancer-predisposing syndrome. • Estrogen receptor status. • Progesterone receptor status. • Hormone receptor status. • Lymphovascular invasion. • HER2 status. • Prior chemotherapy. • Monoelectron therapy. • Dermatologic Rheumatologic conditions (*i.e.,* lupus, scleroderma, rheumatoid arthritis). • Dose-fractionation schemes (*i.e.,* accelerated, nonaccelerated, daily vs every other day vs twice daily, total dose, EQD2). • Target volumes (*i.e.,* size of expansion on cavity, diameter of the inflated balloon, size of the planning target volume). • Motion management. • Planning parameters (*i.e.,* the diameter of the inflated balloon, the planning target volume, and the dose distribution organ-at-risk constraints and dose received [such as ipsilateral breast V50 and V100], number of beams, PTV coverage goals and constraints). • Number of treatment fields. • Image guidance (*i.e.,* MV imaging, kV imaging, cone beam CT, use of clips for localization). • Risk of bias (*i.e.,* low, moderate, high).	
Publications	• Studies published in English as peer reviewed full text. ..... • Published after Year 2000.	• Foreign language studies. • Conference abstracts.

Abbreviations: ASTRO = American Society for Radiation Oncology; *ATM* = ataxia telangiectasia mutated; BCTOS = Breast Cancer Treatment Outcomes Scale; BMI = body mass index; *BRCA1* = breast cancer 1; *BRCA2* = breast cancer 2; *CHEK2* = checkpoint kinase 2; cm = centimeter; CQ = contextual question; CT = computed tomography; CTCAE = Common Terminology Criteria for Adverse Events; DCIS = ductal carcinoma in situ; EORTC = European Organisation for Research and Treatment of Cancer; ESTRO = European Society for Radiotherapy and Oncology; FACT–B = Functional Assessment of Cancer Therapy-Breast; EQD2 = Equivalent Dose in 2 Gy fractions; HER2 = human epidermal growth factor receptor 2; KQ = key question; kV = kilovoltage; LENT–SOMA = Late Effects Normal Tissue Task Force- Subjective, Objective, Management, Analytic; mm = millimeter; MV = megavoltage; N0 = no involved lymph nodes; N1 = 1–3 involved lymph nodes; NX = lymph nodes not assessed; *PALB2* = partner and localizer Of *BRCA2;* PBI = partial breast irradiation; PICOTS = populations, interventions, comparators, outcomes, timing, and settings; PTV = planning target volume; RCT = randomized controlled trial; RTOG = Radiation Therapy Oncology Group; SF–36 = Short Form (36) Health Survey; V50 = volume (%) receiving >= 50% of the prescription dose; V100 = volume (%) receiving >= 100% of the prescription dose; WBI = whole breast irradiation.

Dated: November 2, 2021.

Marquita Cullom,

Associate Director.

[FR Doc. 2021–24403 Filed 11–8–21; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10790]

Agency Information Collection Activities: Proposed Collection; Comment Request; Correction

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Correction of notice.

SUMMARY: This document corrects the information provided for [Document Identifier: CMS–10790] titled ''Medicare-Funded GME Residency Positions in accordance with Section 126 of the Consolidated Appropriations Act, 2020.''

FOR FURTHER INFORMATION CONTACT: William N. Parham, III, (410) 786–4669.

SUPPLEMENTARY INFORMATION:

I. Background

In the October 22, 2021, issue of the **Federal Register** (86 FR 58664), we

published a Paperwork Reduction Act notice requesting a 60-day public comment period for the information collection request identified under CMS–10790, OMB control number 0938-New, and titled ''Medicare-Funded GME Residency Positions in accordance with Section 126 of the Consolidated Appropriations Act, 2020 (Pub. L. 116–93).''

II. Explanation of Error

In the October 22, 2021, notice, the information provided in the middle of the middle column on page 58665, was published with incorrect information in the ''Use'' section. This notice corrects the language found in the ''Use'' section in the middle of the middle column on page 58665. All of the other information contained in the October 22, 2021, notice is correct. The related public comment period remains in effect and ends December 21, 2021.

III. Correction of Error

In FR Doc. 2021–23107 of October 22, 2021, (86 FR 58664), page 58665, the language in the middle of the middle column that begins with ''*Use:*'' and ends with ''in early January 2022'' is corrected to read as follows:

Use: The requirements in this rule were announced in CMS– 1752–P (FY22 IPPS); however, the PRA package has been under development until now. The plan, approved by OMB and CM, is to have the 60-day **Federal Register** notice publish and then have CMS–1752–F3 serve as the required 30-day **Federal Register** notice, with the goal of approval in early January 2022. If this is not possible, CMS will publish a standalone 30-day **Federal Register** notice prior to submitting the information collection request (CMS–10790) to OMB.

Dated: November 3, 2021.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2021–24418 Filed 11–8–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10792, CMS–10793, and CMS–367a–e]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by January 10, 2022.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10792 Patient-Reported Indicator Survey (PaRIS)

CMS–10793 Medicare Advantage and Prescription Drug Plan Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey Field Test

CMS–367a–e Medicaid Drug Rebate Program Labeler Reporting Format

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Patient-Reported Indicator Survey (PaRIS); *Use:* The Centers for Medicare and Medicaid Services (CMS) invites comments on a proposed new Information Collection Request (ICR) to conduct the International Survey of People Living with Chronic Conditions (hereafter referred to as the PaRIS Survey). This survey has been developed by a collaborative workgroup under the auspices of the Organization for Economic Cooperation and Development (OECD), an international organization that works with governments, policy makers, and citizens to shape policies that foster prosperity, equality, opportunity, and well-being for all.

The OECD launched the PaRIS initiative in 2017 to address gaps in health outcomes measures, particularly regarding user experiences with health care services. OECD member countries,

including the U.S., are working together to develop, standardize, and implement indicators that measure outcomes and experiences of health care that matter most to people. The PaRIS Survey will provide a common set of measures that support policy makers across participating countries to improve health care delivery. On behalf of the Department of Health and Human Services (DHHS) Assistant Secretary for Planning and Evaluation (ASPE), the Office of Enterprise Data and Analytics (OEDA) in CMS has been designated as the lead participant for the U.S.

The PaRIS Survey will help to close critical policy gaps by focusing on: (1) Patient Reported Experience Measures (PREMS) which measure how patients experience health care, and (2) Patient Reported Outcome Measures (PROMS) which measure how patients assess the results of the care they receive. The PaRIS survey includes both PREMS and PROMS items and aims to collect vital information about primary health care, by asking about topics such as the respondent's health, health behaviors, patient activation and confidence in managing their health care, experiences with health care and health providers including access to health care, quality of life, physical functioning, and psychological well-being.

OECD and its member countries will use data collected by the PaRIS Survey to shed light on key questions about how well care in each country is organized around the needs of patients. Results from the survey will show how key outcomes and experiences vary across and within countries. This will allow countries to benchmark and learn from each other's approaches. The survey will also help policy makers in OECD member countries understand how health systems are addressing the needs of persons with chronic health conditions. Findings will foster a dialogue with service providers about how to further improve the performance and people-centeredness of primary health care services.

To facilitate U.S. participation in this important initiative, CMS will leverage the existing sample for the Medicare Current Beneficiary Survey (MCBS). The MCBS is a continuous, multi-purpose survey of a representative national sample of the Medicare population, including the population of beneficiaries aged 65 and over and beneficiaries aged 64 and below with certain disabling conditions, residing in the U.S.; it is conducted under OMB clearance number 0938–0568. Given the age and health characteristics of Medicare beneficiaries, the MCBS sample will provide a comparable population to survey respondents selected in other participating OECD countries. Interviewers will telephone MCBS respondents and administer the PaRIS Survey by phone as a one-time standalone survey during January through April 2023. Non-response follow-up will be conducted by telephone and in-person as needed. It is estimated that 7,559 Medicare beneficiaries will participate in this 40-minute survey. CMS plans to release a disclosure protected public use file with accompanying methodological documentation. This public use file will also be made available to OECD for analysis and released with data from other participating countries. *Form Number:* CMS–10792 (OMB: 0938–New); Frequency: One-time collection; *Affected Public:* Individuals residing in households; *Number of Respondents: 7,559; Total Hours: 5,065* (For policy questions regarding this collection contact William Long at 410–786–7927.)

2. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Medicare Advantage and Prescription Drug Plan Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey Field Test; *Use:* CMS is required to collect and report information on the quality of health care services and prescription drug coverage available to persons enrolled in a Medicare health or prescription drug plan under provisions in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Specifically, the MMA under Sec. 1860D–4 (Information to Facilitate Enrollment) requires CMS to conduct consumer satisfaction surveys regarding Medicare PDPs and MA plans and report this information to Medicare beneficiaries prior to the Medicare annual enrollment period. The Medicare CAHPS survey meets the requirement of collecting and publicly reporting consumer satisfaction information.

Currently, the MA & PDP CAHPS Surveys (0938–0732) are administered using a mixed mode data collection protocol (mail+phone) that includes two survey mailings and phone follow-up with non-respondents. This request is to conduct a field test with the main goal of testing the effects of new survey content and a web-based mode on patterns of response and survey scores. The test will also allow for assessment of the measurement properties of new survey items. The results of the field test will inform CMS's decision-making about updates to MA & PDP CAHPS survey content and survey administration procedures. *Form Number:* CMS–10793 (OMB control number: 0938–New); *Frequency:* Yearly; *Affected Public:* Individuals and Households; *Number of Respondents:* 5,000; *Total Annual Responses:* 5,000; *Total Annual Hours:* 1,290. (For policy questions regarding this collection contact Lauren K. Fuentes at 410–786–2290.)

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicaid Drug Rebate Program Labeler Reporting Format; *Use:* Labelers transmit drug product and pricing data to CMS within 30 days after the end of each calendar month and quarter. CMS calculates the unit rebate amount (URA) and the unit rebate offset amount (UROA) for each new drug application (NDC) and distributes to all State Medicaid agencies. States use the URA to invoice the labeler for rebates and the UROA to report onto CMS–64. The monthly data is used to calculate Federal Upper Limit (FUL) prices for applicable drugs and for states that opt to use this data to establish their pharmacy reimbursement methodology. In this November 2021 iteration, CMS–367d (Manufacturer Contact Form) is being revised to include a signature/date line for the submitter to confirm that the information provide is accurate, and we have additionally updated the entire 367d to a fillable format, per multiple labeler requests. CMS–367e (Quarterly VBP–MBP Data) is a new form that is intended for manufacturers to use (as needed) on a quarterly basis, to transmit pricing data (best prices associated with value-based purchasing (VBP) arrangements) for each of their covered outpatient drugs (CODs) to CMS either via direct file upload to the MDP System or manual on-line entry. The CMS–367e form is optional. We are not proposing any changes to the CMS–367a (Quarterly Pricing), CMS–367b (Monthly Pricing), or CMS–367c (Product Data) forms. *Form Number:* CMS–367a, b, c, d, and e (OMB control number: 0938–0578); *Frequency:* Monthly, quarterly, and on occasion; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 780; *Total Annual Responses:* 15,020; *Total Annual Hours:* 564,394. (For policy questions regarding this collection contact Andrea Wellington at 410–786–3490.)

Dated: November 3, 2021.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2021–24393 Filed 11–8–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Child Support Enforcement Program Quarterly Financial Report (OCSE–396) and Quarterly Collection Report (OCSE–34) (OMB #0970–0510)

AGENCY: Office of Child Support Enforcement, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF) is requesting public comment on the following forms: OCSE–34 ''Child Support Enforcement Program Quarterly Collection Report'' and OCSE–396 ''Child Support Enforcement Program Quarterly Financial Report.'' These forms are currently approved under the ACF Generic Clearance for Financial Reports (OMB #0970–0510; expiration June 30, 2024). There are no changes requested to the forms, but the instructions have been updated to address comments received in response to a notice published in the **Federal Register** and update burden hours.

DATES: Comments due within 30 days of publication. OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Form OCSE–396 and Form OCSE–34 are financial reports submitted following the end of each fiscal quarter by grantees administering the Child Support Enforcement Program in accordance with plans approved under title IV–D of the Social Security Act. Submission of these forms enables grantees to meet their statutory and regulatory requirement to report program expenditures and child support collections, respectively, from the previous fiscal quarter.

States use Form OCSE–396 to report quarterly expenditures made in the previous quarter and to estimate program expenditures to be made and the incentive payments to be earned in the upcoming quarter. ACF provides federal funding to states for the Child Support Enforcement Program at the rate of 66 percent for all allowable and legitimate administrative costs of this program. States use Form OCSE–34 to report quarterly collections made under Title IV–D of the Social Security Act.

Tribes use OMB Form SF–425 to report quarterly expenditures made in the previous quarter. Form SF–425 is approved under OMB #4040–0014 and is not included as part of this comment request.

ACF made updates to the instructions and burden estimates, in response to comments received in response to a notice published in the **Federal Register** (86 FR 14756).

Respondents: Fifty-four states (including Puerto Rico, Guam, the Virgin Islands, and the District of Columbia) complete Forms OCSE–396 and OCSE–34. Approximately 60 tribes complete Form OCSE–34.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Form OCSE–396	54	4	14	3,024
Form OCSE–34	114	4	14	6,384

Estimated Total Annual Burden Hours: 9,408.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–24448 Filed 11–8–21; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Updated Evaluation Policy; Cooperative Research or Demonstration Projects

AGENCY: Administration for Children and Families, HHS.

SUMMARY: The Administration for Children and Families is announcing updates to its evaluation policy for research or demonstration projects.

SUPPLEMENTARY INFORMATION: This evaluation policy builds on the Administration for Children and Families' (ACF) strong history of evaluation by outlining key principles to govern our planning, conduct, and use of evaluation. This policy reconfirms our commitment to conducting rigorous, relevant evaluations and to using evidence from evaluations to inform policy and practice. ACF seeks to promote rigor, relevance, transparency, independence, and ethics in the conduct of evaluations. This policy addresses each of these principles.

The mission of ACF is to foster health and well-being by providing federal leadership, partnership, and resources for the compassionate and effective delivery of human services. Our vision is children, youth, families, individuals and communities who are resilient, safe, healthy, and economically secure. The importance of these goals demands that we continually innovate and improve, and that we evaluate our activities and those of our partners. Through evaluation, ACF and our partners can learn systematically so that we can make our services as effective, efficient, and equitable as possible.

Evaluation produces one type of evidence. A learning organization with a culture of continuous improvement requires many types of evidence, including not only evaluation but also descriptive research studies, performance measures, financial and cost data, survey statistics, program administrative data, and feedback from service providers, participants, and other stakeholders. Further, continuous improvement requires systematic approaches to using information, such as regular data-driven reviews of performance and progress. Although this policy focuses on evaluation, the principles and many of the specifics

apply to the development and use of other types of evidence as well.

This policy applies to all ACF-sponsored evaluations. While much of ACF's evaluation activity is overseen by the Office of Planning, Research, and Evaluation (OPRE), ACF program offices also sponsor evaluations through dedicated contracts or as part of their grant-making. In order to promote quality, coordination and usefulness in ACF's evaluation activities, ACF program offices will consult with OPRE in developing evaluation activities. Program offices will discuss evaluation projects with OPRE in early stages to clarify evaluation questions and methodological options for addressing them, and as activities progress OPRE will review designs, plans, and reports. Program offices may also ask OPRE to design and oversee evaluation projects on their behalf or in collaboration with program office staff.

Rigor: ACF is committed to using the most rigorous methods that are appropriate to both the evaluation questions and the populations, circumstances, and settings that are the focus of study; and that are feasible within budget and other constraints. Rigor is not restricted to impact evaluations, but is also necessary in implementation or process evaluations, descriptive studies, outcome evaluations, and formative evaluations; and in both qualitative and quantitative approaches. Rigor requires ensuring that inferences about cause and effect are well founded (internal validity); requires clarity about the populations, settings, or circumstances to which results can be generalized (external validity); and requires the use of measures that accurately capture the intended information (measurement reliability and validity).

In assessing the effects of programs or services, ACF evaluations will use methods that isolate to the greatest extent possible the impacts of the programs or services from other influences such as trends over time, geographic variation, or pre-existing differences between participants and non-participants. For such causal questions, experimental approaches are preferred. When experimental approaches are not feasible, high-quality quasi-experiments offer an alternative. ACF will develop and use methods that are appropriate for understanding diverse populations, taking into account historical, contextual, and cultural factors. Where possible, evaluations will design data collections to allow disaggregation of data and analyses of sub-groups to support understanding of equity.

ACF will recruit and maintain an evaluation workforce with the knowledge, training, and experience appropriate for planning and overseeing a rigorous evaluation portfolio. To accomplish this, ACF will recruit staff with advanced degrees and experience in a range of relevant disciplines such as program evaluation, policy analysis, economics, sociology, child development, *etc.* ACF will recruit staff with a range of backgrounds, lived experiences, and perspectives and with expertise in approaches appropriate for studying diverse populations. ACF will provide professional development opportunities so that staff can keep their skills current.

ACF will ensure that contractors and grant recipients conducting evaluations have appropriate expertise through emphasizing the capacity for rigor in requests for proposal and funding opportunity announcements. This emphasis entails specifying expectations in criteria for the selection of grant recipients and contractors, and engaging reviewers with evaluation expertise. It also requires allocating sufficient resources for evaluation activities. ACF will generally require evaluation contractors to consult with external advisors who are leaders in relevant fields and who represent diverse backgrounds, lived experiences, and perspectives through the formation of technical work groups or other means; and to meaningfully engage stakeholders from programs and communities being studied throughout the evaluation lifecycle.

Relevance: Evaluation priorities should take into account legislative requirements and Congressional interests and should reflect the interests and needs of ACF, HHS, and Administration leadership; ACF program office staff and leadership; ACF partners such as states, territories, tribes, and local grant recipients; service providers; the populations served; researchers; and other stakeholders. Stakeholders should have the opportunity to influence evaluation priorities to meet their interests and needs. Evaluations should be designed to examine questions relevant to the diverse populations that ACF programs serve, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality. ACF will encourage diversity among those carrying out the work, through building awareness of opportunities and building evaluation capacity among under-represented groups. ACF will use inclusive and participatory practices in each phase of evaluation planning, execution, and dissemination, as appropriate and feasible.

There must be strong partnerships among evaluation staff, program staff, policy-makers and service providers. Further, for new initiatives and demonstrations in particular, evaluations will be more feasible and useful when planned in concert with the planning of the initiative or demonstration, rather than as an afterthought. Given federal requirements related to procurement and information collection, it can take many months to award a grant or contract and begin collecting data. Thus, it is critical that planning for research and evaluation be integrated with planning for new initiatives.

It is important for evaluators to disseminate findings in ways that are accessible and useful to policy-makers, service providers, the communities that ACF serves, and other stakeholders. OPRE and program offices will work in partnership to disseminate information about our research and evaluation activities and findings in a manner that is clear, accessible, and useful to our diverse range of audiences; this includes using plain language, using inclusive language, adhering to principles of clear communication, and developing products accessible to people with disabilities. ACF will require contractors to meaningfully engage stakeholders from the programs and communities involved in studies to improve clarity of presentations, accuracy of interpretations, and effectiveness of dissemination activities.

It is ACF's policy to integrate both use of existing evidence and opportunities for further learning into all of our activities. Where an evidence base is lacking, we will build evidence through strong evaluations. Where evidence exists, we will use it. Discretionary funding opportunity announcements will require that successful applicants cooperate with any federal evaluations if selected to participate. As legally allowed, programs with waiver authorities should require rigorous evaluations as a condition of waivers. As appropriate, ACF will encourage, incentivize or require grant recipients to use existing evidence of effective strategies in designing or selecting service approaches. The emphasis on evidence is meant to support, not

inhibit, innovation, improvement, equity, and learning.

Transparency: ACF will make information about planned and ongoing evaluations easily accessible, typically through posting on the web information about the contractor or grant recipient conducting the work and descriptions of the evaluation questions, methods to be used, and expected timeline for reporting results. ACF will present information about study designs, implementation, and findings at professional conferences.

Study plans will be published in advance. ACF will release evaluation results regardless of the findings. Evaluation reports will describe the methods used, including strengths and weaknesses, and discuss the generalizability of the findings. Evaluation reports will present comprehensive results, including favorable, unfavorable, and null findings. ACF will release evaluation results timely—usually within two months of a report's completion.

As appropriate and feasible, ACF will archive evaluation data for secondary use by interested researchers, typically through building requirements into contracts to prepare data sets for secondary use.

Independence: Independence and objectivity are core principles of evaluation. Agency and program leadership, program staff, service providers, populations and communities studied, and others should participate actively in setting evaluation priorities, identifying evaluation questions, and assessing the implications of findings. However, it is important to insulate evaluation functions from undue influence and from both the appearance and the reality of bias. To promote objectivity, ACF protects independence in the design, execution, analysis, and reporting of evaluations. To this end:

- ACF will conduct evaluations through the competitive award of grants and contracts to external experts who are free from conflicts of interest.
- The Deputy Assistant Secretary for Planning, Research, and Evaluation reports directly to the Assistant Secretary for Children and Families; serves as ACF's Chief Evaluation Officer; has authority to approve the design of evaluation projects and analysis plans; and has authority to approve, release and disseminate evaluation reports.

Ethics: ACF-sponsored evaluations will be conducted in an ethical and equitable manner and safeguard the dignity, rights, safety and privacy of participants. ACF-sponsored evaluations will comply with both the spirit and the letter of relevant requirements such as regulations governing research involving human subjects. ACF will expect contractors to meaningfully engage stakeholders from the programs and communities involved in studies to ensure programmatic, cultural, linguistic and historical nuances are accurately and respectfully addressed from the initial study design, through execution, analyses and reporting.

Authority: 42 U.S.C. 1310.

JooYeun Chang,

Acting Assistant Secretary.

[FR Doc. 2021–24493 Filed 11–8–21; 8:45 am]

BILLING CODE 4184–79–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; ACF–800: Child Care and Development Fund (CCDF) Annual Aggregate Report (OMB #0970–0150)

AGENCY: Office of Child Care, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Office of Child Care (OCC), Administration for Children and Families (ACF) is requesting a 3-year extension of the form ACF–800: CCDF Annual Aggregate Report (OMB #0970–0150, expiration 2/28/2022). There are no changes requested to the form.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The ACF–800 provides annual aggregate data on the children and families receiving direct services under CCDF. The ACF–800 provides administrative information on the type and methods of child care delivery, and is used to analyze and evaluate the CCDF program to the extent which state and territory lead agencies are assisting families in addressing child care needs.

Respondents: State and territory lead agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
ACF–800: CCDF Annual Aggregate Report	56	1	40	2,240

Estimated Total Annual Burden Hours: 2,240.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: The Child Care and Development Block Grant Act (42 U.S.C.

9857 *et seq.*); regulations at 45 CFR 98.70 and 98.71.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–24398 Filed 11–8–21; 8:45 am]

BILLING CODE 4184–81–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Success Sequence Qualitative Interviews (New Collection)

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Office of Planning, Research, and Evaluation (OPRE), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), proposes interview data collection activities for the Success Sequence Interviews study.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing *OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: OPRE/ACF/HHS proposes qualitative data collection as part of the Success Sequence Interviews study. The goal of this project is to understand complex decisions and circumstances of youth transitions to adulthood and explore the complexities around achieving the success sequence milestones of high school graduation, full-time employment, getting married, and having children. The data collected from the interviews will help ACF and the broader research field understand adults' perspectives and experiences related to the milestones, and will provide ACF's Family and Youth Services Bureau's Sexual Risk Avoidance Education grant program with greater insight into the program content and strategies related to the success sequence milestones and their ordering that could best resonate with youth. To support these efforts, we seek approval from the Office of Management and Budget to collect qualitative interview data from adults ages 30–35, recruiting from online research panels with participants across all U.S. regions. We propose the following data collection instruments:

(1) *Success Sequence Screener:* The screener will be administered by telephone. Information collected through the screener will be used to screen interview respondents into the study based on respondent demographics, household income, geographic location, and life milestones.

(2) *Success Sequence Interview Protocol:* We will administer an asynchronous interview with adults ages 30–35. Information collected through the interview protocol includes respondent life history focused on education, employment and work experience, family life, and financial status.

Respondents: A total of 225 interview respondents will be recruited from existing large national online panels of research participants.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Avg. burden per response (in hours)	Total/annual burden (in hours)
(1) Success Sequence Screener	675	1	.083	56
(2) Success Sequence Interview Protocol	225	1	.75	169

Estimated Total Annual Burden Hours: 225.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Sec. 510. [42 U.S.C. 710].

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–24397 Filed 11–8–21; 8:45 am]

BILLING CODE 4184–83–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3353]

Agency Information Collection Activities; Proposed Collection; Comment Request; Antimicrobial Animal Drug Distribution Reports and Recordkeeping

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of our reporting and recordkeeping requirements for antimicrobial animal drug sales and distribution.

DATES: Submit either electronic or written comments on the collection of information by January 10, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 10,

2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 10, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–N–3353 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Antimicrobial Animal Drug Distribution Reports and Recordkeeping.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Antimicrobial Animal Drug Distribution Reports and Recordkeeping—21 CFR 514.87

OMB Control Number 0910–0659—Extension

Sponsors of approved or conditionally approved applications for new animal drugs containing an antimicrobial active ingredient are required by section 512 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b) to submit to FDA an annual report on the amount of each such ingredient in the drug that is sold or distributed for use in food-producing animals. Sponsors are also required to maintain distribution records for their animal drug products, including separate information for each month of the calendar year, under section 512(*l*)(3) of the FD&C Act. These provisions were enacted to assist FDA in our continuing analysis of the interactions (including drug resistance), efficacy, and safety of antimicrobials approved for use in both humans and food-producing animals for the purpose of mitigating the public health risk associated with antimicrobial resistance.

Section 514.87 of our regulations (21 CFR 514.87) codifies the reporting requirements established in the FD&C Act. Sponsors submit antimicrobial

animal drug sales and distribution reports to us on Form FDA 3744. Each report must specify: (1) The amount of each antimicrobial active ingredient by container size, strength, and dosage form; (2) quantities distributed domestically and quantities exported; and (3) a listing of the target animals, indications, and production classes that are specified on the approved label of the product. The report must cover the period of the preceding calendar year and include separate information for each month of the calendar year. Each report must also provide a species-specific estimate of the percentage of each product that was sold or distributed domestically in the reporting year for use in cattle, swine, chickens, or turkeys for such species that appear on the approved label.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
514.87(a)–(e)—Annual Reports for Sponsors With Active Applications—Paper Submission	3744	4	1.5	6	62	372
514.87(a)–(e)—Annual Reports for Sponsors With Active Applications—Electronic Submission	3744	16	9.1	146	52	7,592
514.87(a)–(e)—Annual Reports for Sponsors With Inactive Applications—Paper Submission	3744	5	3	15	2	30
514.87(a)–(e)—Annual Reports for Sponsors With Inactive Applications—Electronic Submission	3744	16	12.6	201	2	402
Total						8,396

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We base our estimate of the average burden per response on our recent experience with the existing antimicrobial animal drug distribution reports program. We base our estimate of the number of affected respondents reported in tables 1 and 2 and the average number of responses per respondent in table 1 on a review of our records of sponsors with active and inactive applications. We estimate that 20 sponsors will have active applications, and we assume that 75 percent of the respondents will report electronically, while the other 25 percent will report on paper. We estimate that 4 sponsors with active applications will spend 62 hours annually to assemble the necessary information, prepare, and submit an annual antimicrobial animal drug sales and distribution report on paper and 16 sponsors with active applications will spend 52 hours annually to assemble the necessary information, prepare, and electronically submit an annual antimicrobial animal drug sales and distribution report. We estimate that 21 sponsors will have inactive applications, and we assume that 93 percent of these respondents will report electronically, while the other 7 percent will report on paper. We estimate that sponsors with inactive applications will spend 2 hours to prepare their annual antimicrobial animal drug sales and distribution reports, whether electronically or on paper.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of respondents	Number of records per respondent	Total annual records	Average burden per recordkeeping	Total hours
Recordkeeping required by section 512(*l*)(3) of the FD&C Act	21	1	21	2	42

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Animal drug manufacturers are already required to maintain distribution records for their animal drug products to comply with FDA's current good manufacturing regulations for periodic drug reports under § 514.80(b)(4)(i) (21 CFR 514.80(b)(4)(i)), approved under OMB control number 0910–0284. Section 512(*l*)(3) of the FD&C Act differs from § 514.80(b)(4)(i) in that it requires that records include separate information for each month of the calendar year. In addition, under 21 CFR 211.196 (approved under OMB control number 0910–0139), manufacturers currently are required to maintain distribution records that include dosage form, and date drug is distributed. Based on these requirements, FDA believes that manufacturers already keep detailed records of the dates when antimicrobial drugs are distributed for marketing and recall purposes from which monthly reports can be prepared as part of usual and customary business practices. However, FDA estimates an additional recordkeeping burden of 42 hours for further compliance with section 512(*l*)(3) of the FD&C Act, as detailed in table 2.

We have adjusted our burden estimate, which has resulted in a decrease to the currently approved burden. We attribute this to respondents who reported by paper in previous years and are now reporting electronically. We also note a decrease in recordkeeping respondents. We attribute this to the mergers of sponsors over the years.

Dated: November 3, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–24433 Filed 11–8–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–E–2232 and FDA–2020–E–2204]

Determination of Regulatory Review Period for Purposes of Patent Extension; DOJOLVI

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for DOJOLVI and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of patents which claim that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by January 10, 2022. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by May 9, 2022. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 10, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 10, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket Nos. FDA–2020–E–2232 and FDA–2020–E–2204 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; DOJOLVI.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when

the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product DOJOLVI (triheptanoin). DOJOLVI is indicated as a source of calories and fatty acids for the treatment of pediatric and adult patients with molecularly confirmed long-chain fatty acid oxidation disorders. Subsequent to this approval, the USPTO received patent term restoration applications for DOJOLVI (U.S. Patent Nos. 8,697,748 and 9,186,344) from Ultragenyx Pharmaceutical Inc., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated December 14, 2020, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of DOJOLVI represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for DOJOLVI is 2,511 days. Of this time, 2,175 days occurred during the testing phase of the regulatory review period, while 336 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* August 17, 2013. FDA has verified the applicant's claims that the date the investigational new drug application became effective was on August 17, 2013.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* July 31, 2019. FDA has verified the applicant's claims that the new drug application (NDA) for DOJOLVI (NDA 213687) was initially submitted on July 31, 2019.

3. *The date the application was approved:* June 30, 2020. FDA has verified the applicant's claims that NDA 213687 was approved on June 30, 2020.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,012 days or 1,303 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: November 3, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–24435 Filed 11–8–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Guidances; Draft and Revised Draft Guidances for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of additional draft and revised draft product-specific guidances. The guidances provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific guidances available to the public on FDA's website. The guidances identified in this notice were developed using the process described in that guidance.

DATES: Submit either electronic or written comments on the draft guidance by January 10, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand Delivery/Courier (for written/paper submissions): Dockets

Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2007–D–0369 for ''Product-Specific Guidances; Draft and Revised Draft Guidances for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Christine Le, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4714, Silver Spring, MD 20993–0002, 301–796–2398 and/or *PSG-Questions@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific guidances available to the public on FDA's website at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs.*

As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific guidances and provide a meaningful opportunity for the public to consider and comment on those guidances. Under that process, draft guidances are posted on FDA's website and announced periodically in the **Federal Register**. The public is encouraged to submit comments on those recommendations within 60 days of their announcement in the **Federal Register**. FDA considers any comments received and either publishes final guidances or publishes revised draft guidances for comment. Guidances were last announced in the **Federal Register** on August 23, 2021 (86 FR 47112). This notice announces draft product-specific guidances, either new or revised, that are posted on FDA's website.

II. Drug Products for Which New Draft Product-Specific Guidances Are Available

FDA is announcing the availability of new draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 1—NEW DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Active ingredient(s)
Artesunate.
Beclomethasone dipropionate monohydrate.
Bempedoic acid.
Bempedoic acid; Ezetimibe.
Cenobamate.
Ciclesonide.
Clascoterone.
Colesevelam hydrochloride.
Diclofenac potassium.
Dicyclomine hydrochloride.
Glucagon.
Lactitol.
Lemborexant.
Lurbinectedin.
Minocycline hydrochloride (multiple referenced listed drugs).
Opicapone.
Pemigatinib.
Potassium phosphate, dibasic; Potassium phosphate, monobasic (multiple referenced listed drugs).
Remimazolam besylate.
Riluzole.
Rimegepant sulfate.
Sodium iodide I-131.
Tenapanor hydrochloride.
Tucatinib.

III. Drug Products for Which Revised Draft Product-Specific Guidances Are Available

FDA is announcing the availability of revised draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Active ingredient(s)
Alprazolam.
Aripiprazole.
Carbidopa; Levodopa.
Cetirizine hydrochloride.
Colesevelam hydrochloride (multiple referenced listed drugs).
Desloratadine.
Donepezil hydrochloride.
Lansoprazole.
Leuprolide acetate.
Leuprolide acetate; Norethindrone acetate.
Loratadine.
Methylphenidate.
Metoclopramide hydrochloride.
Mirtazapine.
Olanzapine.
Ondansetron.
Risperidone.
Rizatriptan benzoate.
Triamcinolone acetonide.
Zolmitriptan.

For a complete history of previously published **Federal Register** notices

related to product-specific guidances, go to *https://www.regulations.gov* and enter Docket No. FDA–2007–D–0369.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the current thinking of FDA on, among other things, the product-specific design of BE studies to support ANDAs. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

IV. Paperwork Reduction Act of 1995

FDA tentatively concludes that these draft guidances contain no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or https://www.regulations.gov.*

Dated: November 3, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–24431 Filed 11–8–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1960]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; MedWatch: The Food and Drug Administration Medical Products Reporting Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by December 9, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0291. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

MedWatch: The FDA Medical Products Reporting Program

OMB Control Number 0910–0291—Extension

This information collection supports FDA laws and regulations governing adverse event reports and product experience reports for FDA-regulated products. The Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353b, 355, 360i, 360l, 379aa, and 393) and the Public Health Service Act (42 U.S.C. 262) authorize FDA to collect adverse event reports and product experience reports from regulated industry and to monitor the safety of drugs, biologics, medical devices, and dietary supplements. These reporting and recordkeeping requirements are found in FDA regulations, discussed in Agency guidance, and included in Agency forms. Although there are no laws or regulations mandating postmarket reporting for medical foods, infant formula, cosmetics, or tobacco products, we encourage voluntary reporting of adverse experiences associated with these products.

To facilitate both consumer and industry reporting of adverse events and experiences with FDA-regulated products, we developed the MedWatch program. The MedWatch program allows anyone to submit reports to FDA on adverse events, including injuries and/or deaths, as well as other product experiences associated with the products we regulate. While the MedWatch program provides for both paper-based and electronic reporting, this information collection covers paper-based reporting using Forms FDA 3500, 3500A, and 3500B, available from our website at *https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting.* Requirements regarding mandatory reporting of adverse events or product problems have been codified in parts 310, 314, 329, 600, and 803 (21 CFR 310, 314, 600, and 803), and specified in sections 503B, 760, and 761 of the FD&C Act (21 U.S.C. 353b, 379aa, and 379aa–1). Mandatory reporting of adverse events for human cells, tissues, and cellular- and tissue-based products (HCT/Ps) have been codified in § 1271.350 (21 CFR 1271.350). Other postmarketing reporting associated with requirements found in sections 201, 502, 505, and 701 (21 U.S.C. 321, 352, 355, and 371) of the FD&C Act and applicable to certain drug products with and without approved applications are approved under OMB control number 0910–0230.

Since 1993, mandatory adverse event reporting has been supplemented by voluntary reporting by healthcare professionals, patients, and consumers via the MedWatch reporting process. To carry out its responsibilities, the Agency needs to be informed when an adverse event, product problem, error with use of a human medical product, or evidence of therapeutic failure is suspected or identified in clinical use. When FDA receives this information from healthcare professionals, patients, or consumers, the report becomes data that will be used to assess and evaluate the risk associated with the product. FDA will take any necessary action to reduce, mitigate, or eliminate the public's exposure to the risk through regulatory and public health interventions.

To implement these reporting provisions for FDA-regulated products (except vaccines) during their post-approval and marketed lifetimes, we developed the following three forms, available for download from our website or upon request to the Agency: (1) Form FDA 3500 may be used for voluntary (*i.e.,* not mandated by law or regulation) reporting by healthcare professionals; (2) Form FDA 3500A is used for mandatory reporting (*i.e.,* required by law or regulation); and (3) Form FDA 3500B, available in English and Spanish, is written in plain language and may be used for voluntary reporting (*i.e.,* not mandated by law or regulation) by consumers (*i.e.,* patients and their caregivers). Respondents to the information collection are healthcare

professionals, medical care organizations and other user facilities (*e.g.,* extended care facilities, ambulatory surgical centers), consumers, manufacturers of biological, food products including dietary supplements and special nutritional products (*e.g.,* infant formula and medical foods), cosmetics, drug products or medical devices, and importers.

Use of Form FDA 3500 (Voluntary Reporting)

This voluntary version of the form may be used by healthcare professionals to submit all reports not mandated by Federal law or regulation. Individual healthcare professionals are not required by law or regulation to submit reports to the Agency or the manufacturer, with the exception of certain adverse events following immunization with vaccines as mandated by the National Childhood Vaccine Injury Act of 1986. Reports for vaccines are not submitted via MedWatch or MedWatch forms, but are submitted to the Vaccines Adverse Event Reporting System (VAERS; see *https://vaers.hhs.gov*), which is jointly administered by FDA and the Centers for Disease Control and Prevention (CDC).

Hospitals are not required by Federal law or regulation to submit reports associated with drug products, biological products, or special nutritional products. However, hospitals and other user facilities are required by Federal law to report medical device-related deaths and serious injuries.

Under Federal law and regulation (section 761(b)(1) of the FD&C Act), a dietary supplement manufacturer, packer, or distributor whose name appears on the label of a dietary supplement marketed in the United States is required to submit to FDA any serious adverse event report it receives regarding use of the dietary supplement in the United States. However, FDA bears the burden to gather and review evidence that a dietary supplement may be adulterated under section 402 of the FD&C Act (21 U.S.C. 342) after that product is marketed. Therefore, the Agency depends on the voluntary reporting by healthcare professionals and especially by consumers of suspected serious adverse events and product quality problems associated with the use of dietary supplements. All dietary supplement reports were originally received by the Agency on paper versions of Form FDA 3500 (by mail or fax). Today, electronic reports may be sent to the Agency via an online submission route called the Safety Reporting Portal at *https://www.safetyreporting.hhs.gov/.* In that case, the Form FDA 3500 is not used.

Form FDA 3500 may be used to report to the Agency adverse events, product problems, product use errors, and therapeutic failures. The form is provided in both paper and electronic formats. Reporters may mail or fax paper forms to the Agency. A fillable .pdf version of the form is available at *https://www.accessdata.fda.gov/scripts/medwatch/.* Respondents can also electronically submit a report via the MedWatch Online Voluntary Reporting Form at *https://www.accessdata.fda.gov/scripts/medwatch/.* Reporting is supported for drugs, non-vaccine biologicals, medical devices, food products, special nutritional products, cosmetics, and non-prescription human drug products marketed without an approved application. The paper form may also be used to submit reports about dietary supplements. Electronic reports for dietary supplements may be submitted to the Agency via an online submission route called the Safety Reporting Portal at *https://www.safetyreporting.hhs.gov/.* Electronic reports for tobacco products may be submitted to the Agency via the tobacco questionnaire within the online Safety Reporting Portal at *https://www.safetyreporting.hhs.gov/.*

Use of Form FDA 3500A—Mandatory Reporting

Drug and Biological Products

Sections 503B, 505(j), and 704 of the FD&C Act (21 U.S.C. 374) require that important safety information relating to all human prescription drug products be made available to FDA in the event it becomes necessary to take appropriate action to ensure protection of the public health. Mandatory reporting of adverse events for HCT/Ps is codified in § 1271.350. Consistent with statutory requirements, information is required to be submitted electronically and therefore we account for most all reports under OMB control number 0910–0645, established to support electronic reporting to our MedWatch program. At the same time, regulations provided for waivers from the electronic submission requirements and we therefore account for paper-based reporting in this information collection.

Medical Device Products

Section 519 of the FD&C Act (21 U.S.C. 360i) requires manufacturers and importers, of devices intended for human use to establish and maintain records, make reports, and provide information as the Secretary of Health and Human Services may by regulation reasonably require to ensure that such devices are not adulterated or misbranded and to otherwise assure its safety and effectiveness. The Safe Medical Device Act of 1990 (Pub. L. 101–629), signed into law on November 28, 1990, amends section 519 of the FD&C Act. The amendment requires that user facilities such as hospitals, nursing homes, ambulatory surgical facilities, and outpatient treatment facilities report deaths related to medical devices to FDA and to the manufacturer, if known. Serious illnesses and injuries are to be reported to the manufacturer or to FDA if the manufacturer is not known. These statutory requirements regarding mandatory reporting have been codified by FDA under 21 CFR part 803 (part 803). Part 803 mandates the use of the Form FDA 3500A for reporting to FDA on medical devices. While most reporting associated with medical device products is covered under OMB control number 0910–0437, we retain coverage for paper-based adverse experience report submissions in this collection, as well as coverage for MedWatch electronic reporting in OMB control number 0910–0645.

Dietary Supplements

Section 502(x) in the FD&C Act implements the requirements of The Dietary Supplement and Nonprescription Drug Consumer Protection Act, which became law (Pub. L. 109–462) on December 22, 2006. These requirements apply to manufacturers, packers, and distributors of nonprescription human drug products marketed without an approved application. The law requires reports of serious adverse events to be submitted to the Agency by manufacturers of dietary supplements. Electronic reports for dietary supplements may be submitted using the Safety Reporting Portal at *http://www.safetyreporting.hhs.gov/.* Paper-based dietary supplement reports may be submitted using the MedWatch Form FDA 3500A.

Use of Form FDA 3500B—Consumer Voluntary Reporting

This voluntary version of the form may be used by consumers, patients, or caregivers to submit reports not mandated by Federal law or regulation. Individual consumers, patients, or caregivers are not required by law or regulation to submit reports to the Agency or the manufacturer. FDA supports and encourages direct reporting to the Agency by consumers of suspected adverse events and other product problems associated with

human medical products, food, dietary supplements, and cosmetic products and invite these respondents to visit our website at *https://www.fda.gov/safety/report-problem-fda* for more information. Since the inception of the MedWatch program in July 1993, the program has been promoting and facilitating voluntary reporting by both the public and healthcare professionals. FDA has further encouraged voluntary reporting by requiring inclusion of the MedWatch toll-free phone number or the MedWatch internet address on all outpatient drug prescriptions dispensed, as mandated by section 17 of the Best Pharmaceuticals for Children Act (Pub. L. 107–109).

Section 906 of the FDA Amendments Act amended section 502(n) of the FD&C Act, mandating that published direct-to-consumer advertisements for prescription drugs include the following statement printed in conspicuous text (this includes vaccine products): ''You are encouraged to report negative side effects of prescription drugs to the FDA. Visit *https://www.fda.gov/medwatch,* or call 1–800–FDA–1088.'' Most private vendors of consumer medication information, the drug product-specific instructions dispensed to consumers at outpatient pharmacies, remind patients to report ''side effects'' to FDA and provide contact information to permit MedWatch reporting.

Since 2013, FDA has made available the 3500B form. Proposed during the previous authorization in 2012, the Form FDA 3500B is a version of the 3500 form that is tailored for consumers and written in plain language in conformance with the Plain Writing Act of 2010 (Pub. L. 111–274) (*https://www.govinfo.gov/content/pkg/PLAW-111publ274/pdf/PLAW-111publ274.pdf*). The Form FDA 3500B evolved from several iterations of draft versions, with input from human factors experts, from other regulatory agencies and with extensive input from consumer advocacy groups and the public. Since 2019, the Form FDA 3500B has been available in Spanish at *https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda* and available to upload electronically since 2021 at *https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.spanish.*

Form FDA 3500B, may be used to report adverse events, product problems, product use errors and problems after switching from one product maker to another maker to the Agency. The form is provided in both paper and electronic formats. Respondents may submit reports by mail or fax paper forms to the Agency or electronically submit a report via the MedWatch Online Voluntary Reporting Form at *https://www.accessdata.fda.gov/scripts/medwatch/.* A fillable .pdf version of the form, available at *https://www.fda.gov/media/85598/download may be downloaded, completed, and mailed or faxed to the Agency.* Reporting is supported for drugs, non-vaccine biologicals, medical devices, food products, special nutritional products, cosmetics, and non-prescription human drug products marketed without an approved application. The paper form may also be used to submit reports about dietary supplements. Electronic reports for dietary supplements may be submitted to the Agency via an online submission route called the Safety Reporting Portal at *https://www.safetyreporting.hhs.gov/.* Electronic reports for tobacco products may be submitted to the Agency via the tobacco questionnaire within the online Safety Reporting Portal at *https://www.safetyreporting.hhs.gov/.*

In the **Federal Register** of June 30, 2021 (86 FR 34754), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received requesting clarification with regard to certain terms applicable to medical device reporting and exemptions from reporting. The comment also discussed electronic reporting considerations. We note this information collection supports paper-based reporting, however, we inadvertently included estimates associated with electronic reporting elements required under certain device product regulations. Electronic reporting of adverse experiences associated with FDA-regulated products is currently approved in OMB control number 0910–0645. We also note that information collection associated with additional medical device reporting requirements is currently approved in OMB control number 0910–0437.

At the same time, we appreciate the request for clarification as we continually evaluate our MedWatch forms to increase their utility for the Agency and ease of reporting for respondents. To that end, we are considering making the following revisions and invite comment:

1. Revising the ''gender'' field to Forms FDA 3500, 3500A, and 3500B; to align with the CDC's use of these terms.

2. Revising Section B of Form FDA 3500 to the ''product problem'' field to include information about the root cause(s) of problem(s);

3. Revising instructions to clarify reporting instructions for paper-based reporting pertaining to adverse events associated with tobacco products; and

4. Revising instructions to replace the term ''smoking'' with the term ''tobacco product use,'' to clarify that this information applies to the use combusted and non-combusted tobacco products.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA center or 21 CFR section and/or FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Center for Biologics Evaluation and Research/Center for Drug Evaluation and Research: Form FDA 3500.	14,727	1	14,727	0.66 (40 minutes) ..	9,720
Center for Devices and Radiological Health Form 3500 (voluntary reporting).	5,233	1	5,233	0.66 (40 minutes) ...	3,454
Center for Food Safety and Applied Nutrition: Form FDA 3500.	1,793	1	1,793	0.66 (40 minutes) ..	1,183
Form FDA 3500A	1,659	1	1,659	1.21	2,007
Center for Tobacco Products: Form FDA 3500	39	1	39	0.66 (40 minutes) ..	26
All Centers: Form 3500B	13,750	1	13,750	0.46 (28 minutes) ...	6,325
Written requests for temporary waiver under § 329.100(c)(2).	1	1	1	1	1

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

FDA center or 21 CFR section and/or FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total					22,716

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

While we have retained the currently approved burden estimates for the individual information collection elements, we have removed those elements associated with mandatory electronic reporting inadvertently included in our 60-day notice, as these elements are currently approved under OMB control number 0910–0645.

Dated: November 3, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–24432 Filed 11–8–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of meetings of the National Diabetes and Digestive and Kidney Diseases Advisory Council.

The meeting will be open to the public as indicated below, with a short public comment period at the end. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov*).

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council; Digestive Diseases and Nutrition Subcommittee.

Date: January 26–27, 2022.

Time: 10:00 a.m. to 1:45 p.m.

Agenda: Grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Karl F. Malik, Ph.D., Director, Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Boulevard, Room 7329, MSC 5452, Bethesda, MD 20892, (301) 594–4757, *malikk@niddk.nih.gov*, (301) 594–4757, *malikk@niddk.nih.gov.*

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council; Kidney, Urologic and Hematologic Diseases Subcommittee.

Date: January 26–27, 2022.

Time: 10:00 a.m. to 1:45 p.m.

Agenda: Grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Karl F. Malik, Ph.D., Director, Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Boulevard, Room 7329, MSC 5452, Bethesda, MD 20892, (301) 594–4757, *malikk@niddk.nih.gov.*

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council; Diabetes, Endocrinology and Metabolic Diseases Subcommittee.

Date: January 26–27, 2022.

Time: 10:00 a.m. to 1:45 p.m.

Agenda: Grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Karl F. Malik, Ph.D., Director, Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Boulevard, Room 7329, MSC 5452, Bethesda, MD 20892, (301) 594–4757, *malikk@niddk.nih.gov.*

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council.

Date: January 26–27, 2022.

Open: January 26, 2022, 10:00 a.m. to 1:15 p.m.

Agenda: To present the Director's Report and other scientific presentations.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Closed: January 27, 2022, 1:25 p.m. to 1:45 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Karl F. Malik, Ph.D., Director, Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Boulevard, Room 7329, MSC 5452, Bethesda, MD 20892, (301) 594–4757, *malikk@niddk.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *www.niddk.nih.gov/fund/divisions/DEA/Council/coundesc.htm.,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: November 3, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–24439 Filed 11–8–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Library of Medicine Board of Scientific Counselors.

The meeting will be open to the public as indicated below. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section

552b(c)(6), Title 5 U.S.C., as amended for review, discussion, and evaluation of individual intramural programs and projects conducted by the National Library of Medicine, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Library of Medicine Board of Scientific Counselors.

Date: April 7, 2022.

Open: April 7, 2022, 11:00 a.m. to 12:35 p.m.

Agenda: Program Discussion and Investigator Report.

Place: Virtual Meeting.

Closed: April 7, 2022, 12:35 p.m. to 1:20 p.m.

Agenda: To review and evaluate personal qualifications, performance, and competence of individual investigators.

Open: April 7, 2022, 1:50 p.m. to 2:35 p.m.

Agenda: Investigator Report.

Closed: April 7, 2022, 2:35 p.m. to 4:30 p.m.

Agenda: To review and evaluate personal qualifications, performance, and competence of individual investigators.

Contact Person: Valerie Florance, Ph.D., Acting Scientific Director, National Library of Medicine, National Institutes of Health, 8600 Rockville Pike, Bethesda, MD 20894, 240–603–9822, *florancev@mail.nih.gov*.

Any member of the public may submit written comments no later than 15 days in advance of the meeting. Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Open sessions of this meeting will be broadcast to the public, and available for viewing at *https://videocast.nih.gov* on April 7, 2022. Please direct any questions to the Contact Person listed on this notice.

(Catalogue of Federal Domestic Assistance Program No. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: November 3, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–24438 Filed 11–8–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Child Psychopathology and Developmental Disabilities.

Date: December 1, 2021.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Benjamin G. Shapero, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3182, Bethesda, MD 20892, (301) 402–4786, *shaperobg@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Mechanisms of Learning, Emotion, Stress and Health.

Date: December 3, 2021.

Time: 1:00 p.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Biao Tian, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3089B, MSC 7848, Bethesda, MD 20892, (301) 402–4411, *tianbi@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Mechanisms of Neurodegenerative Diseases.

Date: December 7, 2021.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Mary Custer, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4148, MSC 7850, Bethesda, MD 20892, (301) 435–1164, *custerm@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Drug Discovery and Mechanisms of Resistance in Eukaryotic Pathogenic Organisms.

Date: December 9, 2021.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Dianne Hardy, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6175, MSC 7892, Bethesda, MD 20892, 301–435–1154, *dianne.hardy@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 3, 2021.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–24440 Filed 11–8–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Mechanism for Time-Sensitive Drug Abuse Research.

Date: December 8, 2021.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Soyoun Cho, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, Bethesda, MD 20892, (301) 594–9460, *Soyoun.cho@nih.gov*.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; High-throughput Discovery and Validation of Novel Signal Transducers or Small Molecules that Modulate Opioid or other Substance Use

Disorder Relevant Pathways (R01—Clinical Trials Not Allowed).

Date: January 24, 2022.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Soyoun Cho, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, Bethesda, MD 20892, (301) 594–9460, *Soyoun.cho@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: November 3, 2021.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–24444 Filed 11–8–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Understanding Post-Transcriptional Regulation of Intact and Defective HIV RNA (R61/R33 Clinical Trial Not Allowed).

Date: November 16, 2021.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G36, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Poonam Pegu, Ph.D., Scientific Review Officer, Scientific Review Program, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G36, Rockville, MD 20892, 240–292–0719, *poonam.pegu@nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Prevention Strategies to End the HIV Epidemic (R01 Clinical Trial Optional).

Date: November 18, 2021.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G21A, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Dimitrios N. Vatakis, Ph.D., Scientific Review Officer, Scientific Review Program, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G21A, Rockville, MD 20892, 301–761–7176, *dimitrios.vatakis@nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 3, 2021.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–24442 Filed 11–8–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Tuberculosis Research Advancement Centers (TRACs) (P30 Clinical Trial Not Allowed).

Date: November 10–12, 2021.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G13B, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Yong Gao, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G13B, Rockville, MD 20892–7616, (240) 669–5048, *gaoL2@niaid.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 3, 2021.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–24434 Filed 11–8–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Division of Intramural Research Board of Scientific Counselors, National Institute of Allergy and Infectious Diseases.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute of Allergy and Infectious Diseases, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Division of Intramural Research Board of Scientific Counselors, NIAID.

Date: December 13–15, 2021.

Time: 8:30 a.m. to 11:15 a.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, 50 Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Laurie Lewellen, Committee Manger, Division of Intramural Research Program Support Staff, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Building 33, Room 1N24, 33 North Drive, Bethesda, MD 20892, 301–761–6362, *Laurie.Lewallen@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 3, 2021.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–24443 Filed 11–8–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Use of Tomentosenol in Treating or Preventing Skin Disorders

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive, sublicensable patent license to University of the Sunshine Coast (''USC''), a public university based on the Sunshine Coast, Queensland, Australia, in its rights to the inventions and patents listed in the **SUPPLEMENTARY INFORMATION** section of this notice.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before November 24, 2021 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: Rose M. Freel, Ph.D., Senior Licensing and Patenting Manager, NCI Technology Transfer Center, Telephone (301) 624–8775 or Email: *rose.freel@nih.gov.*

SUPPLEMENTARY INFORMATION: The following and all continuing U.S. and foreign patents/patent applications thereof are the intellectual properties to be licensed under the prospective agreement to USC: Australian Provisional Patent Application No. 2021902329, filed Aug 3, 2021, entitled ''Use of tomentosenol in treating or preventing skin disorders'' (HHS Ref. No. E–107–2021–0).

The patent rights in these inventions have been assigned to the Government of the United States of America and the University of the Sunshine Coast. The prospective patent license will be for the purpose of consolidating the patent rights to USC, one of the co-owners of said rights, for commercial development and marketing. Consolidation of these co-owned rights is intended to expedite development of the invention, consistent with the goals of the Bayh-Dole Act codified as 35 U.S.C. 200–212.

The prospective patent license will be worldwide, exclusive, and may be limited to those fields of use commensurate in scope with the patent rights. It will be sublicensable, and any sublicenses granted by USC will be subject to the provisions of 37 CFR part 401 and 404.

The invention pertains to tomentosenol A, a natural product that may be useful for treating, inhibiting, or preventing scar formation development or progression, reducing pre-existing scar tissue, and/or other fibrotic skin disorders. Based on current available data, the intended use for the invention is as a therapeutic in scar therapy, skin fibrosis, skin diseases, and inhibition of the proliferation or migration of skin cells.

This notice is made pursuant to 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive patent license will include terms for the sharing of royalty income with NCI from commercial sublicenses of the patent rights and may be granted unless within fifteen (15) days from the date of this published notice the NCI receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Complete applications for a license that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent license. In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information from these license applications will be made only as required and upon a request under the *Freedom of Information Act,* 5 U.S.C. 552.

Dated: November 3, 2021.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2021–24445 Filed 11–8–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Regents of the National Library of Medicine.

The meeting will be open to the public as indicated below. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations should notify the Contact Person listed below in advance of the 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 materials, 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: Board of Regents of the National Library of Medicine.

Date: February 8, 2022.

Open: February 8, 2022, 10:00 a.m. to 3:30 p.m.

Agenda: Program Discussion.

Place: Virtual Meeting.

Closed: February 8, 2022, 3:30 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Contact Person: Christine Ireland, Committee Management Officer, Division of Extramural Programs, National Library of Medicine, 6705 Rockledge Drive, Suite 500, Bethesda, MD 20892, 301–594–4929, *irelanc@mail.nih.gov.*

Any member of the public may submit written comments no later than 15 days in advance of the meeting. Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *www.nlm.nih.gov/od/bor/bor.html* where an agenda and any additional information for the meeting will be posted when available. This meeting will be broadcast to the public, and available for viewing at *http://videocast.nih.gov* on February 8, 2022.

(Catalogue of Federal Domestic Assistance Program No. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: November 3, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–24437 Filed 11–8–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; National Neuroscience Research Education Programs (R25).

Date: December 6, 2021.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: DeAnna Lynn Adkins, Ph.D., Scientific Review Officer, Scientific Review Branch, NSC Building, Bethesda, MD 20892, 301–496–9223, *deanna.adkins@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: November 3, 2021.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–24441 Filed 11–8–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2021–0002]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: New or modified Base (1-percent annual chance) Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, and/or regulatory floodways (hereinafter referred to as flood hazard determinations) as shown on the indicated Letter of Map Revision (LOMR) for each of the communities listed in the table below are finalized. Each LOMR revises the Flood Insurance Rate Maps (FIRMs), and in some cases the Flood Insurance Study (FIS) reports, currently in effect for the listed communities.

DATES: Each LOMR was finalized as in the table below.

ADDRESSES: Each LOMR is available for inspection at both the respective Community Map Repository address listed in the table below and online through the FEMA Map Service Center at *https://msc.fema.gov*.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final flood hazard determinations as shown in the LOMRs for each community listed in the table below. Notice of these modified flood hazard determinations has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Insurance and Mitigation has resolved any appeals resulting from this notification.

The modified flood hazard determinations are made pursuant to section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR part 65.

The currently effective community number is shown and must be used for all new policies and renewals.

The new or modified flood hazard information is the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to remain qualified for participation in the National Flood Insurance Program (NFIP).

This new or modified flood hazard information, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities.

This new or modified flood hazard determinations are used to meet the floodplain management requirements of the NFIP. The changes in flood hazard determinations are in accordance with 44 CFR 65.4.

Interested lessees and owners of real property are encouraged to review the final flood hazard information available at the address cited below for each community or online through the FEMA Map Service Center at *https://msc.fema.gov*.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Michael M. Grimm,

Assistant Administrator for Risk Management, Department of Homeland Security, Federal Emergency Management Agency.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Alaska: Fairbanks North Star County (FEMA Docket No.: B–2123).	Fairbanks North Star Borough (20–10–0898P).	The Honorable Bryce Ward, Mayor, Fairbanks North Star Borough, P.O. Box 71267, Fairbanks, AK 99709.	*Community Planning Department, Juanita Helms Administration Center 907 Terminal Street,* Fairbanks, AK 99701.	Jul. 6, 2021	025009
Arizona:					
Apache (FEMA Docket No.: B–2140).	Town of Eagar (21–09–0424P).	The Honorable Bryce Hamblin, Mayor, Town of Eagar 22 West 2nd Street, Eagar, AZ 85925.	*Public Works Department, 1162 South Water Canyon Road,* Eagar, AZ 85925.	Jul. 21, 2021	040103
Maricopa (FEMA Docket No.: B–2132).	City of Glendale (20–09–1036P).	The Honorable Jerry Weiers, Mayor, City of Glendale, 5850 West Glendale Avenue, Glendale, AZ 85301.	City Hall, 5850 West Glendale Avenue, Glendale, AZ 85301.	May 7, 2021	040045
Maricopa (FEMA Docket No.: B–2132).	City of Peoria (20–09–1050P).	The Honorable Cathy Carlat, Mayor, City of Peoria, 8401 West Monroe Street, Peoria, AZ 85345.	City Hall, 8401 West Monroe Street, Peoria, AZ 85345.	Jul. 16, 2021	040050
Maricopa (FEMA Docket No.: B–2140).	City of Peoria (20–09–2036P).	The Honorable Cathy Carlat Mayor, City of Peoria 8401 West Monroe Street Peoria, AZ 85345.	*City Hall 8401 West Monroe Street* Peoria, AZ 85345.	Sep. 3, 2021	040050
Maricopa (FEMA Docket No.: B–2140).	City of Peoria (20–09–2066P).	The Honorable Cathy Carlat, Mayor, City of Peoria, 8401 West Monroe Street, Peoria, AZ 85345.	*City Hall, 8401 West Monroe Street,* Peoria, AZ 85345.	Aug. 20, 2021	040050
Maricopa (FEMA Docket No.: B–2132).	City of Phoenix (20–09–1036P).	The Honorable Kate Gallego, Mayor, City of Phoenix, 200 West Washington Street, 11th Floor, Phoenix, AZ 85003.	Street Transportation Department, 200 West Washington Street, 5th Floor, Phoenix, AZ 85003.	May 7, 2021	040051
Maricopa (FEMA Docket No.: B–2140).	City of Surprise (20–09–2202P).	The Honorable Skip Hall Mayor, City of Surprise, 16000 North Civic Center Plaza, Surprise, AZ 85374.	*Public Works Department Engineering Development Services, 16000 North Civic Center Plaza,* Surprise, AZ 85374.	Aug. 6, 2021	040053
Maricopa (FEMA Docket No.: B–2140).	Unincorporated Areas of Maricopa County (20–09–2036P).	The Honorable Jack Sellers, Chairman, Board of Supervisors Maricopa County, 301 West Jefferson Street, 10th Floor, Phoenix, AZ 85003.	*Flood Control District Maricopa County, 2801 West Durango Street,* Phoenix, AZ 85009.	Sep. 3, 2021	040037
Maricopa (FEMA Docket No.: B–2140).	Unincorporated Areas of Maricopa County (20–09–2202P).	The Honorable Jack Sellers, Chairman, Board of Supervisors Maricopa County, 301 West Jefferson Street, 10th Floor, Phoenix, AZ 85003.	*Flood Control District of Maricopa County, 2801 West Durango Street,* Phoenix, AZ 85009.	Aug. 6, 2021	040037
Maricopa (FEMA Docket No.: B–2123).	Unincorporated Areas of Maricopa County (21–09–0221P).	The Honorable Jack Sellers, Chairman, Board of Supervisors Maricopa County, 301 West Jefferson Street, 10th Floor, Phoenix, AZ 85003.	Flood Control District of Maricopa County, 2801 West Durango Street, Phoenix, AZ 85009.	Jun. 18, 2021	040037
Mohave (FEMA Docket No.: B–2123).	City of Bullhead City (20–09–1910P).	The Honorable Tom Brady, Mayor, City of Bullhead City, 2355 Trane Road, Bullhead City, AZ 86442.	Public Works Department, 2355 Trane Road, Bullhead City, AZ 86442.	Jul. 9, 2021	040125
Pinal (FEMA Docket No.: B–2132).	City of Maricopa (20–09–0399P).	The Honorable Christian Price, Mayor, City of Maricopa, 39700 West Civic Center Plaza, Maricopa, AZ 85138.	City Hall, 39700 West Civic Center Plaza, Maricopa, AZ 85138.	May 21, 2021	040052
Pinal (FEMA Docket No.: B–2132).	Town of Florence (20–09–1409P).	The Honorable Tara Walter, Mayor, Town of Florence, P.O. Box 2670, Florence, AZ 85132.	Public Works Department, 224 West 20th Street, Florence, AZ 85132.	May 28, 2021	040084
Pinal (FEMA Docket No.: B–2140).	Town of Superior (20–09–1494P).	The Honorable Mila Besich-Lira, Mayor, Town of Superior, 199 North Lobb Avenue, Superior, AZ 85173.	Town Hall, 199 North Lobb Avenue, Superior, AZ 85173.	Aug. 5, 2021	040119
Pinal (FEMA Docket No.: B–2132).	Unincorporated Areas of Pinal County (20–09–0399P).	The Honorable Stephen Q. Miller, Chairman, Board of Supervisors, Pinal County, P.O. Box 827, Florence, AZ 85132.	Pinal County Engineering Division, 31 North Pinal Street Building F, Florence, AZ 85132.	May 21, 2021	040077
Pinal (FEMA Docket No.: B–2140).	Unincorporated Areas of Pinal County (20–09–1494P).	The Honorable Stephen Q. Miller, Chairman, Board of Supervisors, Pinal County, P.O. Box 827, Florence, AZ 85132.	Pinal County Engineering Division, 31 North Pinal Street Building F, Florence, AZ 85132.	Aug. 5, 2021	040077
Pima (FEMA Docket No.: B–2123).	Town of Oro Valley (20–09–1981P).	The Honorable Joe Winfield, Mayor, Town of Oro Valley, Town Hall, 11000 North La Cañada Drive, Oro Valley, AZ 85737.	Planning and Zoning Department, 11000 North La Cañada Drive, Oro Valley, AZ 85737.	Jun. 23, 2021	040109
Pima (FEMA Docket No.: B–2123).	Unincorporated Areas of Pima County (20–09–1981P).	The Honorable Sharon Bronson, Chairman, Board of Supervisors, Pima County, 130 West Congress Street, 11th Floor, Tucson, AZ 85701.	Pima County Flood Control District, 201 North Stone Avenue, 9th Floor, Tucson, AZ 85701.	Jun. 23, 2021	040073
Santa Cruz (FEMA Docket No.: B–2123).	Unincorporated Areas of Santa Cruz County (20–09–0530P).	The Honorable Manuel Ruiz, Chairman, Board of Supervisors, Santa Cruz County, 2150 North Congress Drive #119, Nogales, AZ 85621.	Santa Cruz County Flood Control District, Gabilondo-Zehentner Building, 275 Rio Rico Drive, Rio Rico, AZ 85648.	May 5, 2021	040090
Santa Cruz (FEMA Docket No.: B–2123).	Unincorporated Areas of Santa Cruz County (20–09–0547P).	The Honorable Manuel Ruiz, Chairman, Board of Supervisors, Santa Cruz County, 2150 North Congress Drive #119, Nogales, AZ 85621.	Santa Cruz County Flood Control District, Gabilondo-Zehentner Building, 275 Rio Rico Drive, Rio Rico, AZ 85648.	May 5, 2021	040090
California:					
Fresno (FEMA Docket No.: B–2123).	City of Clovis (20–09–2182P).	The Honorable Drew Bessinger, Mayor, City of Clovis, 1033 5th Street, Clovis, CA 93612.	City Clerk's Office, Civic Center, 1033 5th Street, Clovis, CA 93612.	Jun. 21, 2021	060044
Kern (FEMA Docket No.: B–2132).	City of Delano (21–09–0119P).	The Honorable Bryan Osorio, Mayor, City of Delano, 1015 11th Avenue, Delano, CA 93215.	Community Development, 1015 11th Avenue, Delano, CA 93215.	Jun. 1, 2021	060078

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Kern (FEMA Docket No.: B–2132).	Unincorporated Areas of Kern County (21–09–0119P).	The Honorable Phillip Peters, Chairman, Board of Supervisors, Kern County, 115 Truxtun Avenue, 5th Floor, Bakersfield, CA 93301.	Kern County Planning Department, 2700 M Street, Suite 100, Bakersfield, CA 93301.	Jun. 1, 2021	060075
Nevada (FEMA Docket No.: B–2123).	City of Grass Valley (20–09–0976P).	The Honorable Ben Aguilar, Mayor, City of Grass Valley, 125 East Main Street, Grass Valley, CA 95945.	Public Works Department, 125 East Main Street, Grass Valley, CA 95945.	Apr. 30, 2021	060211
Riverside (FEMA Docket No.: B–2123).	City of Banning (20–09–2180P).	The Honorable Colleen Wallace, Mayor, City of Banning, 99 East Ramsey Street, Banning, CA 92220.	Public Works Department, 99 East Ramsey Street, Banning, CA 92220.	May 28, 2021	060246
Riverside (FEMA Docket No.: B–2140).	City of Corona (20–09–0482P).	The Honorable Jacque Casillas, Mayor, City of Corona, 400 South Vicentia Avenue, Corona, CA 92882.	City Hall, 400 South Vicentia Avenue, Corona, CA 92882.	Sep. 14, 2021	060250
San Diego (FEMA Docket No.: B–2123).	City of San Diego (20–09–1465P).	The Honorable Todd Gloria, Mayor, City of San Diego, 202 C Street, 11th Floor, San Diego, CA 92101.	Development Services Department, 1222 1st Avenue, MS 301, San Diego, CA 92101.	Jul. 1, 2021	060295
San Diego (FEMA Docket No.: B–2132).	Unincorporated Areas of San Diego County (20–09–2083P).	The Honorable Nathan Fletcher, Chairman, Board of Supervisors, San Diego County, 1600 Pacific Highway, Room 335, San Diego, CA 92101.	San Diego County Flood Control District, Department of Public Works, 5510 Overland Avenue, Suite 410, San Diego, CA 92123.	Jul. 19, 2021	060284
Santa Barbara (FEMA Docket No.: B–2132).	City of Goleta (21–09–0037P).	The Honorable Paula Perotte, Mayor, City of Goleta, 130 Cremona Drive, Suite B, Goleta, CA 93117.	City Hall, Planning and Environmental Review Department, 130 Cremona Drive Suite B, Goleta, CA 93117.	Jun. 3, 2021	060771
Santa Barbara (FEMA Docket No.: B–2132).	City of Santa Barbara (20–09–0769P).	The Honorable Cathy Murillo, Mayor, City of Santa Barbara, City Hall, 735 Anacapa Street, Santa Barbara, CA 93101.	Community Development Department, Building and Safety Division, 630 Garden Street, Santa Barbara, CA 93101.	Jul. 20, 2021	060335
Santa Barbara (FEMA Docket No.: B–2132).	City of Santa Barbara (21–09–0037P).	The Honorable Cathy Murillo, Mayor, City of Santa Barbara, City Hall, 735 Anacapa Street, Santa Barbara, CA 93101.	Community Development Department, Building and Safety Division, 630 Garden Street, Santa Barbara, CA 93101.	Jun. 3, 2021	060335
Idaho:					
Ada (FEMA Docket No.: B–2132).	City of Kuna (20–10–0884P).	The Honorable Joe Stear, Mayor, City of Kuna, City Hall, 751 West 4th Street, Kuna, ID 83634.	City Hall, 329 West 3rd Street, Kuna, ID 83642.	Jul. 22, 2021	160174
Ada (FEMA Docket No.: B–2132).	City of Meridian (20–10–1391P).	The Honorable Robert Simison, Mayor, City of Meridian, Meridian City Hall, 33 East Broadway Avenue, Suite 300, Meridian, ID 83642.	Public Works Department, 33 East Broadway Avenue, Suite 200, Meridian, ID 83642.	Jul. 26, 2021	160180
Ada (FEMA Docket No.: B–2132).	Unincorporated Areas of Ada County (20–10–0884P).	Mr. Rod Beck, Chairman, Ada County Board of County Commissioners, Ada County Courthouse, 200 West Front Street, 3rd Floor, Boise, ID 83702.	Ada County Courthouse, 200 West Front Street, Boise, ID 83702.	Jul. 22, 2021	160001
Ada (FEMA Docket No.: B–2132).	Unincorporated Areas of Ada County (20–10–1391P).	Mr. Rod Beck, Chairman, Ada County Board of County Commissioners, Ada County Courthouse, 200 West Front Street, 3rd Floor, Boise, ID 83702.	Ada County Courthouse, 200 West Front Street, Boise, ID 83702.	Jul. 26, 2021	160001
Blaine (FEMA Docket No.: B–2140).	City of Ketchum (20–10–0739P).	The Honorable Neil Bradshaw, Mayor, City of Ketchum, P.O. Box 2315, Ketchum, ID 83340.	City Hall, 480 East Avenue North, Ketchum, ID 83340.	Sep. 2, 2021	160023
Blaine (FEMA Docket No.: B–2140).	Unincorporated Areas of Blaine County (20–10–0739P).	Ms. Angenie McCleary, Vice Chair, Blaine County Commissioners, 206 1st Avenue South Suite 300, Hailey, ID 83333.	Blaine County Planning & Zoning, 219 1st Avenue South, Suite 208, Hailey, ID 83333.	Sep. 2, 2021	165167
Blaine (FEMA Docket No.: B–2132).	Unincorporated Areas of Blaine County (20–10–1303P).	Mr. Jacob Greenberg, Chairman, Board of County Commissioners, Blaine County, 206 South 1st Avenue Suite 300, Hailey, ID 83333.	Blaine County Planning & Zoning, 219 South lst Avenue, Suite 208, Hailey, ID 83333.	Jul. 29, 2021	165167
Bonneville (FEMA Docket No.: B–2123).	City of Ammon (20–10–0225P).	The Honorable Sean Coletti, Mayor, City of Ammon, City Hall, 2135 South Ammon Road, Ammon, ID 83406.	City Hall, 2135 South Ammon Road, Ammon, ID 83406.	Oct. 9, 2020	160028
Bonneville (FEMA Docket No.: B–2123).	Unincorporated Areas of Bonneville County (20–10–0225P).	The Honorable Roger Christensen, Chairman, Bonneville County, 605 North Capital Avenue, Idaho Falls, ID 83402.	Bonneville County Courthouse, 605 North Capital Avenue, Idaho Falls, ID 83402.	Oct. 9, 2020	160027
Illinois:					
Kane (FEMA Docket No.: B–2147).	Unincorporated Areas of Kane County (21–05–0452P).	The Honorable Corinne Pierog, Chairman, Kane County Board, Kane County Government Center, 719 South Batavia Avenue, Building A, Geneva, IL 60134.	Kane County Government Center, Water Resources Department, 719 South Batavia Avenue, Building A, Geneva, IL 60134.	Sep. 10, 2021	170896
Kane (FEMA Docket No.: B–2140).	Village of Montgomery (21-05-0213P).	The Honorable Matthew Brolley, Village President, Village of Montgomery, 200 North River Street, Montgomery, IL 60538.	Village Hall, 200 North River Street, Montgomery, IL 60538.	Sep. 10, 2021	170328
Kane (FEMA Docket No.: B–2147).	Village of Pingree Grove (21–05–0452P).	The Honorable Steve Wiedmeyer, Village President, Village of Pingree Grove, 555 Reinking Road, Pingree Grove, IL 60140.	Village Hall, 555 Reinking Road, Pingree Grove, IL 60140.	Sep. 10, 2021	171078
Indiana:					
Lake (FEMA Docket No.: B–2132).	City of Crown Point (20–05–3995P).	The Honorable David Uran, Mayor, City of Crown Point, 101 North East Street, Crown Point, IN 46307.	City Hall, 101 North East Street, Crown Point, IN 46307.	Jul. 23, 2021	180128

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Noble (FEMA Docket No.: B–2132).	Unincorporated Areas of Noble County (21–05–0893P).	The Honorable Gary Leatherman, President, Noble County Board of Commissioners, Noble County Courthouse, 101 North Orange Street, Albion, IN 46701.	Noble County South Complex, 2090 North State Road 9, Suite 2, Albion, IN 46701.	Jul. 23, 2021	180183
Iowa: Polk (FEMA Docket No.: B–2132).	City of Urbandale (21–07–0009P).	The Honorable Bob Andeweg, Mayor, City of Urbandale, City Hall, 3600 86th Street, Urbandale, IA 50322.	City Hall, 3600 86th Street, Urbandale, IA 50322.	Jul. 26, 2021	190230
Kansas:					
Johnson (FEMA Docket No.: B–2123).	City of Olathe (20–07–1546P).	The Honorable John Bacon, Mayor, City of Olathe, P.O. Box 768, Olathe, KS 66051.	City Hall, Olathe Planning Office, 100 West Santa Fe Drive, Olathe, KS 66061.	Jun. 17, 2021	200173
Johnson (FEMA Docket No.: B–2140).	City of Shawnee (20–07–0627P).	The Honorable Michelle Distler, Mayor, City of Shawnee, City Hall, 11110 Johnson Drive, Shawnee, KS 66203.	City Hall, 11110 Johnson Drive, Shawnee, KS 66203.	Sep. 1, 2021	200177
Sedgwick (FEMA Docket No.: B–2123).	City of Wichita (19–07–1328P).	The Honorable Brandon Whipple, Mayor, City of Wichita, City Hall, 455 North Main Street, 1st Floor, Wichita, KS 67202.	Office of Storm Water Management, 455 North Main Street, 8th Floor, Wichita, KS 67202.	Jun. 24, 2021	200328
Sedgwick (FEMA Docket No.: B–2123).	Unincorporated Areas of Sedgwick County (19–07–1328P).	Mr. Pete Meitzner, Chairman, 1st District Commissioner, Sedgwick County, 525 North Main Street, Suite 320, Wichita, KS 67203.	Sedgwick County Metropolitan Area, Building and Construction Department, 1144 South Seneca Street, Wichita, KS 67213.	Jun. 24, 2021	200321
Minnesota: Anoka (FEMA Docket No.: B–2123).	City of Blaine (20–05–3678P).	The Honorable Tim Sanders, Mayor, City of Blaine, City Hall, 10801 Town Square Drive Northeast, Blaine, MN 55449.	City Hall, 10801 Town Square Drive Northeast, Blaine, MN 55449.	Jun. 21, 2021	270007
Nebraska: Lancaster (FEMA Docket No.: B–2123).	City of Lincoln (20–07–1451P).	The Honorable Leirion Gaylor Baird, Mayor, City of Lincoln, 555 South 10th Street, Lincoln, NE 68508.	Building & Safety Department, 555 South 10th Street, Lincoln, NE 68508.	Jul. 5, 2021	315273
Nevada:					
Clark (FEMA Docket No.: B–2132).	City of Henderson (20–09–1687P).	The Honorable Debra March, Mayor, City of Henderson, 240 South Water Street, Henderson, NV 89015.	Public Works Department, 240 South Water Street, Henderson, NV 89015.	Apr. 29, 2021	320005
Elko (FEMA Docket No.: B–2140).	City of Elko (20–09–1987P).	The Honorable Reece Keener, Mayor, City of Elko, 1751 College Avenue, Elko, NV 89801.	City Hall, 1751 College Avenue, Elko, NV 89801.	Aug. 5, 2021	320010
Washoe (FEMA Docket No.: B–2140).	City of Reno (21–09–0352P).	The Honorable Hillary Schieve, Mayor, City of Reno, 1 East 1st Street, Reno, NV 89501.	City Hall, 1 East 1st Street, Reno, NV 89501.	Aug. 10, 2021	320020
Washoe (FEMA Docket No.: B–2140).	Unincorporated Areas of Washoe County (21–09–0352P).	The Honorable Bob Lucey, Chairman, Board of Commissioners, Washoe County, 1001 East 9th Street, Reno, NV 89512.	Washoe County Administration Building, Department of Public Works, 1001 East 9th Street, Reno, NV 89512.	Aug. 10, 2021	320019
New Jersey: Morris (FEMA Docket No.: B–2123).	Borough of Lincoln Park (21–02–0107P).	The Honorable David A. Runfeldt, Mayor, Borough of Lincoln Park, 34 Chapel Hill Road, Lincoln Park, NJ 07035.	Borough Building Department, 34 Chapell Hill Road, Lincoln Park, NJ 07035.	Jun. 29, 2021	345300
New York:					
Westchester (FEMA Docket No.: B–2132).	City of Rye (20–02–1384P).	The Honorable Josh Cohn, Mayor, City of Rye, City Hall, 1051 Boston Post Road, Rye, NY 10580.	City Hall, 1051 Boston Post Road, Rye, NY 10580.	Sep. 24, 2021	360931
Westchester (FEMA Docket No.: B–2123).	Village of Mamaroneck (20–02–1481P).	The Honorable Thomas A. Murphy, Mayor, Village of Mamaroneck, 123 Mamaroneck Avenue, Mamaroneck, NY 10543.	Building Inspector, The Regatta Building, 123 Mamaroneck Avenue, Mamaroneck, NY 10543.	Aug. 24, 2021	360916
Ohio:					
Fairfield (FEMA Docket No.: B–2140).	City of Lancaster (21–05–0317P).	The Honorable David L. Scheffler, Mayor, City of Lancaster, 104 East Main Street, Room 101, Lancaster, OH 43130.	City Building Department, 121 East Chestnut Street, Lancaster, OH 43130.	Sep 8, 2021	390161
Fairfield (FEMA Docket No.: B–2140).	Unincorporated Areas of Fairfield County (21–05–0317P).	Mr. Dave Levacy, Commissioner, Fairfield County Commissioners, 210 East Main Street, Room 301, Lancaster, OH 43130.	Fairfield County Regional Planning Commission, 210 East Main Street, Room 104, Lancaster, OH 43130.	Sep 8, 2021	390158
Oregon:					
Lane (FEMA Docket No.: B–2123).	City of Cottage Grove (20–10–0681P).	The Honorable Jeff Gowing, Mayor, City of Cottage Grove, 337 North 9th Street, Cottage Grove, OR 97424.	City Hall, 400 East Main Street, Cottage Grove, OR 97424.	Jun. 25, 2021	410120
Lane (FEMA Docket No.: B–2140).	City of Eugene (20–10–1089P).	The Honorable Lucy Vinis, Mayor, City of Eugene, 101 West 10th Avenue, 2nd Floor, Eugene, OR 97401.	Planning Department, 99 West 10th Avenue, Eugene, OR 97401.	Aug. 18, 2021	410122
Lane (FEMA Docket No.: B–2140).	Unincorporated Areas of Lane County (20–10–1089P).	Ms. Heather Buch, Commissioner, Board of County Commissioners, Lane County, Public Service Building, 125 East 8th Avenue, Eugene, OR 97401.	Lane County, Customer Service Center, 3050 North Delta Highway, Eugene, OR 97408.	Aug. 18, 2021	415591
Texas:					
Dallas (FEMA Docket No.: B–2123).	City of Grand Prairie (20–06–2268P).	The Honorable Ron Jensen, Mayor, City of Grand Prairie, P.O. Box 534045, Grand Prairie, TX 75053.	Community Development Center, 206 West Church Street, Grand Prairie, TX 75050.	Jun. 21, 2021	485472
Dallas (FEMA Docket No.: B–2123).	City of Irving (20–06–2268P).	The Honorable Rick Stopfer, Mayor, City of Irving, 825 West Irving Boulevard, Irving, TX 75060.	Capital Improvement Development Program, 825 West Irving Boulevard, Irving, TX 75060.	Jun. 21, 2021	480180
Hunt (FEMA Docket No.: B–2132).	City of Greenville (20–06–2492P).	The Honorable David Dreiling, Mayor, City of Greenville, 2821 Washington Street, Greenville, TX 75401.	City Hall, 2821 Washington Street, Greenville, TX 75401.	Jul. 14, 2021	485473
Washington:					

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
King (FEMA Docket No.: B–2140).	City of Kent (21–10–0511P).	The Honorable Dana Ralph, Mayor, City of Kent, 220 4th Avenue South, Kent, WA 98032.	City Hall, 220 4th Avenue South, Kent, WA 98032.	Aug. 27, 2021	530080
Yakima (FEMA Docket No.: B–2140).	City of Yakima (20–10–1163P).	The Honorable Patricia Byers, Mayor, City of Yakima, 129 North 2nd Street, Yakima, WA 98901.	City Hall, 129 North 2nd Street, Yakima, WA 98901.	Sep. 7, 2021	530311
Yakima (FEMA Docket No.: B–2140).	Unincorporated Areas of Yakima County (20–10–1163P).	Mr. Ron Anderson, District 2 Commissioner Yakima County, 128 North 2nd Street, Room 232, Yakima, WA 98901.	Yakima County Public Services, 128 North 2nd Street, Yakima, WA 98901.	Sep. 7, 2021	530217
Wisconsin:					
Brown (FEMA Docket No.: B–2132).	Unincorporated Areas of Brown County (20–05–2406P).	Mr. Troy Streckenbach, County Executive, Brown County, P.O. Box 23600, Green Bay, WI 54305.	Zoning Office, 305 East Walnut Street, Green Bay, WI 54301.	Aug. 2, 2021	550020
Brown (FEMA Docket No.: B–2140).	Village of Hobart (21–05–0115P).	Mr. Rich Heidel, President, Village of Hobart, 2990 South Pine Tree Road, Hobart, WI 54155.	Village Hall, 2456 Glendale Avenue, Green Bay, WI 54313.	Sep. 6, 2021	550626
Brown (FEMA Docket No.: B–2132).	Village of Pulaski (20–05–2406P).	The Honorable Reed A. Woodward, Mayor, Village of Pulaski, P.O. Box 320, Pulaski, WI 54162.	Village Hall, 421 South St. Augustine Street, Pulaski, WI 54162.	Aug. 2, 2021	550024
La Crosse (FEMA Docket No.: B–2132).	Unincorporated Areas of La Crosse County (21–05–0431P).	Ms. Monica Kruse, Chair, La Crosse County Board, Administrative Center, 212 6th Street North, La Crosse, WI 54601.	La Crosse County Administration Center, 400 4th Street North, Room 3260, La Crosse, WI 54601.	Aug. 5, 2021	550217
Ozaukee (FEMA Docket No.: B–2140).	City of Cedarburg (19–05–5425P).	The Honorable Mike O'Keefe, Mayor, City of Cedarburg, W63 N645 Washington Avenue, Cedarburg, WI 53012.	City Hall, W63 N645 Washington Avenue, Cedarburg, WI 53012.	Aug. 25, 2021	550312
Ozaukee (FEMA Docket No.: B–2140).	Unincorporated Areas of Ozaukee County (19–05–5425P).	Mr. Lee Schlenvogt, Chairperson, Ozaukee County Board, 121 West Main Street, Port Washington, WI 53074.	Ozaukee County Administration Center, 121 West Main Street, Port Washington, WI 53074.	Aug. 25, 2021	550310
Ozaukee (FEMA Docket No.: B–2140).	Village of Grafton (19–05–5425P).	Mr. James A. Brunnquell, Village President, Village of Grafton, 860 Badger Circle, Grafton, WI 53024.	Village Hall, 1971 Washington Street, Grafton, WI 53024.	Aug. 25, 2021	550314
Waukesha (FEMA Docket No.: B–2123).	Village of Sussex (20–05–1875P).	Mr. Anthony LeDonne, Village President, Village of Sussex, Sussex Civic Center, N64 W23760 Main Street, Sussex, WI 53089.	Village Hall, N64 W23760 Main Street, Sussex, WI 53089.	Mar. 18, 2021	550490

[FR Doc. 2021–24404 Filed 11–8–21; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2021–0002; Internal Agency Docket No. FEMA–B–2174]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

DATES: Comments are to be submitted on or before February 7, 2022.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location *https://hazards.fema.gov/femaportal/prelimdownload* and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

You may submit comments, identified by Docket No. FEMA–B–2174, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP.

The communities affected by the flood hazard determinations are provided in the tables below. Any

request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at *https://www.floodsrp.org/pdfs/srp_overview.pdf.*

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location *https://hazards.fema.gov/femaportal/prelimdownload* and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Michael M. Grimm,

Assistant Administrator for Risk Management, Department of Homeland Security, Federal Emergency Management Agency.

Community	Community map repository address
Bartholomew County, Indiana and Incorporated Areas Project: 10–05–2671S Preliminary Date: May 21, 2021	
City of Columbus	Bartholomew County Planning Department, 123 Washington Street, Suite 8, Columbus, IN 47201.
Town of Hope	Town Hall, 404 Jackson Street, Hope, IN 47246.
Unincorporated Areas of Bartholomew County	Bartholomew County Planning Department, 123 Washington Street, Suite 8, Columbus, IN 47201.
Elko County, Nevada and Incorporated Areas Project: 18–09–0008S Preliminary Date: June 28, 2021	
City of Carlin	Building Department, 810 Oak Street, Carlin, NV 89822.
City of Elko	Elko County Administration Building, 540 Court Street, Suite 104, Elko, NV 89801.
City of Wells	Elko County Administration Building, 540 Court Street, Suite 104, Elko, NV 89801.
Unincorporated Areas of Elko County	Elko County Administration Building, 540 Court Street, Suite 104, Elko, NV 89801.
Clallam County, Washington and Incorporated Areas Project: 16–10–0561S Preliminary Date: October 31, 2019	
City of Forks	City Hall, 500 East Division Street, Forks, WA 98331.
City of Port Angeles	City Hall, 321 East 5th Street, Port Angeles, WA 98362.
City of Sequim	Civic Center, 152 West Cedar Street, Sequim, WA 98382.
Jamestown S'Klallam Tribe	Jamestown S'Klallam Tribe Government Office, 1033 Old Blyn Highway, Sequim, WA 98382.
Lower Elwha Klallam Tribe	Lower Elwha Klallam Tribe Center, 2851 Lower Elwha Road, Port Angeles, WA 98363.
Makah Tribe	Makah Tribe Center, 101 Resort Drive, Neah Bay, WA 98357.
Quileute Indian Tribe	Quileute Indian Tribe Office, 90 Main Street, La Push, WA 98350.
Unincorporated Areas of Clallam County	Clallam County Courthouse, 223 East 4th Street, Port Angeles, WA 98362.

[FR Doc. 2021–24405 Filed 11–8–21; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2021–0002; Internal Agency Docket No. FEMA–B–2178]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This notice lists communities where the addition or modification of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports, prepared by the Federal Emergency Management Agency (FEMA) for each

community, is appropriate because of new scientific or technical data. The FIRM, and where applicable, portions of the FIS report, have been revised to reflect these flood hazard determinations through issuance of a Letter of Map Revision (LOMR), in accordance with Federal Regulations. The currently effective community number is shown in the table below and must be used for all new policies and renewals.

DATES: These flood hazard determinations will be finalized on the dates listed in the table below and revise the FIRM panels and FIS report in effect prior to this determination for the listed communities.

From the date of the second publication of notification of these changes in a newspaper of local circulation, any person has 90 days in which to request through the community that the Deputy Associate Administrator for Insurance and Mitigation reconsider the changes. The flood hazard determination information may be changed during the 90-day period.

ADDRESSES: The affected communities are listed in the table below. Revised flood hazard information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

Submit comments and/or appeals to the Chief Executive Officer of the community as listed in the table below.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The specific flood hazard determinations are not described for each community in this notice. However, the online location and local community map repository address where the flood hazard determination information is available for inspection is provided.

Any request for reconsideration of flood hazard determinations must be submitted to the Chief Executive Officer of the community as listed in the table below.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR part 65.

The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

These flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. The flood hazard determinations are in accordance with 44 CFR 65.4.

The affected communities are listed in the following table. Flood hazard determination information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Michael M. Grimm,

Assistant Administrator for Risk Management, Department of Homeland Security, Federal Emergency Management Agency.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Delaware:						
Sussex	Town of South Bethany (21–03–0951P).	The Honorable Tim Saxton, Mayor, Town of South Bethany, 402 Evergreen Road, South Bethany, DE 19930.	Town Hall, 402 Evergreen Road, South Bethany, DE 19930.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 14, 2022	100051
Sussex	Unincorporated areas of Sussex County (21–03–0951P).	The Honorable Michael H. Vincent, President, Sussex County Council, P.O. Box 589, Georgetown, DE 19947.	Sussex County, Administrative Building, 2 The Circle, Georgetown, DE 19947.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 14, 2022	100029
Florida:						
Lee	City of Sanibel (21–04–4276P).	The Honorable Holly D. Smith, Mayor, City of Sanibel, 800 Dunlop Road, Sanibel, FL 33957.	Community Services Department, 800 Dunlop Road, Sanibel, FL 33957.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 12, 2022	120402
Monroe	City of Key West (21–04–3573P).	The Honorable Teri Johnston, Mayor, City of Key West, P.O. Box 1409, Key West, FL 33041.	City Hall, 1300 White Street, Key West, FL 33041.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 24, 2022	120168
Monroe	Unincorporated areas of Monroe County (21–04–4442P).	The Honorable Michelle Coldiron, Mayor, Monroe County Board of Commissioners, 25 Ships Way, Big Pine Key, FL 33043.	Monroe County Building Department, 2798 Overseas Highway, Suite 300, Marathon, FL 33050.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 24, 2022	125129

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Monroe	Unincorporated areas of Monroe County (21–04–4719P).	The Honorable Michelle Coldiron, Mayor, Monroe County, Board of Commissioners, 25 Ships Way, Big Pine Key, FL 33043.	Monroe County Building Department, 2798 Overseas Highway, Suite 300, Marathon, FL 33050.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 3, 2022	125129
Polk	Unincorporated areas of Polk County (21–04–1458P).	Mr. Bill Beasley, Polk County Manager, 330 West Church Street, Bartow, FL 33831.	Polk County Land Development Division, 330 West Church Street, Bartow, FL 33830.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 10, 2022	120261
Sarasota	City of Sarasota (21–04–4173P).	The Honorable Hagen Brody, Mayor, City of Sarasota, 1565 1st Street, Room 101, Sarasota, FL 34236.	Development Services Department, 1565 1st Street, Sarasota, FL 34236.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 7, 2022	125120
Massachusetts: Worcester.	Town of Holden, (20–01–1690P).	The Honorable Chiara M. Barnes, Chair, Town of Holden, Board of Selectmen, 1204 Main Street, Holden, MA 01520.	Town Hall, 1204 Main Street, Holden, MA 01520.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 3, 2022	250309
Mississippi: DeSoto..	City of Southaven (21–04–1757P)	The Honorable Darren Musselwhite, Mayor, City of Southaven, 8710 Northwest Drive, Southaven, MS 38671.	Geographic Information Systems (GIS) Department, 8710 Northwest Drive, Southaven, MS 38671.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 28, 2022	280331
South Carolina:						
Berkeley	Unincorporated areas of Berkeley County, (21–04–5806P).	Mr. John Cribb, Berkeley County Supervisor, 1003 Highway 52, Moncks Corner, SC 29461.	Berkeley County, Administration Building, 1003 Highway 52, Moncks Corner, SC 29461.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 3, 2022	450029
Charleston	Town of Mount Pleasant (21–04–4673P).	The Honorable Will Haynie, Mayor, Town of Mount Pleasant, 100 Ann Edwards Lane, Mount Pleasant, SC 29464.	Engineering and Development Services Department, 100 Ann Edwards Lane, Mount Pleasant, SC 29464.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 31, 2022	455417
Texas:						
Collin	City of Dallas (21–06–1108P).	The Honorable Eric Johnson, Mayor, City of Dallas, 1500 Marilla Street, Suite 5EN, Dallas, TX 75201.	Oak Cliff Municipal Center, 320 East Jefferson Boulevard, Room 312, Dallas, TX 75203.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 31, 2022	480171
Collin	City of Lavon (21–06–1485P).	The Honorable Vicki Sanson, Mayor, City of Lavon, P.O. Box 340, Lavon, TX 75166.	City Hall, 120 School Road, Lavon, TX 75166.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 22, 2022	481313
Dallas	City of Garland (21–06–2234P).	The Honorable Scott LeMay, Mayor, City of Garland, P.O. Box 469002, Garland, TX 75046.	Engineering Department, 800 Main Street, Garland, TX 75040.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 3, 2022	485471
Ellis	City of Waxahachie (20–06–3749P).	The Honorable Doug Barnes, Mayor, City of Waxahachie, P.O. Box 757, Waxahachie, TX 75168.	Public Works and Engineering Department, 401 South Rogers Street, Waxahachie, TX 75168.	*https://msc.fema.gov/portal/advanceSearch.*	Dec. 20, 2021	480211
Navarro	City of Corsicana (21–06–0729P).	The Honorable Don Denbow, Mayor, City of Corsicana, 200 North 12th Street, Corsicana, TX 75110.	City Hall, 200 North 12th Street, Corsicana, TX 75110.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 26, 2022	480498
Virginia:						
Loudoun	Unincorporated areas of Loudoun County (21–03–0460P).	Mr. Tim Hemstreet, Loudoun County Administrator, P.O. Box 7000, Leesburg, VA 20177.	Loudoun County, Mapping and Geographic Information Department, 1 Harrison Street Southeast, 3rd Floor, Leesburg, VA 20175.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 18, 2022	510090
Loudoun	Unincorporated areas of Loudoun County (21–03–1384P).	Mr. Tim Hemstreet, Loudoun County Administrator, P.O. Box 7000, Leesburg, VA 20177.	Loudoun County, Mapping and Geographic Information Department, 1 Harrison Street Southeast, 3rd Floor, Leesburg, VA 20175.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 31, 2022	510090
Prince William	City of Manassas (21–03–0728P).	Mr. W. Patrick Pate, City of Manassas Manager, 9027 Center Street, Manassas, VA 20110.	Department of Public Works, 8500 Public Works Drive, Manassas, VA 20110.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 14, 2022	510122

[FR Doc. 2021–24408 Filed 11–8–21; 8:45 am]
BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0015]

Agency Information Collection Activities; Extension, Without Change, of a Currently Approved Collection: Immigrant Petition for Alien Workers

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 30-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The purpose of this notice is to allow an additional 30 days for public comments.

DATES: Comments are encouraged and will be accepted until December 9, 2021.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, must be submitted via the Federal eRulemaking Portal website at *http://www.regulations.gov* under e-Docket ID number USCIS–2007–0018. All submissions received must include the OMB Control Number 1615–0015 in the body of the letter, the agency name and Docket ID USCIS–2007–0018.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, Telephone number (240) 721–3000 (This is not a toll-free number; comments are not accepted via telephone message.). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at *http://www.uscis.gov,* or call the USCIS Contact Center at (800) 375–5283; TTY (800) 767–1833.

SUPPLEMENTARY INFORMATION:

Comments

The information collection notice was previously published in the **Federal Register** on July 30, 2021, at 86 FR 41078, allowing for a 60-day public comment period. USCIS did not receive any comments in connection with the 60-day notice.

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2007–0018 in the search box. The comments submitted to USCIS via this method are visible to the Office of Management and Budget and comply with the requirements of 5 CFR 1320.12(c). All submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

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

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

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection Request:* Extension, Without Change, of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Immigrant Petition for Alien Workers.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* I–140; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Business or other for-profit; Not-for-profit institutions. The information collected on this form will be used by USCIS to determine eligibility for the requested immigration benefits under section 203(b)(1), 203(b)(2), or 203(b)(3) of the Immigration and Nationality Act.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection I–140 is 148,000 and the estimated hour burden per response is 1.08 hour.

(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 159,840 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $20,596,559.

Dated: November 4, 2021.

Samantha L. Deshommes,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2021–24482 Filed 11–8–21; 8:45 am]
BILLING CODE 9111–97–P

DEPARTMENT OF THE INTERIOR

Geological Survey

[GX22GS00EMMA900]

2021 Draft List of Critical Minerals

AGENCY: U.S. Geological Survey, Department of the Interior.

ACTION: Notice of opportunity for public comment.

SUMMARY: The United States remains heavily dependent on imports of certain mineral commodities that are vital to the Nation's economic and national security interests. This dependency has the potential to create strategic vulnerabilities arising from adverse foreign actions, pandemics, natural disasters, or other events that can disrupt the supply of critical minerals. The Department of the Interior (DOI)

published a list of 35 critical minerals [1] or mineral groups on May 18, 2018, in response to Executive Order 13817—A Federal Strategy to Ensure Secure and Reliable Supplies of Critical Minerals.

DATES: To ensure consideration, written comments must be submitted before December 9, 2021.

ADDRESSES: You may submit written comments online at *http://www.regulations.gov* by entering ''DOI–2021–xxxx'' in the Search bar and clicking ''Search,'' or by mail to Draft List of Critical Minerals, MS–102, U.S. Geological Survey, 12201 Sunrise Valley Dr., Reston, VA 20192.

FOR FURTHER INFORMATION CONTACT: James Mosley, (703) 648–6312, *jmosley@usgs.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact Mr. Mosley during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with this individual. You will receive a reply during normal business hours. Normal business hours are 9:00 a.m. to 5:30 p.m., Monday through Friday, except for Federal holidays.

SUPPLEMENTARY INFORMATION: Pursuant to Section 7002 (''Mineral Security'') of Title VII (''Critical Minerals'') of the Energy Act of 2020 (The Energy Act) (Pub. L. 116–260, December 27, 2020, 116th Cong.),[2] the Secretary of the Interior (The Secretary), acting through the Director of the U.S. Geological Survey, and in consultation with the Secretaries of Defense, Commerce, Agriculture, and Energy and the United States Trade Representative, is to ''publish in the **Federal Register** for public comment—(A) a description of the draft methodology used to identify a draft list of critical minerals; (B) a draft list of minerals, elements, substances, and materials that qualify as critical minerals; and (C) a draft list of critical minerals recovered as byproducts and their host minerals.'' Under the Energy Act, Sec. 7002 (c)(5)(A) the methodology and list shall be reviewed at least every 3 years.

On behalf of the Secretary, the Associate Director for Natural Hazards exercising the authority of the Director of the U.S. Geological Survey presents here a draft list of 50 mineral commodities proposed for inclusion on the 2021 list of critical minerals: Aluminum, antimony, arsenic, barite, beryllium, bismuth, cerium, cesium, chromium, cobalt, dysprosium, erbium, europium, fluorspar, gadolinium, gallium, germanium, graphite, hafnium, holmium, indium, iridium, lanthanum, lithium, lutetium, magnesium, manganese, neodymium, nickel, niobium, palladium, platinum, praseodymium, rhodium, rubidium, ruthenium, samarium, scandium, tantalum, tellurium, terbium, thulium, tin, titanium, tungsten, vanadium, ytterbium, yttrium, zinc, and zirconium.

Much of the increase in the number of mineral commodities, from 35 commodities and groups on the final 2018 list to 50 commodities on the 2021 draft list, is the result of splitting the rare earth elements and platinum group elements into individual entries rather than including them as mineral groups. In addition, the 2021 draft list adds nickel and zinc and removes helium, potash, rhenium, and strontium. The Energy Act of 2020 explicitly excluded fuel minerals from the definition of a critical mineral and the Mining and Mineral Policy Act of 1970 [3] formally defined uranium as a mineral fuel, so uranium was not evaluated for inclusion on the 2021 draft list of critical minerals.

Minerals were included on the 2021 draft list of critical minerals based on three evaluations: (1) A quantitative evaluation wherever sufficient data were available, (2) a semi-quantitative evaluation of whether the supply chain had a single point of failure, and (3) a qualitative evaluation when other evaluations were not possible. The report [4] describing the methodology and the technical input from the U.S. Geological Survey may be found at the following link: *https://doi.org/10.3133/ofr20211045* and further details are summarized in the supplementary information section below. The U.S. Geological Survey seeks comments on the make-up of the draft list and the rationale associated with potential additions or subtractions to the draft list as described in the methodology report.

The Energy Act of 2020, Section 7002(c)(4)(A), defined critical minerals as those which:

(i) ''are essential to the economic or national security of the United States;

(ii) the supply chain of which is vulnerable to disruption (including restrictions associated with foreign political risk, abrupt demand growth, military conflict, violent unrest, anti-competitive or protectionist behaviors, and other risks through-out the supply chain); and

(iii) serve an essential function in the manufacturing of a product (including energy technology-, defense-, currency-, agriculture-, consumer electronics-, and healthcare-related applications), the absence of which would have significant consequences for the economic or national security of the United States.''

Section 7002(a)(3)(B) further defined the term by stating that ''The term ''critical mineral'' does not include—

(i) fuel minerals;

(ii) water, ice, or snow;

(iii) common varieties of sand, gravel, stone, pumice, cinders, and clay.''

The Mining and Minerals Policy Act of 1970, 30 U.S.C. 21(a), defined ''mineral fuels'' as ''including oil, gas, coal, oil shale and uranium''. Based on these definitions, uranium was not evaluated for inclusion on the 2021 draft list of critical minerals.

The U.S. Government and other organizations may also use other definitions and rely on other criteria to identify a material or mineral as ''critical'' or otherwise important. This list is not intended to replace related terms and definitions of materials that are deemed strategic, critical or otherwise important (such as definitions related to the National Defense Stockpile, Specialty Materials, and Militarily Critical Materials). In addition, there are many minerals not listed on the critical minerals list that are important to the U.S. economy. These materials are not considered critical as defined by the Energy Act because the U.S. largely meets its needs for these through domestic mining and processing and thus a supply disruption is considered unlikely.

The 2021 draft list of critical minerals is based on a methodology developed over several years with leadership by the U.S. Geological Survey and interagency input coordinated by the White House Office of Science and Technology Policy's National Science and Technology Council (NSTC) Critical Minerals Subcommittee. The 2021 update to the methodology was published by the U.S. Geological Survey in 2021 (*https://doi.org/10.3133/ofr20211045*) and includes three evaluations: (1) A quantitative evaluation wherever sufficient data were available, (2) a semi-quantitative evaluation of whether the supply chain

[1] Final Critical Minerals List 2018 *https://www.federalregister.gov/documents/2018/05/18/2018-10667/final-list-of-critical-minerals-2018.*

[2] Energy Act of 2020 (Division Z of the Consolidated Appropriations Act, 2021): *https://rules.house.gov/sites/democrats.rules.house.gov/files/BILLS-116HR133SA-RCP-116-68.pdf.*

[3] Mining and Minerals Policy Act of 1970 *https://openei.org/wiki/Mining_and_Minerals_Policy_Act_of_1970.*

[4] Nassar, N.T., and Fortier, S.M., 2021, Methodology and technical input for the 2021 review and revision of the U.S. Critical Minerals List: U.S. Geological Survey Open-File Report 2021–1045, 31 p., *https://doi.org/10.3133/ofr20211045.*

had a single point of failure, and (3) a qualitative evaluation when other evaluations were not possible. The quantitative evaluation is an enhancement of the NSTC methodology published in 2018 (*https://doi.org/10.3133/ofr20181021*) and used to develop the 2018 list of critical minerals. The 2021 quantitative evaluation uses (A) a net import reliance indicator of the dependence of the U.S. manufacturing sector on foreign supplies, (B) an enhanced production concentration indicator which focuses on production concentration outside of the United States, (C) weights for each producing country's production contribution by its ability or willingness to continue to supply the United States, and converts the 2018 methodology's qualitative evaluation of economic importance into a quantitative evaluation of economic vulnerability for the U.S. manufacturing sector. Further details on the underlying rationale and the specific approach, data sources, and assumptions used to calculate each component of the supply risk metrics are described in the references cited in this notice.

Table 1 shows the result of the review of the list of critical minerals for 2021, ranked in order of decreasing supply chain risk when a quantitative evaluation was possible. The table columns indicate whether each mineral commodity recommended for inclusion on the 2021 draft list of critical minerals, the basis for the recommendation (quantitative evaluation, single point of failure, or qualitative evaluation), whether the commodity was included in on the 2018 final list of critical minerals, and whether it is produced primarily as a byproduct of another mineral commodity. Of the sixty-six mineral commodities listed in Table 1, fifty-four (82% of the minerals considered) could be evaluated using the quantitative NSTC methodology. This includes mineral commodities that are recommended for inclusion on the list based on a single point of supply chain failure, as applicable, even if the commodity did not meet the quantitative threshold cutoff. See methodology references for further details.

TABLE 1—SUMMARY OF EVALUATION OF MINERAL COMMODITIES FOR THE 2021 LIST OF CRITICAL MINERALS

Highest to lowest supply chain risk, based on quantitative evaluation [5]	Mineral commodity	Included on draft 2021 list of critical minerals?	Basis for recommended inclusion	On 2018 list of critical minerals?	Predominantly recovered as byproduct? [6]
1	Gallium	Yes	Quantitative evaluation	Yes	Yes.
2	Niobium	Yes	Quantitative evaluation	Yes	No.
3	Cobalt	Yes	Quantitative evaluation	Yes	Yes.
4	Neodymium	Yes	Quantitative evaluation	Yes	Yes.
5	Ruthenium	Yes	Quantitative evaluation	Yes	Yes.
6	Rhodium	Yes	Quantitative evaluation	Yes	Yes.
7	Dysprosium	Yes	Quantitative evaluation	Yes	Yes.
8	Aluminum	Yes	Quantitative evaluation	Yes	No.
9	Fluorspar	Yes	Quantitative evaluation	Yes	No.
10	Platinum	Yes	Quantitative evaluation	Yes	No.
11	Iridium	Yes	Quantitative evaluation	Yes	Yes.
12	Praseodymium	Yes	Quantitative evaluation	Yes	Yes.
13	Cerium	Yes	Quantitative evaluation	Yes	Yes.
14	Lanthanum	Yes	Quantitative evaluation	Yes	Yes.
15	Bismuth	Yes	Quantitative evaluation	Yes	Yes.
16	Yttrium	Yes	Quantitative evaluation	Yes	Yes.
17	Antimony	Yes	Quantitative evaluation	Yes	Yes.
18	Tantalum	Yes	Quantitative evaluation	Yes	No.
19	Hafnium	Yes	Quantitative evaluation	Yes	Yes.
20	Tungsten	Yes	Quantitative evaluation	Yes	No.
21	Vanadium	Yes	Quantitative evaluation	Yes	Yes.
22	Tin	Yes	Quantitative evaluation	Yes	No.
23	Magnesium	Yes	Quantitative evaluation	Yes	No.
24	Germanium	Yes	Quantitative evaluation	Yes	Yes.
25	Palladium	Yes	Quantitative evaluation	Yes	Yes.
26	Titanium	Yes	Quantitative evaluation	Yes	No.
27	Zinc	Yes	Quantitative evaluation	No	No.
28	Graphite	Yes	Quantitative evaluation	Yes	No.
29	Chromium	Yes	Quantitative evaluation	Yes	No.
30	Arsenic	Yes	Quantitative evaluation	Yes	Yes.
31	Barite	Yes	Quantitative evaluation	Yes	No.
32	Indium	Yes	Quantitative evaluation	Yes	Yes.
33	Samarium	Yes	Quantitative evaluation	Yes	Yes.
34	Manganese	Yes	Quantitative evaluation	Yes	No.
35	Lithium	Yes	Quantitative evaluation	Yes	No.
36	Tellurium	Yes	Quantitative evaluation	Yes	Yes.
37	Lead	No	Not applicable	No	No.
38	Potash	No	Not applicable	Yes	No.
39	Strontium	No	Not applicable	Yes	No.
40	Rhenium	No	Not applicable	Yes	Yes.
41	Nickel	Yes	Single point of failure	No	No.
42	Copper	No	Not applicable	No	No.
43	Beryllium	Yes	Single point of failure	Yes	No.
44	Feldspar	No	Not applicable	No	No.
45	Phosphate	No	Not applicable	No	No.
46	Silver	No	Not applicable	No	Yes.

TABLE 1—SUMMARY OF EVALUATION OF MINERAL COMMODITIES FOR THE 2021 LIST OF CRITICAL MINERALS—Continued

Highest to lowest supply chain risk, based on quantitative evaluation [5]	Mineral commodity	Included on draft 2021 list of critical minerals?	Basis for recommended inclusion	On 2018 list of critical minerals?	Predominantly recovered as byproduct? [6]
47	Mica	No	Not applicable	No	No.
48	Selenium	No	Not applicable	No	Yes.
49	Cadmium	No	Not applicable	No	Yes.
50	Zirconium	Yes	Single point of failure	Yes	Yes.
51	Molybdenum	No	Not applicable	No	No.
52	Gold	No	Not applicable	No	No.
53	Helium	No	Not applicable	Yes	Yes.
54	Iron ore	No	Not applicable	No	No.
([7])	Cesium	Yes	Qualitative evaluation	Yes	Yes.
([8])	Erbium	Yes	Qualitative evaluation	Yes	Yes.
([8])	Europium	Yes	Qualitative evaluation	Yes	Yes.
([8])	Gadolinium	Yes	Qualitative evaluation	Yes	Yes.
([8])	Holmium	Yes	Qualitative evaluation	Yes	Yes.
([8])	Lutetium	Yes	Qualitative evaluation	Yes	Yes.
([8])	Rubidium	Yes	Qualitative evaluation	Yes	Yes.
([8])	Scandium	Yes	Qualitative evaluation	Yes	Yes.
([8])	Terbium	Yes	Qualitative evaluation	Yes	Yes.
([8])	Thulium	Yes	Qualitative evaluation	Yes	Yes.
([8])	Uranium	Not evaluated	Not applicable	Yes	No.
([8])	Ytterbium	Yes	Qualitative evaluation	Yes	Yes.

Table 1 includes 11 mineral commodities that are not recommended for inclusion on the 2021 list of critical minerals. These mineral commodities did not meet the NSTC quantitative evaluation criteria, were determined not to have a single point of failure and were not included on the 2018 list of critical minerals. These eleven commodities (17% of the minerals evaluated) are: Lead, copper, feldspar, phosphate, silver, mica, selenium, cadmium, molybdenum, gold, and iron ore, ranked in order of their overall supply chain risk. While several of these are essential mineral commodities, their supply chain vulnerability is mitigated by domestic production, lack of import dependence, and diverse, secure sources of supply.

Mineral commodities that did not meet the criteria for the NSTC quantitative evaluation, but that have an identified single point of supply chain failure and an essential economic function, are recommended for inclusion on the 2021 list of critical minerals regardless of whether the commodities in question were on the 2018 list. Examples are beryllium and zirconium, which were on the 2018 list, and nickel, which was not. Increasing demand for nickel as a component for producing cathodes for lithium-ion batteries, and the limited mining, smelting, and refinery capacity in the United States make a compelling case for inclusion.

Zinc, which was not on the 2018 list of critical minerals, was above the quantitative threshold for inclusion on the 2021 draft list of critical minerals due to the increasing concentration of mine and smelter capacities globally and the continued refinement and development of the quantitative evaluation criteria.

Potash, rhenium, and strontium were on the 2018 list of critical minerals but do not meet the quantitative threshold and do not have a single point of failure. Potash, strontium, and rhenium have supply risk scores just below the quantitative threshold. This highlights the fact that the metrics developed with this methodology are best viewed as a continuum of supply risk rather than an as indication that supply risk does not exist for commodities below the quantitative cutoff. These three commodities all had very high trade exposure but low disruption potential. This reflects the fact that, while the United States was highly net import reliant for all three commodities, the production of these minerals was either not highly concentrated or was concentrated in countries considered to be reliable trade partners. Any changes in the supply chain dynamics of these commodities will be closely monitored, but none of the three is recommended for inclusion on the 2021 draft list of critical minerals.

Helium (like potash, rhenium, and strontium) was on the 2018 list of critical minerals but does not meet the quantitative threshold nor have a single point of failure. The United States is the world's leading producer and a net exporter of helium. Helium's trade exposure score was thus 0 and, in turn, its supply risk score was 0. Crude helium was produced in more than a dozen plants across several U.S. States, and several other plants produced grade-A Helium. Therefore, helium does not qualify for inclusion on the list based on the single point of failure criterion. Helium production outside the United States was concentrated in Qatar and Algeria. Both countries, as well as Canada, Russia, and Tanzania, are poised to increase their production as additional capacity becomes available in the near term. The Helium Stewardship Act of 2013-directed closure of the Federally managed helium reserve by the Bureau of Land Management has the potential to

[5] Ranked in order from highest to lowest risk based on a recency-weighted mean of the commodities' overall supply risk scores. See the published methodology (*https://doi.org/10.3133/ofr20211045*) for further details.

[6] Most mineral commodities are recovered as byproducts to some degree, but the share of primary production as a byproduct for the mineral commodities that are not identified as byproducts in the table is typically small. Rare earth elements (REEs) are mined both as byproducts of other mineral commodities (for example, iron ore or heavy-mineral sands) and as the main product. Where REEs are mined as the main product, the individual REEs are either byproducts or coproducts of each other. For simplicity, all REEs are labeled in the table as having been produced mostly as byproducts. Byproduct status can and does change, although notable changes over short periods of time are rare.

[7] Commodities that were not evaluated using the quantitative evaluation are not given a rank and are ordered alphabetically.

[8] USGS Mineral Commodity Summaries 2021 *https://pubs.usgs.gov/periodicals/mcs2021/mcs2021.pdf.*

increase uncertainty in the market. The global shift from conventional natural gas toward shale gas, which lacks recoverable quantities of helium, also has the potential to reduce the supply of helium, especially for the United States. While these factors make helium a commodity that bears watching, it is not recommended for inclusion on the 2021 draft list of critical minerals.

There were insufficient data to quantitatively evaluate several commodities that were on the 2018 list of critical minerals: Cesium, rubidium, scandium, and several REEs (europium, gadolinium, terbium, holmium, erbium, thulium, ytterbium, and lutetium). The United States has been completely net import reliant for all these commodities for many years.[8] No specific global production data were available for these commodities; however, general information suggests that production for each of these commodities is highly concentrated in a few countries. Scandium was produced mainly as a byproduct in China, Kazakhstan, the Philippines, Russia, and Ukraine. Cesium and rubidium had been produced in Australia, Canada, China, Namibia, and Zimbabwe; however, it is thought that all cesium and rubidium mine production outside of China has either ceased in recent years or come under control of Chinese companies. The REEs that were not analyzed because of the lack of data (namely europium, gadolinium, terbium, holmium, erbium, thulium, ytterbium, and lutetium) were all heavy REEs that were produced only or predominantly in China. Based on this qualitative evaluation, none of these commodities are recommended for removal from the list of critical minerals.

Mineral criticality is not static, but changes over time. This analysis represents the most recent available data for non-fuel mineral commodities and the current state of the methodology for evaluation of criticality.

Please submit written comments on this draft list by December 9, 2021 to facilitate consideration. In particular, the U.S. Geological Survey is interested in comments addressing the following topics: The make-up of the draft list and the rationale associated with potential additions or subtractions to the draft list. Before including your address, phone number, email address, or other personally identifiable information (PII) in your comment, you should be aware that your entire comment, including your PII, may be made publicly available at any time. While you can ask us in your comment to withhold your PII from public review, we cannot guarantee that we will be able to do so.

Authority: E.O. 13817, 82 FR 60835 (December 26, 2017) and The Energy Act of 2020, Section 7002 of Title VII (December 27, 2020).

Dated: November 4, 2021.

James D. Applegate,

Associate Director for Natural Hazards, Exercising the Delegated Authority of the Director, U.S. Geological Survey.

[FR Doc. 2021–24488 Filed 11–8–21; 8:45 am]

BILLING CODE 4334–63–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–CR–NAGPRA–NPS0031736; PPWOCRADN0–PCU00RP14.R50000 (211); OMB Control Number 1024–0144]

Agency Information Collection Activities; Native American Graves Protection and Repatriation Regulations

AGENCY: National Park Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the National Park Service (NPS) are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before January 10, 2022.

ADDRESSES: Send your comments on this information collection request (ICR) to Phadrea Ponds, NPS Information Collection Clearance Officer by email to *phadrea_ponds@nps.gov.* Please reference OMB Control Number 1024–0144 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Melanie O'Brien, Manager, National NAGPRA Program by email at *melanie_o'brien@nps.gov,* or by telephone at (202) 354–2204. Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (PRA, 44 U.S.C. 3501 *et seq.)* and 5 CFR 1320.8(d)(1), all information collections require approval under the PRA. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility.

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used.

(3) Ways to enhance the quality, utility, and clarity of the information to be collected.

(4) How might the agency 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 response.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: Authorized by the Native American Graves Protection and Repatriation Act (NAGPRA), U.S.C. 3001–3013, all public and private museums receiving Federal funds compile information regarding Native American cultural items in their possession or control. This information must be provided to lineal descendants, likely interested Indian tribes, Native Hawaiian organizations, and the NPS National NAGPRA Program. Under NAGPRA and its implementing regulations, we are mandated to collect any information that is pertinent in determining the cultural affiliation and geographical origin of Native American human remains and cultural items. This

include descriptions, acquisition data, and records of consultation. Once the identity and cultural affiliation of human remains and cultural items are determined, the museum must send written notice of determination to the affected Indian tribes or Native Hawaiian organizations and the NAGPRA Program for publication in the **Federal Register**.

Title of Collection: Native American Graves Protection and Repatriation Regulations.

OMB Control Number: 1024–0144.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: State, local and tribal governments, universities, museums, etc. that receive Federal funds and have possession of, or control over, Native American human remains, funerary objects, sacred objects, or objects of cultural patrimony.

Total Estimated Number of Annual Respondents: 448.

Total Estimated Number of Annual Responses: 448.

Estimated Completion Time per Response: Varies from 10 hours to 100 hours depending on respondent and/or activity.

Total Estimated Number of Annual Burden Hours: 4,470.

Respondent's Obligation: Mandatory.

Frequency of Collection: On occasion.

Total Estimated Annual Nonhour Burden Cost: None.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Phadrea Ponds,

Information Collection Clearance Officer, National Park Service.

[FR Doc. 2021–24473 Filed 11–8–21; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB 1140–0009]

Agency Information Collection Activities; Proposed eCollection of eComments Requested; Revision of a Currently Approved Collection; Application To Register as an Importer of U.S. Munitions Import List (USMIL) Articles—ATF Form 4587(5330.4)

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

ACTION: 60-Day notice.

SUMMARY: The Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), Department of Justice (DOJ), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection (IC) OMB 1140–0009 (Application to Register as an Importer of U.S. Munitions Import List (USMIL) Articles)—ATF Form 4587(5330.4)) is being revised due to an increase in the total annual responses, respondents and burden hours. The *pay.gov* feature is also being implemented to facilitate form completion and processing of registration fees. The proposed IC is also being published to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and will be accepted for 60 days until January 10, 2022.

FOR FURTHER INFORMATION CONTACT: If you have additional comments regarding the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact: Corey Bodencak, Office 1350/Imports Branch/FESD either by mail at 244 Needy Rd., Martinsburg, WV 25405, by email at *Corey.Bodencak@atf.gov,* or by telephone at (304) 616–4558.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—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;
—Evaluate whether and, if so, how the quality, utility, and clarity of the information to be collected can be enhanced; and
—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection (check justification or form 83):* Revision of a Currently Approved Collection.

2. *The Title of the Form/Collection:* Application to Register as an Importer of U.S. Munitions Import List (USMIL) Articles.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number (if applicable): ATF Form 4587(5330.4).

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Business or other for-profit.

Other (if applicable): Individuals or households.

Abstract: The Application to Register as an Importer of U.S. Munitions Import List (USMIL) Articles—ATF Form 4587(5330.4) is used to register an individual or company as an importer of USMIL articles and facilitate the collection of registration fees.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 400 respondents will prepare explosives transaction records for this collection once annually, and it will take each respondent approximately 30 minutes to complete their responses.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 200 hours, which is equal to 400 (total respondents) * 1 (# of response per respondent) * .5 (30 minutes or the time taken to prepare each response).

7. *An Explanation of the change in estimates:* Due to more individuals registering to import defense articles and services, the total respondents, responses, and burden hours to this collection have increased from 300, 300, and 150 hours respectively in 2018, to 400, 400, and 200 hours currently.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, Mail Stop 3E.405A, Washington, DC 20530.

Dated: November 4, 2021.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2021–24469 Filed 11–8–21; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Cable Television Laboratories, Inc.

Notice is hereby given that, on October 13, 2021, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Cable Television Laboratories, Inc. (''CableLabs'') 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, Classic Communications Inc., Tyler, TX, Cablevision Systems Corporation, Bethpage, NY, and Buckeye Cablevision, Inc., Toledo, OH have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and CableLabs intends to file additional written notifications disclosing all changes in membership.

On August 8, 1988, CableLabs 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 September 7, 1988 (53 FR 34593).

The last notification was filed with the Department on January 9, 2020. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on January 27, 2020 (85 FR 4704).

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

[FR Doc. 2021–24410 Filed 11–8–21; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Border Security Technology Consortium

Notice is hereby given that, on October 6, 2021, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Border Security Technology Consortium (''BSTC'') 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, 1st1 Technologies LLP, Olalla, WA; Arete Associates, Northridge, CA; Cerium Laboratories, LLC, Austin, TX; Echodyne, Kirkland, WA; Imperative Systems LLC, Herndon, VA; Moog Inc., Northbrook, IL; Sea Machines Robotics, Inc., Boston, MA; and The Domenix Corporation dba Relevant Technology, Chantilly, VA have been added as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and BSTC intends to file additional written notifications disclosing all changes in membership.

On May 30, 2012, BSTC 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 June 18, 2012 (77 FR 36292).

The last notification was filed with the Department on July 13, 2021. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on August 23, 2021 (86 FR 47149).

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

[FR Doc. 2021–24446 Filed 11–8–21; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—IMS Global Learning Consortium, Inc.

Notice is hereby given that, on October 13, 2021, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), IMS Global Learning Consortium, Inc. (''IMS Global'') 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, apenutmize, Utrecht, NETHERLANDS; Aspire Ability, Payson, UT; Cambium Learning Group, Dallas, TX; Classera Inc., San Francisco, CA; KC TEK ARGE BILISIM. VE ENERJI SA. TIC, Cankaya, TURKEY; North Clackamas School District, Milwaukie, OR; Northwest RESA (GA), Rome, GA; School District of Osceola County FL, St. Cloud, FL; University of Arkansas, Fayetteville, Fayetteville, AR; and University of Central Oklahoma, Edmond, OK, have been added as parties to this venture.

Also, Xquiry, Amersfoort NL, NETHERLANDS; UVII, New York, NY; Lumina Foundation, Indianapolis, IN; Squirrel AI Learning by Yixue Group, Highland Park, NJ; Australian Council for Educational Research, Camberwell, AUSTRALIA; University of Florida, Gainesville, FL; and NWEA, Portland, OR, have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and IMS Global intends to file additional written notifications disclosing all changes in membership.

On April 7, 2000, IMS Global 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 September 13, 2000 (65 FR 55283).

The last notification was filed with the Department on July 22, 2021. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on August 23, 2021 (86 FR 47149).

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

[FR Doc. 2021–24436 Filed 11–8–21; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF LABOR

Employee Benefits Security Administration

Agency Information Collection Activities; Request for Public Comment

AGENCY: Employee Benefits Security Administration (EBSA), Department of Labor.

ACTION: Notice.

SUMMARY: The Department of Labor (the Department), in accordance with the Paperwork Reduction Act of 1995 (PRA 95) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the reporting burden on the public and helps the public understand the Department's information collection requirements and provide the requested data in the desired format. Currently, the Employee Benefits Security Administration (EBSA) is soliciting comments on No Surprises Act: IDR Process, Affordable Care Act Internal Claims and Appeals and External Review Procedures for ERISA Plans, and Opt-in State Balance Bill Process. A copy of the information collection request (ICR) may be obtained by contacting the office listed in the **ADDRESSES** section of this notice.

DATES: Written comments must be submitted to the office shown in the **ADDRESSES** section on or before January 10, 2022.

ADDRESSES: James Butikofer, Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW, Room N–5718, Washington, DC 20210, or *ebsa.opr@dol.gov.*

SUPPLEMENTARY INFORMATION:

I. Current Actions

This notice requests public comment pertaining to the Department's request for extension of OMB's approval of the Application. After considering comments received in response to this notice, the Department intends to submit an ICR to OMB for continuing approval. No change to the existing ICR is proposed or made at this time. The Department notes that an agency may not conduct or sponsor, and a person is not required to respond to, an information collection unless it displays a valid OMB control number. A summary of the ICR and the current burden estimates follows:

Agency: Employee Benefits Security Administration, Department of Labor.

Title: No Surprises Act: IDR Process.

Type of Review: Extension of a currently approved collection of information.

OMB Number: 1210–0169.

Affected Public: Business or other for-profit; Not-for-profit institutions.

Respondents: 22,257.

Frequency of Responses: On occasion.

Responses: 36,675.

Estimated Total Burden Hours: 65,948.

Estimated Total Burden Cost (Operating and Maintenance): $187,546.

Description: On December 27, 2020, the Consolidated Appropriations Act, 2021 (CAA), which includes the No Surprises Act, was signed into law. The No Surprises Act provides Federal protections against surprise billing and limits out-of-network cost sharing under many of the circumstances in which surprise bills arise most frequently. The CAA added provisions applicable to group health plans and health insurance issuers in the group and individual markets in a new Part D of title XXVII of the Public Health Service Act (PHS Act) and also added new provisions to part 7 of the Employee Retirement Income Security Act (ERISA), and Subchapter B of chapter 100 of the Internal Revenue Code (Code).

Section 102 of the No Surprises Act added Code section 9816, ERISA section 716, and PHS Act section 2799A–1, which contain limitations on cost sharing and requirements for initial payments for emergency services. In addition, Section 103 of the No Surprises Act amended Code section 9816, ERISA section 716, and PHS Act section 2799A–1 to establish a Federal independent dispute resolution (Federal IDR) process that nonparticipating providers or facilities and group health plans and health insurance issuers in the group and individual market may use following the end of an unsuccessful open negotiation period to determine the out-of-network rate for certain services. More specifically, the Federal IDR provisions may be used to determine the out-of-network rate for certain emergency services, nonemergency items and services furnished by nonparticipating providers at participating health care facilities, where an All-Payer Model Agreement or specified state law does not apply. Finally, Section 105 of the No Surprises Act created Code section 9817, ERISA section 717, and PHS Act section 2799A–2 which contain limitations on cost sharing and requirements for initial payments for air ambulance services, and allow plans and issuers and providers of air ambulance services to access the Federal IDR process.

The Federal IDR process requires a number of disclosures from plans, issuers, FEHB carriers, and nonparticipating providers or nonparticipating emergency facilities.

Before accessing the Federal IDR process to determine the out-of-network rate for a qualified item or service, the parties must engage in a 30-business-day open negotiation period to attempt to reach an agreement regarding the total out-of-network rate (including any cost sharing). To initiate the open negotiation period, the initiating party must provide notice to the other party within 30 business days of the receipt of initial payment or notice of denial of payment for the qualified item or service. The open negotiation notice must include information sufficient to identify the items or services subject to negotiation, including the date the item or service was furnished, the service code, the initial payment amount or notice of denial of payment, as applicable, an offer for the out-of-network rate, and contact information of the party sending the open negotiation notice.

When the parties do not reach an agreed upon amount for the out-of-network rate by the last day of the open negotiation period, either party may initiate the Federal IDR process by submitting the Notice of IDR Initiation to the other party and to the Departments during the 4-business day period beginning on the 31st business day after the start of the open negotiation period. If the parties to the Federal IDR process agree on an out-of-network rate for a qualified IDR item or service after providing notice to the Departments of initiation of the Federal IDR process, but before the certified IDR entity has made its payment determination, the initiating party must send a notification to the Departments and to the certified IDR entity (if

selected) electronically through the Federal IDR portal, in a form and manner specified by the Departments, as soon as possible, but no later than 3 business days after the date of the agreement. This notification should include the out-of-network rate for the qualified IDR item or service and signatures from authorized signatories for both parties.

If the plan, issuer, or FEHB carrier and the nonparticipating provider or nonparticipating emergency facility select a certified IDR entity, or if they fail to select a certified IDR entity, they must notify the Departments of their selection no later than 1 business day after such selection or failure to select. To the extent the non-initiating party does not believe that the Federal IDR process applies, the non-initiating party must also provide information that demonstrates the lack of applicability by the same date that the notice of selection or failure to select must be submitted. If the plan, issuer, or FEHB carrier and the nonparticipating provider or nonparticipating emergency facility fail to select a certified IDR entity, the Departments will select a certified IDR entity that charges a fee within the allowed range of IDR entity costs (or has received approval from the Departments to charge a fee outside of the allowed range) through a random selection method.

Additionally, no later than 10 business days after the date of selection of the certified IDR entity with respect to a payment determination for a qualified IDR item or service, the provider or facility and the plan or issuer must submit to the certified IDR entity an offer for a payment amount for the qualified IDR item or service furnished by such provider or facility though the Federal IDR portal. After the selected certified IDR entity has reviewed the offer, the certified IDR entity must notify the provider or facility and the plan, issuer, or FEHB carrier of the payment determination and the reason for such determination, in a form and manner specified by the Departments.

If the certified IDR entity does not choose the offer closest to the QPA, the certified IDR entity's written decision must include an explanation of the credible information that the certified IDR entity determined demonstrated that the QPA was materially different from the appropriate out-of-network rate, based on the permitted considerations, with respect to the qualified IDR item or service.

On October 7, 2021, the Office of Management and Budget (OMB) approved the information collection request (OMB Control Number 1210–0169) under the emergency procedures for review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35) and 5 CFR 1320.13. The approval is scheduled to expire on April 30, 2022.

Agency: Employee Benefits Security Administration, Department of Labor.

Title: Affordable Care Act Internal Claims and Appeals and External Review Procedures for ERISA Plans.

Type of Review: Extension of a currently approved collection of information.

OMB Number: 1210–0144.

Affected Public: Business or other for-profit; Not-for-profit institutions.

Respondents: 2,524,241.

Frequency of Responses: On occasion.

Responses: 381,826.

Estimated Total Burden Hours: 3,241.

Estimated Total Burden Cost (Operating and Maintenance): $1,627,679.

Description: The Patient Protection and Affordable Care Act, Public Law 111–148, (the Affordable Care Act or the Act) was enacted on March 23, 2010. As part of the Act, Congress added Public Health Service Act (the PHS Act) section 2719, which provides rules relating to internal claims and appeals and external review processes. The Departments issued final regulations (80 FR 72191) that set forth rules implementing PHS Act section 2719 for internal claims and appeals and external review processes. With respect to internal claims and appeals processes for group health coverage, PHS Act section 2719 and paragraph (b)(2)(i) of the interim final regulations provide that group health plans and health insurance issuers offering group health insurance coverage must comply with the internal claims and appeals processes set forth in 29 CFR 2560.503–1 (the DOL claims procedure regulation) and update such processes in accordance with standards established by the Secretary of Labor in paragraph (b)(2)(ii) of the regulations.

The DOL claims procedure regulation requires plans to provide every claimant who is denied a claim with a written or electronic notice that contains the specific reasons for denial, a reference to the relevant plan provisions on which the denial is based, a description of any additional information necessary to perfect the claim, and a description of steps to be taken if the participant or beneficiary wishes to appeal the denial. The regulation also requires that any adverse decision upon review be in writing (including electronic means) and include specific reasons for the decision, as well as references to relevant plan provisions. Paragraph (b)(2)(ii)(C) of the final regulations adds a requirement that non-grandfathered ERISA-covered group health plans provide to the claimant, free of charge, any new or additional evidence considered relied upon, or generated by the plan or issuer in connection with the claim. Also, PHS Act section 2719 and the final regulations provide that group health plans and issuers offering group health insurance coverage must comply either with a State external review process or a Federal review process. The regulations provide a basis for determining when plans and issuers must comply with an applicable State external review process and when they must comply with the Federal external review process.

The No Surprises Act of 2020 extends the balance billing protection related to external reviews to grandfathered plans. The definitions of group health plan and health insurance issuer that are cited in section 110 of the No Surprises Act include both grandfathered and non-grandfathered plans and coverage. Accordingly, the practical effect of section 110 of the No Surprises Act is that grandfathered health plans must provide external review for adverse benefit determinations involving benefits subject to these surprise billing protections.

On October 7, 2021, the Office of Management and Budget (OMB) approved the information collection request (OMB Control Number 1210–0144 under the emergency procedures for review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35) and 5 CFR 1320.13. The approval is scheduled to expire on April 30, 2022.

Agency: Employee Benefits Security Administration, Department of Labor.

Title: Opt-in State Balance Bill Process.

Type of Review: Extension of a currently approved collection of information.

OMB Number: 1210–0168.

Affected Public: Business or other for-profit; Not-for-profit institutions.

Respondents: 103.

Frequency of Responses: On occasion.

Responses: 103.

Estimated Total Burden Hours: 155.

Estimated Total Burden Cost (Operating and Maintenance): $54.

Description: The No Surprises Act was enacted as part of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260). The interim final rules allow plans to voluntarily opt in to state law that provides for a method for determining the cost-sharing amount or total amount payable under such a plan, where a state

has chosen to expand access to such plans, to satisfy their obligations under section 9816(a)–(d) of the Code, section 716(a)–(d) of ERISA, and section 2799A–1(a)–(d) of the PHS Act. A plan that has chosen to opt into a state law must prominently display in its plan materials describing the coverage of out-of-network services a statement that the plan has opted into a specified state law, identify the state (or states), and include a general description of the items and services provided by nonparticipating facilities and providers that are covered by the specified state law.

On September 22, 2021, the Office of Management and Budget (OMB) approved the information collection request (OMB Control Number 1210–0168 under the emergency procedures for review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35) and 5 CFR 1320.13. The approval is scheduled to expire on March 31, 2022.

II. Focus of Comments

The Department is particularly interested in comments that:

- Evaluate whether the collections of information are 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 collections 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.,* by permitting electronic submissions of responses.
- Evaluate the effectiveness of the additional demographic questions.

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

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

Signed at Washington, DC, this 29th day of October, 2021.

Ali Khawar,

Acting Assistant Secretary, Employee Benefits Security Administration, U.S. Department of Labor.

[FR Doc. 2021–24497 Filed 11–8–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF LABOR

Employee Benefits Security Administration

Agency Information Collection Activities; Request for Public Comment

AGENCY: Employee Benefits Security Administration (EBSA), Department of Labor.

ACTION: Notice.

SUMMARY: The Department of Labor (the Department), in accordance with the Paperwork Reduction Act, provides the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. The Employee Benefits Security Administration (EBSA) is soliciting comments on the proposed extension of the information collection requests (ICRs) contained in the documents described below. A copy of the ICRs may be obtained by contacting the office listed in the **ADDRESSES** section of this notice. ICRs also are available at reginfo.gov (*http://www.reginfo.gov/public/do/PRAMain*).

DATES: Written comments must be submitted to the office shown in the Addresses section on or before January 10, 2022.

ADDRESSES: James Butikofer, Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW, Room N–5718, Washington, DC 20210, or *ebsa.opr@dol.gov.*

SUPPLEMENTARY INFORMATION:

I. Current Actions

This notice requests public comment on the Department's request for extension of the Office of Management and Budget's (OMB) approval of ICRs contained in the rules and prohibited transaction exemptions described below. The Department is not proposing any changes to the existing ICRs at this time. An agency may not conduct or sponsor, and a person is not required to respond to, an information collection unless it displays a valid OMB control number. A summary of the ICRs and the current burden estimates follows:

Agency: Employee Benefits Security Administration, Department of Labor.

Title: Bank Collective Investment Funds, Prohibited Transaction Class Exemption 1991–38.

Type of Review: Extension of a currently approved collection of information.

OMB Number: 1210–0082.

Affected Public: Businesses or other for-profits, Not-for-profit institutions..

Respondents: 7,719.

Responses: 7,719.

Estimated Total Burden Hours: 1,287.

Estimated Total Burden Cost (Operating and Maintenance): $0.

Description: Prohibited Transaction Class Exemption (PTE) 91–38 provides an exemption from the restrictions of sections 406(a), 406(b)(2), and 407(a) of ERISA for certain transactions between a bank collective investment fund in which an employee benefit plan has invested assets and persons who are parties in interest to the employee benefit plan, as long as the plan's total participation in the collective investment fund does not exceed 10 percent of the total assets in the collective investment fund. In addition, the bank managing the common investment fund must not itself be a party in interest to the participating plan, the terms of the transaction must be at least as favorable to the collective investment fund as those available in an arm's length transaction with an unrelated party, and the bank must maintain records of the transactions for six years and make the records available for inspection to specified interested persons (including the Department and the Internal Revenue Service).

The information collections relates to recordkeeping and disclosure on request to the Department and other interested persons. The information collection requirements allow the Department, the Internal Revenue Service, and other interested persons to verify that the bank collective investment fund has complied with the conditions of the exemption. These conditions are necessary, as required under section 408(a) of ERISA, to ensure that respondents rely on the exemption only in the circumstances protective of plan participants and beneficiaries. The Department has received approval from OMB for this ICR under OMB Control No. 1210–0082. The current approval is scheduled to expire on April 30, 2022.

Agency: Employee Benefits Security Administration, Department of Labor.

Title: PTE 1990–1; Insurance Company Pooled Separate Accounts.

Type of Review: Extension of a currently approved collection of information.

OMB Number: 1210–0083.

Affected Public: Businesses or other for-profits.

Respondents: 102.

Responses: 1,020.

Estimated Total Burden Hours: 170.

Estimated Total Burden Cost (Operating and Maintenance): $0.

Description: Prohibited Transaction Class Exemption (PTE) 90–1 provides an exemption from the restrictions of section 406, in part, for certain transactions between insurance company pooled separate accounts and parties in interest to plans that invest assets in the pooled separate accounts. PTE 90–1 provides a general exemption for any transaction between a party in interest with respect to a plan and an insurance company pooled separate account in which the plan has an interest (or any acquisition or holding by the pooled separate account of employer securities or employer real estate), provided that the party in interest is not the insurance company (or an affiliate of the insurance company) and that the amount of the plan's investment in the separate account does not exceed certain specified percentages (or that the separate account is a specialized account with a policy of investing substantially all of its assets in short-term obligations).

PTE 90–1 also provides specific, additional relief for the following types of transactions with a party in interest: (1) Furnishing goods to an insurance company pooled separate account, (2) leasing of real property of the pooled separate account, (3) transactions involving persons who are parties in interest to a plan merely because they are service providers or provide nondiscretionary services to the plan; (4) the insurance company's provision of real property management services in connection with real property investments of the pooled separate account, and (5) furnishing of services, facilities and goods by a place of public accommodation owned by the separate account.

In addition to other specified conditions, the insurance company intending to rely on the general exemption or any of the specific exemptions must maintain records of the transactions to which the exemption applies for a period of six years and make the records available on request to specified interested persons (including plan fiduciaries, the Department, and the Internal Revenue Service). This information collection requirement is considered necessary in order to ensure that the exemption meets the standards of section 408(a) of ERISA. The Department has received approval from OMB for this ICR under OMB Control No. 1210–0083. The current approval is scheduled to expire on April 30, 2022.

Agency: Employee Benefits Security Administration, Department of Labor.

Title: Foreign Currency Transactions, Prohibited Transaction Class Exemption 1994–20.

Type of Review: Extension of a currently approved collection of information.

OMB Number: 1210–0085.

Affected Public: Businesses or other for-profits, Not-for-profit institutions.

Respondents: 243.

Responses: 1,215.

Estimated Total Burden Hours: 203.

Estimated Total Burden Cost (Operating and Maintenance): $0.

Description: PTE 94–20 permits banks, broker-dealers, and their affiliates that are parties in interest to a plan to engage in foreign currency transactions with the plan, provided the transaction is directed by a plan fiduciary independent of the bank, broker-dealer, and their affiliates and that certain other conditions are satisfied.

To protect the interests of participants and beneficiaries of the employee benefit plan, the exemption requires, among other things, that a bank, broker-dealer, and their affiliates wishing to rely on the exemption (1) maintain written policies and procedures applicable to trading in foreign currencies with an employee benefit plan; (2) provide a written confirmation statement of each foreign currency transaction to the independent plan fiduciary directing the transaction for the plan; and (3) maintain records of the transactions for a period of six years and make them available upon request to specified interested persons, including plan fiduciaries, participants and beneficiaries, the Internal Revenue Service, and the Department. The Department has received approval from OMB for this ICR under OMB Control No. 1210–0085. The current approval is scheduled to expire on April 30, 2022.

Agency: Employee Benefits Security Administration, Department of Labor.

Title: Settlement Agreements Between a Plan and a Party in Interest.

Type of Review: Extension of a currently approved collection of information.

OMB Number: 1210–0091.

Affected Public: Businesses or other for-profits.

Respondents: 4.

Responses: 1,080.

Estimated Total Burden Hours: 23.

Estimated Total Burden Cost (Operating and Maintenance): $275.

Description: This information collection request (ICR) relates to two prohibited transaction class exemptions (PTEs) that the Department has granted, both of which involve settlement agreements.

Granted on October 7, 1994, PTE 94–71 exempts from certain restrictions of ERISA and certain taxes imposed by the Code, a transaction or activity that is authorized, prior to the execution of the transaction or activity, by a settlement agreement resulting from an investigation of an employee benefit plan conducted by the Department. The following information collections are among the conditions for the exemption: (1) *Written Notice.* A party engaging in a settlement agreement arising out of a Department investigation must provide written notice to the affected participants and beneficiaries of the plan. The notice must contain an objective description of the transaction or activity, the approximate date on which the transaction will occur, the address of the regional or district office of the Department that negotiated the settlement agreement, and a statement informing participants and beneficiaries of their right to forward their comments to such office. (2) *Pre-Approval.* A copy of the notice and a description of the method by which it will be distributed must be approved in advance by the regional or district office of the Department which negotiated the settlement.

Granted on December 31, 2003, and later amended on June 15, 2010, PTE 2003–39 exempts from certain restrictions of ERISA and certain taxes imposed by the Code, transactions arising out of the settlement of litigation that involve the release of claims against parties in interest in exchange for payment by or on behalf of the party in interest, provided that certain conditions are met, such as the requirement of an independent fiduciary who has no relationship to any parties in the litigation to authorize the settlement. The other conditions include the following information collections: (1) *Written Agreement.* The terms of the settlement must be specifically described in a written agreement or consent decree. (2) *Acknowledgement by Fiduciary.* The fiduciary acting on behalf of the plan must acknowledge in writing that s/he

is a fiduciary with respect to the settlement of the litigation.

The Department has received approval from OMB for this ICR under OMB Control No. 1210–0091. The current approval is scheduled to expire on April 30, 2022.

Agency: Employee Benefits Security Administration, Department of Labor.

Title: Definition of Plan Assets—Participant Contributions.

Type of Review: Extension of a currently approved collection of information.

OMB Number: 1210–0100.

Affected Public: Businesses or other for-profits.

Respondents: 1.

Responses: 251.

Estimated Total Burden Hours: 8.

Estimated Total Burden Cost (Operating and Maintenance): $1,626.

Description: The Department's regulation at 29 CFR 2510.3–102 states that monies that a participant pays to, or has withheld by, an employer for contribution to an employee benefit plan become ''plan assets'' for purposes of Title I of ERISA and the related prohibited transaction provisions of the Internal Revenue Code (the Code) as of the earliest date on which such monies can be reasonably segregated from the employer's general assets. With respect to employee pension benefit plans, the regulation further sets a maximum time limit for such contributions: The 15th business day following the end of the month in which the participant contribution amounts are received or withheld by the employer. Under ERISA, ''plan assets'' cannot be held by the employer as part of its general assets, but must be contributed to the employee benefit plan to which they belong and, with few exceptions, held in trust. With respect to small plans (those with less than 100 participants), a safe harbor period exists under which participant contributions will be deemed to comply with the law if those amounts are deposited with the plan within seven business days of receipt or withholding.

The regulation includes a procedure through which an employer receiving or withholding participant contributions for an employee pension benefit plan may obtain a 10-business-day extension of the 15-day maximum time period if certain requirements, including information collection requirements, are met. The regulation requires, among other things, that the employer provide written notice to plan participants, within five business days after the end of the extension period and the employer's transfer of the contributions to the plan, which the employer elected to take the extension for that month. The notice must explain why the employer could not transfer the participant contributions within the maximum time period, state that the participant contributions in question have in fact been transmitted to the plan, and provide the date on which this was done. The employer must also provide a copy of the participant notice to the Secretary, along with a certification that the notice was distributed to participants and that the other requirements under the extension procedure were met, within five business days after the end of the extension period.

The Department has received approval from OMB for this ICR under OMB Control No. 1210–0100. The current approval is scheduled to expire on April 30, 2022.

Agency: Employee Benefits Security Administration, Department of Labor.

Title: Collective Investment Funds Conversion Transactions, Prohibited Transaction Class Exemption 1997–41.

Type of Review: Extension of a currently approved collection of information.

OMB Number: 1210–0104.

Affected Public: Businesses or other for-profits, Not-for-profit institutions..

Respondents: 50.

Responses: 105.

Estimated Total Burden Hours: 1,760.

Estimated Total Burden Cost (Operating and Maintenance): $508,282.

Description: Prohibited Transaction Class Exemption 97–41 permits an employee benefit plan to purchase shares of a registered open-end investment company (mutual fund) in exchange for plan assets transferred from a collective investment fund (CIF) maintained by a bank or plan adviser, even though the bank or plan adviser is the investment adviser for the mutual fund and also serves as a fiduciary for the plan, provided that the purchase and transfer is in connection with a complete withdrawal of the plan's investment in the CIF and certain other conditions are met.

Among other conditions, the exemption requires the bank or plan adviser to provide an independent fiduciary of the plan with advance written notice of the proposed transfer and full written disclosure of information concerning the mutual fund, including the current prospectus; disclosure of the investment advisory and other fees the plan will be charged or pay to the bank or any unrelated third party, including the nature and extent of any differential between the rates of the fees; the reasons why the bank or plan adviser considers the in-kind transfers appropriate for the plan; and a statement of whether there are any limitations applicable to the bank with respect to which plan assets may be invested in the mutual fund and, if so, the nature of such limitations; and the identity of securities that will have to be valued for the transfer. The independent fiduciary must give prior written approval of the transfer (and written approval of any electronic transmission of subsequent confirmations from the bank or plan adviser); and the bank or adviser must send written (or electronic, if approved) confirmation of the transfer. Subsequent to a transfer, the bank or plan adviser must provide the plan with updated prospectuses at least annually for mutual funds in which the plan remains invested; the bank or plan adviser must also provide, upon the independent fiduciary's request, a report or statement of all fees paid by the mutual fund to the bank or plan adviser, which may be in the form of the most recent financial report.

The Department has received approval from OMB for this ICR under OMB Control No. 1210–0104. The current approval is scheduled to expire on April 30, 2022.

Agency: Employee Benefits Security Administration, Department of Labor.

Title: Prohibited Transaction Class Exemption for Cross-Trades of Securities by Index and Model-Driven Funds (PTE 2002–12).

Type of Review: Extension of a currently approved collection of information.

OMB Number: 1210–0115.

Affected Public: Businesses or other for-profits.

Respondents: 60.

Responses: 840.

Estimated Total Burden Hours: 855.

Estimated Total Burden Cost (Operating and Maintenance): $1,146.

Description: PTE 2002–12 permits private-sector pension plans and the Federal Thrift Savings Plan to invest plan assets in certain types of investment funds that participate in passive or model-driven ''cross-trading'' (purchase and sale of securities) programs pursuant to objective criteria specified in the exemption. Cross-trades occur whenever a manager causes the purchase and sale of a particular security to be made directly between two or more investment funds under his/her management. If one or both of the funds contain invested assets of a pension plan, the cross-trade could constitute a prohibited transaction, in the absence of the exemption.

In order to grant a class exemption under section 408(a) of ERISA, section 8477(c)(3) of FERSA, and section

4975(c)(2) of the Code, the Department must determine that the exemption is administratively feasible, in the interest of the plan and its participants and beneficiaries, and protective of the rights of the participants and beneficiaries. In order to protect the participants and beneficiaries of plans that invest in cross-traded Funds, the Department included specific disclosure and recordkeeping requirements as conditions to the exemption. These information collections are designed to safeguard plan assets by requiring that managers relying on the exemption both periodically provide information on the cross-trading programs to independent plan fiduciaries and keep detailed records about cross-trades conducted in reliance on the exemption. The Department has received approval from OMB for this ICR under OMB Control No. 1210–0115. The current approval is scheduled to expire on April 30, 2022.

Agency: Employee Benefits Security Administration, Department of Labor.

Title: Voluntary Fiduciary Correction Program.

Type of Review: Extension of a currently approved collection of information.

OMB Number: 1210–0118.

Affected Public: Businesses or other for-profits.

Respondents: 1,621.

Responses: 207,209.

Estimated Total Burden Hours: 7,295.

Estimated Total Burden Cost (Operating and Maintenance): $551,111.

Description: This information collection arises from two related actions: The Voluntary Fiduciary Correction Program (the VFC Program or the Program) and Prohibited Transaction Class Exemption (PTE) 2002–51 (the VFC Exemption or the Exemption). The Department adopted the Program and the Exemption in order to encourage members of the public to voluntarily correct transactions that violate (or are suspected of violating) the fiduciary or prohibited transaction provisions of the Employee Retirement Income Security Act of 1974 (ERISA). The information collection provisions of the Program and the Exemption include third-party disclosures, recordkeeping, and disclosures to the Federal government, which enable the Department to oversee the appropriate use of the Program and the Exemption. The Department has received approval from OMB for this ICR under OMB Control No. 1210–0118. The current approval is scheduled to expire on April 30, 2022.

Title: Acquisition and Sale of Trust Real Estate Investment Trust Shares by Individual Account Plans Sponsored by Trust Real Estate Investment Trusts.

Type of Review: Extension of a currently approved collection of information.

OMB Number: 1210–0124.

Affected Public: Businesses or other for-profits.

Respondents: 69.

Responses: 144,900.

Estimated Total Burden Hours: 7,457.

Estimated Total Burden Cost (Operating and Maintenance): $459,333.

Description: Prohibited Transaction Exemption 2004–07 permits an individual account pension plan sponsored by a real estate investment trust (REIT) that is organized as a business trust under State law (Trust REIT), or by its affiliates, to purchase, hold and sell publicly traded shares of beneficial interest in the Trust REIT. The relief also covers contributions in-kind of REIT shares. Such purchases, holdings, and sales would otherwise be prohibited under sections 406 of ERISA and 4975 of the Code.

The class exemption requires, among other conditions, that the Trust REIT (or its agent) provide the person who has authority to direct acquisition or sale of REIT shares with the most recent prospectus, quarterly report, and annual report concerning the Trust REIT immediately before an initial investment in the Trust REIT. The person with such authority may be, under the terms of the plan, either an independent fiduciary or a participant exercising investment rights pertaining to his or her individual account under the plan. Updated versions of the reports must be provided to the directing person as subsequently published. The exemption further requires the plan to maintain records concerning investments in a Trust REIT, subject to appropriate confidentiality procedures, for a period of six years and make them available to interested persons including the Department and participants and beneficiaries. The confidentiality procedures must be designed to protect against the possibility that an employer may exert undue influence on participants regarding share-related transactions, and the participants and beneficiaries of the plan must be provided with a statement describing the confidentiality procedures in place and the fiduciary responsible for monitoring these procedures. The Department has received approval from OMB for this ICR under OMB Control No. 1210–0124. The current approval is scheduled to expire on April 30, 2022.

Title: Abandoned Individual Account Plan Termination, 404a–3.

Type of Review: Extension of a currently approved collection of information.

OMB Number: 1210–0127.

Affected Public: Businesses or other for-profits.

Respondents: 25,105.

Responses: 1,014,463.

Estimated Total Burden Hours: 37,680.

Estimated Total Burden Cost (Operating and Maintenance): $562,225.

Description: This information collections relates to the three regulations and exemption relate to terminating or abandoned plans and/or to distribution and rollover of distributed benefits for which no participant investment election has been made. The abandoned plan initiative includes the following actions, which impose the following information collections.

(1) The Qualified Termination Administrator (QTA) Regulation (29 CR 2578.1) creates an orderly and efficient process by which a financial institution that holds the assets of a plan that is deemed to have been abandoned may undertake to terminate the plan and distribute its assets to participants and beneficiaries holding accounts under the plan, with protections and approval of the Department under the standards of the regulation. The regulation requires the QTA to provide certain notices to the Department, to participants and beneficiaries, and to the plan sponsor (or service providers to the plan, if necessary), and to keep certain records pertaining to the termination.

(2) The Abandoned Plan Terminal Report Regulation (29 CFR 2520.103–11) regulation provides an alternative, simplified method for a QTA to satisfy the annual report requirement otherwise applicable to a terminating plan by filing a special simplified terminal report with the Department after terminating an abandoned plan and distributing its accounts to participants and beneficiaries.

(3) The Terminated Plan Distribution Regulation (29 CFR 2550.404a-3) regulation establishes a safe harbor method by which fiduciaries who are terminating individual account pension plans (whether abandoned or not) may select an investment vehicle to receive account balances distributed from the terminated plan when the participant has failed to provide investment instructions. The regulation requires the fiduciaries to provide advance notice to participants and beneficiaries of how such distributions will be invested, if no other investment instructions are provided.

(4) The Abandoned Plan Class Exemption (PTE 2006–06) permits a QTA that terminates an abandoned plan under the QTA regulation to receive payment for its services from the abandoned plan and to distribute the account balance of a participant who has failed to provide investment direction into an individual retirement account (IRA) maintained by the QTA or an affiliate. One of the conditions of the exemption requires that the QTA keep records of the distributions for a period of six years and make such records available on request to interested persons (including the Department and participants and beneficiaries). If a QTA wishes to be paid out of plan assets for services provided prior to becoming a QTA, the exemption requires the QTA to enter into a written agreement with a plan fiduciary or the plan sponsor prior to receiving payment and a copy of the agreement to be provided to the Department.

The Department has received approval from OMB for this ICR under OMB Control No. 1210–0127. The current approval is scheduled to expire on April 30, 2022.

Title: Genetic Information Nondiscrimination Act of 2008 Research Exception Notice.

Type of Review: Extension of a currently approved collection of information.

OMB Number: 1210–0136.

Affected Public: Not-for-profit institutions, Businesses or other for-profits.

Respondents: 24.

Responses: 24.

Estimated Total Burden Hours: 6.

Estimated Total Burden Cost (Operating and Maintenance): $83.

Description: The Genetic Information Nondiscrimination Act of 2008 (GINA), Public Law 110–233, was enacted on May 21, 2008. Title I of GINA amended the Employee Retirement Income Security Act of 1974 (ERISA), the Public Health Service Act (PHS Act), the Internal Revenue Code of 1986 (the Code), and the Social Security Act (SSA) to prohibit discrimination in health coverage based on genetic information. Sections 101 through 103 of Title I of GINA prevent employment-based group health plans and health insurance issuers in the group and individual markets from discriminating based on genetic information and from collecting such information. The interim final regulations, which are codified at 29 CFR 2590.702A, only interpret Sections 101 through 103 of Title I of GINA.

GINA and the interim final regulations (29 CFR 2590.702A(c)(5)) provide an exception to the limitations on requesting or requiring genetic testing that allows a group health plan or group health insurance issuer to request, but not require, a participant or beneficiary to undergo a genetic test if all of the following conditions of the research exception are satisfied.

(1) The request must be made pursuant to research that complies with 45 CFR part 46 (or equivalent Federal regulations) and any applicable State or local law or regulations for the protection of human subjects in research. To comply with the informed consent requirements of 45 CFR 46.116(a)(8), a participant must receive a disclosure that participation in the research is voluntary, refusal to participate cannot involve any penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at anytime without penalty or loss of benefits to which the participant is entitled (the Participant Disclosure). The interim final regulations provide that when the Participant Disclosure is received by participants when their informed consent is sought, no additional disclosures are required for purposes of the GINA research exception.

(2) The plan or issuer must make the request in writing and must clearly indicate to each participant or beneficiary (or in the case of a minor child, to the legal guardian of such beneficiary) to whom the request is made that compliance with the request is voluntary and noncompliance will have no effect on eligibility for benefits, premium, or contribution amounts.

(3) None of the genetic information collected or acquired as a result of the research may be used for underwriting purposes.

(4) The plan or issuer must complete a copy of the ''*Notice of Research Exception under the Genetic Information Nondiscrimination Act*'' (the Notice) and provide it to the address specified in its instructions.

The Department has received approval from OMB for this ICR under OMB Control No. 1210–0136. The current approval is scheduled to expire on April 30, 2022.

II. Focus of Comments

The Department is particularly interested in comments that:

- Evaluate whether the collections of information are 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 collections 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.,* by permitting electronic submissions of responses.
- Evaluate the effectiveness of the additional demographic questions.

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

Signed at Washington, DC, this 29th day of October, 2021.

Ali Khawar,

Acting Assistant Secretary, Employee Benefits Security Administration, U.S. Department of Labor.

[FR Doc. 2021–24498 Filed 11–8–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF LABOR

Employment and Training Administration

Workforce Information Advisory Council

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice of two virtual meetings in December 2021.

SUMMARY: Notice is hereby given that the Workforce Information Advisory Council (WIAC or Advisory Council) will meet for two days, virtually. Information for public attendance at the virtual meetings will be posted at *www.dol.gov/agencies/eta/wioa/wiac/meetings* several days prior to each meeting date. The meetings will be open to the public.

DATES: The meetings will take place December 1, 2021, and December 8, 2021. Each meeting will begin at 12:00 p.m. EST and conclude at approximately 4:00 p.m. EST. Public statements and requests for special accommodations or to address the Advisory Council must be received by November 29, 2021.

ADDRESSES: Information for public attendance at the virtual meetings will be posted at *www.dol.gov/agencies/eta/wioa/wiac/meetings* several days prior to each meeting date. If problems arise accessing the meetings, please contact

Donald Haughton, Unit Chief in the Division of National Programs, Tools, and Technical Assistance, Employment and Training Administration, U.S. Department of Labor, at 202–693–2784.

FOR FURTHER INFORMATION CONTACT: Steven Rietzke, Chief, Division of National Programs, Tools, and Technical Assistance, Employment and Training Administration, U.S. Department of Labor, Room C–4510, 200 Constitution Ave. NW, Washington, DC 20210; Telephone: 202–693–3912; Email: *WIAC@dol.gov.* Mr. Rietzke is the WIAC Designated Federal Officer.

SUPPLEMENTARY INFORMATION:

Background: These meetings are being held pursuant to Sec. 308 of the Workforce Innovation and Opportunity Act of 2014 (WIOA) (Pub. L. 113–128), which amends Sec. 15 of the Wagner-Peyser Act of 1933 (29 U.S.C. 491–2). The WIAC is an important component of the WIOA. The WIAC is a federal advisory committee of workforce and labor market information experts representing a broad range of national, State, and local data and information users and producers. The WIAC was established in accordance with provisions of the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. app.) and will act in accordance with the applicable provisions of FACA and its implementing regulation at 41 CFR 102–3. The purpose of the WIAC is to provide recommendations to the Secretary of Labor (Secretary), working jointly through the Assistant Secretary for Employment and Training and the Commissioner of Labor Statistics, to address: (1) The evaluation and improvement of the nationwide workforce and labor market information (WLMI) system and statewide systems that comprise the nationwide system; and (2) how the Department and the States will cooperate in the management of those systems. These systems include programs to produce employment-related statistics and State and local workforce and labor market information.

The Department of Labor anticipates the WIAC will accomplish its objectives by: (1) Studying workforce and labor market information issues; (2) seeking and sharing information on innovative approaches, new technologies, and data to inform employment, skills training, and workforce and economic development decision making and policy; and (3) advising the Secretary on how the workforce and labor market information system can best support workforce development, planning, and program development. Additional information is available at *www.dol.gov/agencies/eta/wioa/wiac/meetings.*

Purpose: The WIAC is currently in the process of identifying and reviewing issues and aspects of the WLMI system and statewide systems that comprise the nationwide system and how the Department and the States will cooperate in the management of those systems. As part of this process, the Advisory Council meets to gather information and to engage in deliberative and planning activities to facilitate the development and provision of its recommendations to the Secretary in a timely manner.

Agenda: The agenda topics for the December 1, 2021 meeting are: (1) Review and approve minutes from the previous meeting, (2) review and discuss the sub-committee work on identifying and collecting information on skills, (3) develop a set of recommendations regarding skills, (4) comment period for the general public, and (5) other business as needed. The agenda topics for the December 8, 2021 meeting are: (1) Review and approve minutes from the previous meeting, (2) review and discuss the sub-committee work on data sharing, (3) develop a set of recommendations regarding data sharing, (4) comment period for the general public, and (5) other business as needed. A detailed agenda will be available at *www.dol.gov/agencies/eta/wioa/wiac/meetings* shortly before the meetings commence.

The Advisory Council will open the floor for public comment at approximately 2:30 p.m. EST on for both meeting dates, for approximately 10 minutes. However, that time may change at the WIAC chair's discretion.

Attending the meetings: Members of the public who require reasonable accommodations to attend any of the meetings may submit requests for accommodations via email to the email address indicated in the **FOR FURTHER INFORMATION CONTACT** section with the subject line ''December 2021 WIAC Meeting Accommodations'' by the date indicated in the **DATES** section. Please include a specific description of the accommodations requested and phone number or email address where you may be contacted if additional information is needed to meet your request.

Public statements: Organizations or members of the public wishing to submit written statements may do so by mailing them to the person and address indicated in the **FOR FURTHER INFORMATION CONTACT** section by the date indicated in the **DATES** section or transmitting them as email attachments in PDF format to the email address indicated in the **FOR FURTHER INFORMATION CONTACT** section with the subject line ''December 2021 WIAC Meeting Public Statements'' by the date indicated in the **DATES** section. Submitters may include their name and contact information in a cover letter for mailed statements or in the body of the email for statements transmitted electronically. Relevant statements received before the date indicated in the **DATES** section will be included in the record of each meeting. No deletions, modifications, or redactions will be made to statements received, as they are public records. Please do not include personally identifiable information in your public statement.

Requests to Address the Advisory Council: Members of the public or representatives of organizations wishing to address the Advisory Council should forward their requests to the contact indicated in the **FOR FURTHER INFORMATION CONTACT** section, or contact the same by phone, by the date indicated in the **DATES** section. Oral presentations will be limited to 10 minutes, time permitting, and shall proceed at the discretion of the Advisory Council chair. Individuals with disabilities, or others who need special accommodations, should indicate their needs along with their request.

Angela Hanks,

Acting Assistant Secretary for Employment and Training Administration.

[FR Doc. 2021–24494 Filed 11–8–21; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Roof Control Plan for Underground Coal Mines

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Mine Safety and Health Administration (MSHA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before December 9, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this

notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Crystal Rennie by telephone at 202–693–0456 or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: In order to prevent occupational injuries resulting from falls of roofs, faces, and ribs, which are a leading cause of injuries and death in underground coal mines, all underground coal mine operators are required to develop and submit roof control plans to MSHA for evaluation and approval. These plans are evaluated to determine if they are adequate for prevailing mining conditions. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on July 6, 2021 (86 FR 35538).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–MSHA.

Title of Collection: Roof Control Plan for Underground Coal Mines.

OMB Control Number: 1219–0004.

Affected Public: Private Sector: Businesses or other for-profits.

Total Estimated Number of Respondents: 145.

Total Estimated Number of Responses: 896.

Total Estimated Annual Time Burden: 4,513 hours.

Total Estimated Annual Other Costs Burden: $2,490.

Authority: 44 U.S.C. 3507(a)(1)(D).

Crystal Rennie,

Senior PRA Analyst.

[FR Doc. 2021–24495 Filed 11–8–21; 8:45 am]

BILLING CODE 4510–43–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2011–0747]

Standard on Blasting Operations and the Use of Explosives; Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration, Labor.

ACTION: Request for public comment.

SUMMARY: OSHA solicits public comments concerning the proposal to the Office of Management and Budget's (OMB) approval of the information collection requirements specified in the Standard on Blasting Operations and the Use of Explosives.

DATES: Comments must be submitted (postmarked, sent, or received) by January 10, 2022.

ADDRESSES:

Electronically: You may submit comments, including attachments, electronically at *http://www.regulations.gov,* the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Docket: To read or download comments or other material in the docket, go to *http://www.regulations.gov.* Documents in the docket are listed in the *http://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download through the website. All submissions, including copyrighted material, are available for inspection through the OSHA Docket Office. Contact the OSHA Docket Office at (202) 693–2350 (TTY (877) 889–5627) for assistance in locating docket submissions.

Instructions: All submissions must include the agency name and the OSHA docket number for this **Federal Register** notice (OSHA–2011–0747). OSHA will place comments and requests to speak, including personal information, in the public docket, which may be available online. Therefore, OSHA cautions interested parties about submitting personal information such as Social Security numbers and birthdates. For further information on submitting comments, see the ''Public Participation'' heading in the section of this notice titled **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Seleda Perryman or Theda Kenney, 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 the 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, reporting burden (time and costs) is minimal, 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 OSH Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657). The OSH Act also requires that OSHA obtain such information with minimum burden upon employers, especially those operating small businesses, and to reduce to the maximum extent feasible unnecessary duplication of effort in obtaining information (29 U.S.C. 657).

The Standard on Blasting and the Use of Explosives (29 CFR part 1926, subpart U) specifies a number of paperwork requirements. The following is a brief description of the collection of information requirements contained in the Subpart.

General Provisions (§ 1926.900)

§ 1926.900(d)—Paragraph (d) states that employers must ensure that explosives not in use are kept in a locked magazine, unavailable to persons not authorized to handle explosives. The employers must maintain an inventory and use record of all explosives—in use and not in use. In addition, the employer must notify the appropriate authorities in the event of any loss, theft, or unauthorized entry into a magazine.

§ 1926.900(k)(3)(i)—Paragraph (k)(3)(i) requires employers to display adequate signs warning against the use of mobile radio transmitters on all roads within 1,000 feet of blasting operations to prevent the accidental discharge of electric blasting caps caused by current induced by radar, radio transmitters, lighting, adjacent power lines, dust storms, or other sources of extraneous electricity. The employer must certify and maintain a record of alternative provisions made to adequately prevent any premature firing of electric blasting caps.

§ 1926.900(o)—Employers must notify the operators and/or owners of overhead power lines, communication lines, utility lines, or other services and structures when blasting operations will take place in proximity to those lines, services, or structures.

§ 1926.903(d)—The employer must notify the hoist operator prior to transporting explosives or blasting agents in a shaft conveyance.

§ 1926.903(e)—Employers must perform weekly inspections on the electrical system of trucks used for underground transportation of explosives. The weekly inspection is to detect any failure in the system which would constitute an electrical hazard. The most recent certification of inspection must be maintained and must include the date of inspection, a serial number or other identifier of the truck inspected, and the signature of the person who performed the inspection.

§ 1926.905(t)—The employer blaster must maintain an accurate and up-to-date record of explosives, blasting agents, and blasting supplies used in a blast. The employer must also maintain an accurate running inventory of all explosives and blasting agents stored on the operation.

§ 1926.909(a)—Employers must post a code of blasting agents on one or more conspicuous places at the operation. All employees also shall familiarize themselves with the code and conform to it at all times. Danger signs warning of blasting agents shall also be placed at suitable locations.

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 approve the information collection requirements contained in the OSHA Standard on Blasting and the Use of Explosives (29 CFR part 1926, subpart U).

Type of Review: Extension of currently approved collection.

Title: Blasting and the Use of Explosives (29 CFR part 1926, subpart U).

OMB Control Number: 1218–0217.

Affected Public: Business or other for-profits.

Number of Respondents: 193.

Frequency of Responses: On occasion.

Average Time per Response: Various.

Estimated Total Burden Hours: 1,602.

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) at (202) 693–1648; or (3) by hard copy. All comments, attachments, and other materials must identify the agency name and the OSHA docket number for the ICR (Docket No. OSHA–2011–0747). You may supplement electronic submissions by uploading document files electronically. *Please note:* While OSHA's Docket Office is continuing to accept and process submissions by regular mail, due to the COVID–19 pandemic, the Docket Office is closed to the public and not able to receive submissions to the docket by hand, express mail, messenger, and courier service. 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.

Because of security procedures, the use of regular mail may cause a significant delay in the receipt of comments.

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 date 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 through 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 through the website, and for assistance in using the internet to locate docket submissions.

V. Authority and Signature

James S. Frederick, Acting 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 2, 2021.

James S. Frederick,

Acting Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2021–24500 Filed 11–8–21; 8:45 am]

BILLING CODE 4510–26–P

LIBRARY OF CONGRESS

Copyright Office

[Docket No. 2021–5]

Publishers' Protections Study: Request for Additional Comments

AGENCY: Copyright Office, Library of Congress.

ACTION: Notice of inquiry.

SUMMARY: The U.S. Copyright Office seeks further comments on the

effectiveness of copyright protections for publishers, with a focus on press publishers. This request provides an opportunity for interested parties to raise new issues related to the topic of the study, amplify initial comments, present empirical studies, or to address, reply to, or expand upon any issues raised in the initial request for written comments—responses to which are due on or before November 26, 2021—or during the virtual public roundtable, which will be held on December 9, 2021. On November 29, 2021, the Office will post a link at *https://copyright.gov/policy/publishersprotections/* through which parties can submit second-round comments.

DATES: Additional comments are due on or before January 5, 2022.

ADDRESSES: The Copyright Office is using the *regulations.gov* system for the submission and posting of public comments in this proceeding. All comments are therefore to be submitted electronically through *regulations.gov.* Specific instructions are available on the Copyright Office website at *http://www.copyright.gov/policy/publishersprotections/*. If electronic submission of comments is not feasible due to lack of access to a computer and/or the internet, please contact the Office using the contact information below, for special instructions.

FOR FURTHER INFORMATION CONTACT: Kimberley Isbell, Deputy Director of Policy and International Affairs, at *kisbell@copyright.gov,* or Andrew Foglia, Senior Counsel for Policy and International Affairs, at *afoglia@copyright.gov.* Both can be reached by telephone at 202–707–8350.

SUPPLEMENTARY INFORMATION: The United States Copyright Office is undertaking a public study at the request of Congress to evaluate current copyright protections for publishers. Among other issues, the Office is considering the effectiveness of publishers' existing rights in news content, including under the provisions of title 17 of the U.S. Code, as well as other federal and state laws; whether additional protections are desirable or appropriate; the possible scope of any such new protections, including how their beneficiaries could be defined; and how any such protections would interact with existing rights, exceptions and limitations, and international treaty obligations. On October 12, 2021, the Office published an initial request for comments on several questions related to these issues. It also announced that it would hold a virtual public roundtable on the same topics on December 9, 2021.

In the interests of gathering the fullest possible record on the question of copyright protections for publishers, with a focus on press publishers, the Office is now announcing an additional round of comments, responses to which are due on or before January 5, 2022. On November 29, 2021, the Office will post a link at *https://copyright.gov/policy/publishersprotections/* through which parties can submit second-round comments. Comments submitted in this second round may address the same questions set forth in the October 12 notice, or any other issues related to the topic of the study. In submitting second-round comments, parties may raise new issues, amplify their initial comments, present empirical studies, or address, reply to, or expand upon any issues raised in the initial request for written comments or at the December 9, 2021 virtual public roundtable. As with the initial comments, the Office requests that parties submitting second-round comments identify their affiliation and the factual or legal basis for their responses.

Please note that the issuance of this notice does not mean that the deadline for submission of initial comments has expired. Initial comments may still be submitted through November 26, 2021. Additionally, a party does not have to have submitted initial comments or participated in the roundtable in order to submit second-round comments.

Dated: November 4, 2021.

Shira Perlmutter,

Register of Copyrights and Director of the U.S. Copyright Office.

[FR Doc. 2021–24506 Filed 11–8–21; 8:45 am]

BILLING CODE 1410–30–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Office of Government Information Services

[NARA–2022–008]

Meeting Announcement; Chief Freedom of Information Act (FOIA) Officers Council

AGENCY: Office of Government Information Services (OGIS), National Archives and Records Administration (NARA), and Office of Information Policy (OIP), Department of Justice (DOJ).

ACTION: Notice of meeting.

SUMMARY: We are announcing a meeting of the Chief Freedom of Information Act (FOIA) Officers Council, co-chaired by the Director of OGIS and the Director of OIP.

DATES: The meeting will be on Wednesday November 17, 2021, from 10:00 a.m. to 12:30 p.m. EST. Please register for the meeting no later than 11:59 p.m. EST on Monday, November 15, 2021 (registration information is detailed below).

Location: The November 17, 2021, meeting will be a virtual meeting. We will send access instructions to those who register according to the instructions below.

FOR FURTHER INFORMATION CONTACT: Martha Murphy, by email at *ogis@nara.gov* with the subject line ''Chief FOIA Officers Council,'' or by telephone at 202.741.5770.

SUPPLEMENTARY INFORMATION: This meeting is open to the public in accordance with the Freedom of Information Act (5 U.S.C. 552(k)). Additional details about the meeting, including the agenda, will be available on OGIS's website at *https://www.archives.gov/ogis/about-ogis/chief-foia-officers-council* and OIP's website at *https://www.justice.gov/oip/chief-foia-officers-council.*

Procedures: This virtual meeting is open to the public. You must register through Eventbrite at *https://cfo-council-meeting-nov-17-2021.eventbrite.com* in advance if you wish to submit oral statements. You must include an email address so that we can provide you access information. We will also live-stream the meeting on the National Archives' YouTube channel at *https://www.youtube.com/user/usnationalarchives,* and include a captioning option. To request additional accommodations (*e.g.,* a transcript), email *ogis@nara.gov* or call 202–741–5770. Members of the media who wish to register, those who are unable to register online, and those who require special accommodations, should contact Martha Murphy (contact information listed above).

Alina M. Semo,

Director, Office of Government Information Services.

[FR Doc. 2021–24395 Filed 11–8–21; 8:45 am]

BILLING CODE 7515–01–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, 2021.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2021–24450 Filed 11–8–21; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Privacy Act of 1974; System of Records

AGENCY: National Science Foundation.

ACTION: Notice of a new system of records.

SUMMARY: The National Science Foundation (NSF) is creating a new system of records: NSF–77 Data Analytics Application Suite. This system is a vital step in NSF's commitment to maintaining U.S. leadership across all fields of science, technology, engineering, mathematics (STEM), and STEM education, and doing so with efficiency, openness, and transparency. The new system of records will aggregate, link, and analyze information reported by individuals and organizations participating in NSF-supported activities along with published information related to the research enterprise. More comprehensive information on NSF-funded research outcomes and the STEM workforce will advance NSF's understanding of its return on investments and the evolution of the scientific landscape. This system will also enable NSF to uphold the scientific community's core values of openness, transparency, honesty, equity, fair competition, and objectivity.

DATES: Persons wishing to comment on the changes set out in this notice may do so on or before December 9, 2021.

Effective Date: This action will be effective without further notice on December 9, 2021 unless modified by subsequent notice to incorporate comments received from the public.

ADDRESSES: You may submit comments, identified by [INSERT DOCKET NUMBER] by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email:* The Chief Data Officer, Dorothy Aronson, at *daronson@nsf.gov.* Include [INSERT DOCKET NUMBER] in the subject line of the message.
- *Mail:* Dorothy Aronson, Chief Data Officer, Office of Information and Resource Management, National Science Foundation, 2415 Eisenhower Ave., Alexandria, VA 22331.

Instructions: NSF will post all comments on the NSF's website (*https://www.nsf.gov/policies/privacy_act.jsp*). All comments submitted in response to this Notice will become a matter of public record. Therefore, you should submit only information that you wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: If you wish to submit general questions about the proposed new system of records NSF–77, please contact Dorothy Aronson, Chief Data Officer, at *daronson@nsf.gov.*

SUPPLEMENTARY INFORMATION: As part of the current proposal review and funding process, Principal Investigators (PIs) and other senior personnel already provide their biographic information (''Biographical Sketch''), Current and Pending Support information, and Collaborator and Other Affiliation information in their proposal submissions to NSF. PIs are also required to submit annual project reports describing funded activities. These researcher-supplied details would be matched to scientific literature from scientific journals along with public information on patent grants supplied by the U.S. Patent Office (USPTO).

SYSTEM NAME AND NUMBER:

Data Analytics Application Suite, NSF–77.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

National Science Foundation; 2415 Eisenhower Ave.; Alexandria, VA 22314.

SYSTEM MANAGER(S):

The Data Analytics Application Suite will be overseen by the Chief Data Officer.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Data Analytics Application Suite is critical for NSF to appropriately collect, combine, and utilize information obtained from individuals who interact with NSF and information that is publicly available to meet NSF's analysis and evaluation requirements consistent with the following Executive Order and laws: Foundations for Evidence-Based Policymaking Act of 2018 Evidence (44 U.S.C. 3520); Federal Data Strategy (OMB, Memorandum 19–18, 19–23); Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking (EOP, 86 FR 8845); National Defense Authorization Act FY20 (Pub. L. 116–92 Sec. 1746); and the National Science Foundation Act of 1950 (Pub. L. 507–81).

PURPOSE(S) OF THE SYSTEM:

The purpose of this system is to enhance NSF's capabilities to collect and analyze data about the scientific research enterprise (participants, outputs, and outcomes) to better assess the effectiveness of NSF's programs and inform funding and policy decisions.

This mission-critical challenge requires gold standard data and analytic techniques such as bibliometrics and network analysis that build upon pre-existing information provided by individuals who interact with NSF, as described in SORNs NSF–12, NSF–50, NSF–51, and NSF–59. These systems collect proposal, participant, fellowship, and reviewer information, and can be paired in the Data Analytics Application Suite with public publication records, patent information, co-author connections and other related information (see categories). Such pairing of information is necessary for NSF to understand on an organizational, national, and global level the outcomes of its grants to the research community.

Information collected in the Data Analytics Application Suite may be utilized for the following purposes:

(1) To empower NSF's portfolio management and merit review process by providing program officers and leadership with analytics tools that enhance their understanding of existing decision criteria, PI capacity and potential overlap/duplication of proposals and awards.

(2) To evaluate impact and return on investment of awards.

(3) To provide necessary analyses for strategic priorities such as science and research integrity, security, equity, and partnerships.

(4) To understand the dynamics of the global scientific landscape, explore opportunities for investment and collaboration, and inform research conducted for NSF.

(5) To support NSF's function as a leading federal agency for graduate student funding by tracking career development, mentorship, and outcomes of education grants and other training activities.

(6) To merge internal data to facilitate agency organizational efficiency and portfolio analysis.

(7) To identify inconsistencies in information reported by individuals to NSF related to submitted proposals, terms and conditions, and project reports of an NSF award or other funding opportunity.

(8) To inform pre-onboarding and onboarding evaluations of NSF staff. For the purpose of this SORN, 'staff' applies to NSF employees, contractors, Intergovernmental Personnel Act (IPA) assignees, and Visiting Scientists, Engineers, and Educators (VSEEs), as well as fellows and interns.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The system will include information on the following groups of individuals: PIs and senior personnel submitting proposals to NSF; graduate students, postdoctoral researchers and undergraduate students who have either participated in NSF funded research, or received funding from NSF; fellows funded by NSF; researchers who have published academic articles or other related material in the public domain; individuals who publish media related to science and technology; individuals who publicly report work and titles in science and technology related sectors (industry, non-profits, education, governments).

CATEGORIES OF RECORDS IN THE SYSTEM:

Records will be collected to connect NSF proposals, award, and participant information to dimensions including publication record and career development. Combined, the Data Analytics Application Suite will include the following: Proposal and award information; annual and final project reports; research participants supported under NSF grants; research articles, conference presentations, reviews, protocols, datasets, and other DOI-citable S&T materials created by the author; co-author connections; citations of other papers present in the author's publications as well as citations of the item by future publications; funded awards from other agencies that have supported the author's work; patents filed; job positions and titles obtained, as displayed in public platforms; undergraduate, graduate and postdoctoral training; academic, professional and institutional appointments; mainstream articles and other media sources; publication content (abstract, grant acknowledgement, etc.)

RECORD SOURCE CATEGORIES:

Proposal and fellowship Information is supplied by individuals at time of proposal submission. In the case of awardees, updates are submitted annually to NSF in the form of annual and final project reports. Publication and patent information published by PIs will be obtained from third parties that compile related public information. Such resources include, but are not limited to, Clarivate (Web of Science), Elsevier (Scopus), Dimensions, USPTO, PubMed, arxiv databases, ORCID, and Google Scholar.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

The following NSF standard routine uses apply:

1. *Members of Congress.* Information from a system may be disclosed to congressional offices in response to inquiries from the congressional offices made at the request of the individual to whom the record pertains.

2. *Freedom of Information Act/ Privacy Act Compliance.* Information from a system may be disclosed to the Department of Justice or the Office of Management and Budget in order to obtain advice regarding NSF's obligations under the Freedom of Information Act and the Privacy Act.

3. *Counsel.* Information from a system may be disclosed to NSF's legal representatives, including the Department of Justice and other outside counsel, where the agency is a party in litigation or has an interest in litigation, including when any of the following is a party to litigation or has an interest in such litigation: (a) NSF, or any component thereof; (b) any NSF employee in his or her official capacity; (c) any NSF employee in his or her individual capacity, where the Department of Justice has agreed to, or is considering a request to, represent the employee; or (d) the United States, where NSF determines that litigation is likely to affect the agency or any of its components.

4. *National Archives, General Services Administration.* Information from a system may be disclosed to representatives of the General Services Administration and the National Archives and Records Administration (NARA) during the course of records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906.

5. *Response to an Actual or Suspected Compromise or Breach of Personally Identifiable Information.* Information from a system may be disclosed to appropriate agencies, entities, and persons when (a) NSF suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised; (b) NSF has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by NSF or another agency or entity) that rely upon the compromised information; and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist with NSF's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

6. *Courts.* Information from a system may be disclosed to the Department of Justice or other agencies in the event of a pending court or formal administrative proceeding, when records are relevant to that proceeding, for the purpose of representing the government, or in the course of presenting evidence, or they may be produced to parties or counsel involved in the proceeding in the course of pre-trial discovery.

7. *Contractors.* Information from a system may be disclosed to contractors, agents, experts, consultants, or others performing work on a contract, service, cooperative agreement, job, or other activity for NSF and who have a need to access the information in the performance of their duties or activities for NSF.

8. *Audit.* Information from a system may be disclosed to government

agencies and other entities authorized to perform audits, including financial and other audits, of the agency and its activities.

9. *Law Enforcement.* Information from a system may be disclosed to appropriate federal, state, or local agencies responsible for investigating, prosecuting, enforcing, or implementing a statute, rule, regulation, or order, to disclose pertinent information when NSF becomes aware of an indication of a violation or potential violation of civil or criminal law or regulation.

10. *Disclosure When Requesting Information.* Information from a system may be disclosed to federal, state, or local agencies which maintain civil, criminal, or other relevant enforcement information or other pertinent information, such as current licenses, if necessary, to obtain information relevant to an agency decision concerning the hiring or retention of an employee, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant, or other benefit.

11. *To the news media and the public when:* (1) A matter has become public knowledge, (2) the NSF Office of the Director determines that disclosure is necessary to preserve confidence in the integrity of NSF or is necessary to demonstrate the accountability of NSF's officers, employees, or individuals covered by this system, or (3) the Office of the Director determines that there exists a legitimate public interest in the disclosure of the information, except to the extent that the Office of the Director determines in any of these situations that disclosure of specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

12. Information obtained from the system that demonstrate a potential inconsistency with NSF's disclosure requirements for submitted proposals, terms and conditions of an NSF award, and project reports, may be shared with the organizations that submitted the proposal to cross-reference and verify information.

13. Information obtained from the system that demonstrate an inconsistency with NSF's disclosure requirements for submitted proposals, terms and conditions of an award, and project reports, may be disclosed to appropriate federal agencies to inform efforts related to national and research security. This includes law enforcement, security, and intelligence agencies, or relevant agency components. This includes OIG, FBI, CIA, DOD, DOJ, DHS, FDA, NSA, DIA, NRO, and ODNI. Additionally, information may be disclosed to federal agencies contributing to cross-governmental forums on research security such as the National Science and Technology Council Subcommittee on Research Security (OSTP, NIH, DOE, NASA, NIST, NOAA, USGS, FDA, OMB, NSC, USPTO, EPA, DOT, DoEd, USDA, DOS). All inconsistencies will be verified according to internal guidelines and review processes. For the purpose of this routine use, personally identifiable information shared with agencies will be restricted to information about senior personnel only and coordinated with the Office of the Inspector General (OIG).

14. Information from the system may be shared with federal science and technology agencies to improve portfolio management, coordinate initiatives, and enhance the government's understanding of the scientific landscape.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are stored on electronic digital media. NSF proposal information, product information including publication and patent information, and Data Analytics Application Suite outputs will be located on secure NSF servers managed by the Division of Information Systems (DIS). The storage and integrity of public bibliometric and patent information is the responsibility of external vendors (*e.g.,* Clarivate/Elsevier) and USPTO.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Information of individuals who interact with NSF will be retrieved by the individual's name, email, persistent identifiers (*e.g.,* ORCID), or NSF identifier (NSF ID).

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Data will be retained according to the General Records Schedules 1.2, item 030, and 5.6, item 170.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

All data are maintained on NSF internal servers, which are managed under federal security protocols. The public bibliometric data and USTPO patent information is also stored in the same security certified environment.

RECORD ACCESS PROCEDURES:

Individuals seeking to access their record information stored on the Data Analytics Application Suite are required to follow the procedures found at 45 CFR part 613.

CONTESTING RECORD PROCEDURES:

Individuals seeking to contest their record information generated by the Data Analytics Application Suite are required to follow the procedures found at 45 CFR part 613.

NOTIFICATION PROCEDURES:

Individuals request access or contesting records with the Data Analytics Application Suite will be notified according to the procures found at 45 CFR part 613.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

Dated: November 4, 2021.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2021–24487 Filed 11–8–21; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

691st Meeting of the Advisory Committee on Reactor Safeguards (ACRS)

In accordance with the purposes of Sections 29 and 182b of the Atomic Energy Act (42 U.S.C. 2039, 2232(b)), the Advisory Committee on Reactor Safeguards (ACRS) will hold meetings on November 30–December 3, 2021. As part of the coordinated government response to combat the COVID–19 public health emergency, the Committee will be conducting meetings that will include some Members being physically present at the NRC while other Members will be participating remotely. The public will be able to participate in any open sessions via 301–576–2978, passcode 707 083 531#. A more detailed agenda may be found at the ACRS public website at *https://www.nrc.gov/reading-rm/doc-collections/acrs/agenda/index.html.*

Tuesday, November 30, 2021

8:30 a.m.–8:35 a.m.: Opening Remarks by the ACRS Chairman (Open)—The ACRS Chairman will make opening remarks regarding the conduct of the meeting.

8:35 a.m.–10:00 a.m.: Kairos TR, ''KP–FHR Mechanistic Source Term Methodology Topical Report'' (Open/Closed)—The Committee will have presentations and discussion with representatives from the NRC and Kairos staff regarding the subject topic. [*Note: Pursuant to 5 U.S.C. 552b(c)(4), a*

portion of this session may be closed in order to discuss and protect information designated as proprietary.]

10:00 a.m.–11:30 a.m.: Committee Deliberation on Kairos TR, ''KP–FHR Mechanistic Source Term Methodology Topical Report'' (Open/Closed)—The Committee will deliberate regarding the subject topic. [*Note: Pursuant to 5 U.S.C. 552b(c)(4), a portion of this session may be closed in order to discuss and protect information designated as proprietary.*]

1:00 p.m.–3:00 p.m.: Draft Guide (DG)-5061, Revision 1, ''Cyber Security Programs for Nuclear Power Reactors'' (Open)—The Committee will have presentations and discussion with representatives from the NRC staff regarding the subject topic.

3:15 p.m.–4:15 p.m.: Committee Deliberation on Proposed DG–5061, Revision 1, ''Cyber Security Programs for Nuclear Power Reactors'' (Open)—The Committee will deliberate regarding the subject topic.

4:15 p.m.–5:00 p.m.: Preparation of Reports (Open/Closed)—The Committee will continue its discussion of proposed ACRS reports. [*Note: Pursuant to 5 U.S.C. 552b(c)(4), a portion of this session may be closed in order to discuss and protect information designated as proprietary.*]

Wednesday, December 1, 2021

8:30 a.m.–10:00 a.m.: Research Information Letter (RIL) for Fuel Fragmentation, Relocation and Dispersal during LOCA (Open/Closed)—The Committee will have presentations and discussion with representatives from the NRC staff regarding the subject topic. [*Note: Pursuant to 5 U.S.C. 552b(c)(4), a portion of this session may be closed in order to discuss and protect information designated as proprietary.*]

10:00 a.m.–11:00 a.m.: Committee Deliberation on RIL for Fuel Fragmentation, Relocation and Dispersal during LOCA (Open/Closed)—The Committee will deliberate regarding the subject topic. [*Note: Pursuant to 5 U.S.C. 552b(c)(4), a portion of this session may be closed in order to discuss and protect information designated as proprietary.*]

1:00 p.m.–2:30 p.m.: Biennial Report on Research Program (Open)—The Committee will have presentations and discussion with representatives from the NRC staff regarding the subject topic.

2:30 p.m.–5:00 p.m.: Preparation of Reports (Open/Closed)—The Committee will continue its discussion of proposed ACRS reports. [*Note: Pursuant to 5 U.S.C. 552b(c)(4), a portion of this session may be closed in order to discuss and protect information designated as proprietary.*]

Thursday, December 2, 2021

8:30 a.m.–12:00 p.m.: Future ACRS Activities/Report of the Planning and Procedures Subcommittee and Reconciliation of ACRS Comments and Recommendations/Preparation of Reports (Open/Closed)—The Committee will hear discussion of the recommendations of the Planning and Procedures Subcommittee regarding items proposed for consideration by the Full Committee during future ACRS meetings, and/or proceed to preparation of reports as determined by the Chairman. [*Note:* Pursuant to 5 U.S.C. 552b(c)(4), a portion of this session may be closed in order to discuss and protect information designated as proprietary.] [*Note: Pursuant to 5 U.S.C. 552b(c)(2)and (6), a portion of this meeting may be closed to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of the ACRS, and information the release of which would constitute a clearly unwarranted invasion of personal privacy.*].

2:00 p.m.–5:00 p.m.: Preparation of Reports (Open/Closed)—The Committee will continue its discussion of proposed ACRS reports. [*Note: Pursuant to 5 U.S.C. 552b(c)(4), a portion of this session may be closed in order to discuss and protect information designated as proprietary.*]

Friday, December 3, 2021

8:30 a.m.–5:00 p.m.: Preparation of Reports (Open/Closed)—The Committee will continue its discussion of proposed ACRS reports and Commission Meeting preparation. [*Note: Pursuant to 5 U.S.C. 552b(c)(4), a portion of this session may be closed in order to discuss and protect information designated as proprietary.*]

Procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on June 13, 2019 (84 FR 27662). In accordance with those procedures, oral or written views may be presented by members of the public, including representatives of the nuclear industry. Persons desiring to make oral statements should notify Quynh Nguyen, Cognizant ACRS Staff and the Designated Federal Officer (DFO) (Telephone: 301–415–5844, Email: *Quynh.Nguyen@nrc.gov*), 5 days before the meeting, if possible, so that appropriate arrangements can be made to allow necessary time during the meeting for such statements. In view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with the Cognizant ACRS staff if such rescheduling would result in major inconvenience.

An electronic copy of each presentation should be emailed to the Cognizant ACRS Staff at least one day before meeting.

In accordance with Subsection 10(d) of Public Law 92–463 and 5 U.S.C. 552b(c), certain portions of this meeting may be closed, as specifically noted above. Use of still, motion picture, and television cameras during the meeting may be limited to selected portions of the meeting as determined by the Chairman. Electronic recordings will be permitted only during the open portions of the meeting.

ACRS meeting agendas, meeting transcripts, and letter reports are available through the NRC Public Document Room (PDR) at *pdr.resource@nrc.gov,* or by calling the PDR at 1–800–397–4209, or from the Publicly Available Records System (PARS) component of NRC's Agencywide Documents Access and Management System (ADAMS), which is accessible from the NRC website at *http://www.nrc.gov/reading-rm/adams.html* or *http://www.nrc.gov/reading-rm/doc-collections/#ACRS/*.

Dated: November 4, 2021.

Russell E. Chazell,

Federal Advisory Committee Management Officer, Office of the Secretary.

[FR Doc. 2021–24453 Filed 11–8–21; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–266 and 50–301; NRC–2020–0277]

NextEra Energy Point Beach, LLC; Point Beach Nuclear Plant, Units 1 and 2

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft supplemental environmental impact statement; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment draft plant-specific Supplement 23, Second Renewal, to the Generic Environmental Impact Statement (GEIS) for License Renewal of Nuclear Plants, NUREG–1437, regarding the proposed subsequent renewal of Renewed Facility Operating License Nos. DPR–24 and DPR–27 for an additional 20 years of operation for Point Beach Nuclear Plant, Units 1 and

2 (Point Beach). The Point Beach facility is located on the western shore of Lake Michigan (approximately 15 miles NNE of Manitowoc, WI). Possible alternatives to the proposed action (subsequent license renewal) include no action and reasonable replacement power alternatives.

DATES: The staff will hold a public meeting through online webinar and teleconference call on the draft Supplemental Environmental Impact Statement (SEIS) in December, including a presentation on the preliminary findings and a transcribed public comment session. The public meeting details will be announced in the near future. Members of the public are invited to submit comments by January 3, 2022. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal Rulemaking website:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov/* and search for Docket ID NRC–2020–0277. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.
- *Email comments to: PointBeach-SLRSEIS@nrc.gov.*

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Phyllis M. Clark, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–6647; email: *Phyllis.Clark@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2020–0277 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov/* and search for Docket ID NRC–2020–0277.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* Draft plant-specific Supplement 23, Second Renewal, to the GEIS for License Renewal of Nuclear Plants, NUREG–1437, is available in ADAMS under Accession No. ML21306A226.
- *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.
- *Project Website:* Information related to the Point Beach second license renewal can be accessed on the NRC's Point Beach website at *https://www.nrc.gov/reactors/operating/licensing/renewal/applications/point-beach-subsequent.html.* Under the section titled ''Public Involvement,'' click on Draft EIS, NUREG–1437, Supplement 23, Second Renewal, Draft Report for Comment.
- *Public Library:* A copy of draft plant-specific Supplement 23, Second Renewal, to the GEIS for License Renewal of Nuclear Plants, NUREG–1437, is available at the following location (library access and hours are determined by local policy):
  - Lester Public Library, 1001 Adams Street, Two Rivers, WI 54241.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal Rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2020–0277 in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Discussion

The NRC is issuing for public comment draft plant-specific Supplement 23, Second Renewal, to the GEIS for License Renewal of Nuclear Plants, NUREG–1437, regarding the proposed subsequent renewal of Renewed Facility Operating License Nos. DPR–24 and DPR–27 for an additional 20 years of operation for Point Beach. Draft plant-specific Supplement 23, Second Renewal, to the GEIS includes the preliminary analysis that evaluates the environmental impacts of the proposed action and alternatives to the proposed action. Based on the NRC staff's (i) review of the subsequent license renewal application, which includes the environmental report, supplemental documents, and the licensee's responses to the NRC staff's requests for additional information; (ii) consultation with Federal, State, Tribal, and local governmental agencies and consideration of input from other stakeholders; and (iii) independent review as documented in the assessments summarized in the draft SEIS, the NRC staff's preliminary recommendation is that the adverse environmental impacts of subsequent license renewal for Point Beach are not so great that preserving the option of subsequent license renewal for energy-planning decisionmakers would be unreasonable.

Dated: November 3, 2021.

For the Nuclear Regulatory Commission.

Robert B. Elliott,

Chief, Environmental Review License Renewal Branch, Division of Rulemaking, Environmental, and Financial Support, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2021–24407 Filed 11–8–21; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

Senior Executive Service-Performance Review Board

AGENCY: Office of Personnel Management.

ACTION: Notice.

SUMMARY: Notice is hereby given of the appointment of members of the OPM Performance Review Board.

FOR FURTHER INFORMATION CONTACT: Carmen Garcia, OPM Human Resources, Office of Personnel Management, 1900 E Street NW, Washington, DC 20415, (202) 606–1048.

SUPPLEMENTARY INFORMATION: Section 4314(c)(1) through (5) of Title 5, U.S.C., requires each agency to establish, in accordance with regulations prescribed by the Office of Personnel Management, one or more SES performance review boards. The board reviews and evaluates the initial appraisal of a senior executive's performance by the supervisor and considers recommendations to the appointing authority regarding the performance of the senior executive.

Office of Personnel Management.

Alexys Stanley,

Regulatory Affairs Analyst.

The following have been designated as members of the Fiscal Year 2021 Performance Review Board of the U.S. Office of Personnel Management:

Anne Harkavy, Chief of Staff, Chair
Lynn Eisenburg, General Counsel
David Padrino, Director for Human Capital Data Management & Modernization
Dennis Coleman, Chief Management Officer
Tyshawn Thomas, Chief Human Capital Officer
Laurie Bodenheimer, Associate Director for Healthcare and Insurance
Robert Shriver, Associate Director of Employee Services
Reid Hilliard, Director of Facilities, Security, and Emergency Management
Rita Sampson, Director, Office of Diversity, Equity, Inclusion, and Accessibility

[FR Doc. 2021–24491 Filed 11–8–21; 8:45 am]

BILLING CODE 6325–45–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93513; File No. SR–BX–2021–051]

Self-Regulatory Organizations; Nasdaq BX, Inc.; Notice of Filing of Proposed Rule Change To Amend Exchange Rules in Connection With the Proposed Merger of BX Equities LLC With and Into the Exchange

November 3, 2021.

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 22, 2021, Nasdaq BX, Inc. (''BX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its rules in connection with the proposed merger of BX Equities LLC (''BX Equities'') with and into the Exchange (the ''Merger''). As a result of the Merger, BX Equities will be eliminated, and the Exchange will directly operate its equities and options markets.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/bx/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

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 rules in connection with the proposed Merger of BX Equities with and into the Exchange. The Exchange notes that the proposed Merger is the second part of a two-step process, the first part of which is the transfer of Nasdaq, Inc.'s (''Nasdaq HoldCo'') entire ownership interest in BX Equities to the Exchange, which will result in the Exchange becoming the 100% direct owner and sole LLC member of BX Equities (the ''Transfer'' and together with the Merger, the ''Transactions'').[3] The Transactions will ultimately result in the elimination of BX Equities. The Transactions are designed to simplify the corporate structure of the Exchange's sole stockholder Nasdaq HoldCo and Nasdaq HoldCo's subsidiaries, specifically the Exchange and BX Equities. The Transactions will not have any effect on Nasdaq HoldCo's direct ownership of the Exchange.

By way of background, BX Equities was established in 2008 as a facility of and controlled subsidiary owned and operated by the Exchange for the listing and trading of cash equity securities.[4] BX Equities is currently governed by a Delegation Agreement between the Exchange and BX Equities (''Delegation Agreement''), under which the Exchange has delegated certain responsibilities to BX Equities to operate the Exchange's equities market.[5] BX Equities is also currently governed by the Fifth Amended and Restated Operating Agreement (''Operating Agreement''). As noted above, the Exchange is concurrently submitting a separate filing that amends the Operating Agreement to reflect the Transfer, which will result in the

[3] The proposed Transfer is the subject of a separate rule filing to be filed by the Exchange with the Commission concurrent with this filing. Specifically, the Transfer filing would amend the BX Equities Operating Agreement to reflect Nasdaq HoldCo's transfer of ownership interest in BX Equities to the Exchange. The Merger filing would then delete the BX Equities Operating Agreement that was amended in the Transfer filing and delete the Delegation Agreement to reflect the Merger. *See* SR–BX–2021–050 (not yet published).

[4] *See* Securities Exchange Act Release No. 59154 (December 23, 2008), 73 FR 80468 (December 31, 2008) (SR–BSE–2008–48) (''BX Equities Approval Order''). The NASDAQ OMX Group, Inc. (as referenced in the BX Equities Approval Order) is now Nasdaq, Inc.

[5] The Exchange also directly operates an options market.

Exchange becoming the sole owner and LLC member of BX Equities.[6]

Following the Merger, the Exchange will be the surviving entity, and it will directly operate both the Exchange's equities and options markets. The Exchange is proposing amendments in order to reflect those changes.

Specifically, the proposed amendments would ultimately allow the Exchange to directly operate both markets by:

- Terminating the existing delegation to BX Equities;
- removing the BX Equities Operating Agreement; and
- amending the Exchange's rules to eliminate all references to the Delegation Agreement, BX Equities Operating Agreement, and BX Equities LLC.

Each item will be discussed in detail below. The Exchange intends to implement the Transactions (including the proposed changes in this filing to reflect the Merger) by the end of Q4 2021. The Exchange anticipates that the Merger will occur immediately after the Transfer.

Termination of Delegation

The Delegation Agreement was executed in 2008 following the establishment of BX Equities as a cash equities trading facility of the Exchange. The delegation is limited to the Exchange's equities market functions and does not include other functions not specifically mentioned in the limited delegation. However, the Exchange retains ultimate responsibility for its equities market, including the responsibility to ensure the fulfillment of statutory and self-regulatory obligations under the Act.[7]

In connection with the proposed Merger, the Exchange now proposes to terminate the delegation of functions to BX Equities set forth in the Delegation Agreement, and remove the Delegation Agreement from its rules. With the termination of the Delegation Agreement, all of the functions that were previously delegated to BX Equities will now be performed by the Exchange as the Exchange will directly operate its equities market upon the elimination of BX Equities. Furthermore, the Exchange will continue to bear responsibility over its equities market of ensuring the fulfillment of its statutory and self-regulatory obligations.

Removal of Operating Agreement

As discussed above, the Exchange is concurrently proposing amendments to the Operating Agreement to reflect that the Exchange will be the only owner and sole LLC member of BX Equities. In addition, management of BX Equities is vested solely in the Exchange.[8] As stated in the BX Equities Approval Order, having the managerial powers vested solely in the Exchange is designed to preserve the Exchange's regulatory authority over BX Equities, and grants the Exchange the ability to direct BX Equities to perform any required, necessary, or appropriate act.[9] By virtue of BX Equities' structure as a facility of the Exchange, and the Exchange's exclusive management rights, BX Equities is bound by all of the regulatory obligations of its SRO-member. For instance, the Exchange's independent regulatory oversight committee (''ROC'') currently oversees the regulatory program of the Exchange and its facilities, and meets regularly with the Exchange's Chief Regulatory Officer (''CRO'').[10] In addition, the Exchange' independent regulatory department under the oversight of the ROC carries out the Exchange's regulatory functions, including administering its membership and disciplinary rules, and performing real-time surveillance over participants in the Exchange's equities and options market. Ultimately, BX Equities can only act through the action of the Exchange and its officers and directors by virtue of the fact that there is no separate BX Equities board of directors and all BX Equities officers are officers of the Exchange.[11]

With the termination of the Delegation Agreement proposed above, BX Equities would no longer be operating the Exchange's equities market and as a result, the Operating Agreement will become obsolete. Accordingly, the Exchange proposes to remove the Operating Agreement from its rules.

Exchange Rule Amendments

The Exchange proposes to make certain conforming amendments to its rules to reflect the proposed Merger of BX Equities into the Exchange and the resulting deletion of the Delegation Agreement and Operating Agreement. In particular, the Exchange proposes to make the following conforming amendments:

- General 2, Section 8 currently references the Delegation Agreement, and states that the staff, books, records and premises of BX Equities LLC are the staff, books, records and premises of the Exchange subject to oversight pursuant to the Act, and all officers, employees and agents of BX Equities LLC are the officers, employees and agents of the Exchange for purposes of the Act. The Exchange now proposes to delete the rule text and reserve the rule.
- Equity 1, Section 1 currently includes the definitions of Delegation Agreement (Equity 1, Section 1(a)(2)) and BX Equities (Equity 1, Section 1(a)(5)). The Exchange now proposes to delete these definitions and reserve the respective rules.
- In Equity 1, Section 1(a)(3), the Exchange proposes to delete the references to the Delegation Agreement and Operating Agreement.
- In Equity 1, Section 1(a)(6), the Exchange proposes to delete ''through BX Equities LLC as a facility of the Exchange'' from the first sentence.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[12] in general, and furthers the objectives of Section 6(b)(1) of the Act,[13] in particular, in that it enables the Exchange to be so organized as to have the capacity to be able to carry out the purposes of the Exchange Act and to comply, and to enforce compliance by its exchange members and persons associated with its exchange members, with the provisions of the Exchange Act, the rules and regulations thereunder, and the rules of the Exchange.

Specifically, termination of the Delegation Agreement would result in the Exchange directly operating the equities market facility of the Exchange. With the termination of the Delegation Agreement, all of the functions that were previously delegated to BX Equities will now be performed by the Exchange as the Exchange will directly operate its equities market upon the elimination of BX Equities. Furthermore, the Exchange will continue to bear responsibility over its

[6] *See supra* note 3.

[7] *See* Delegation Agreement (providing that the Exchange shall have ultimate responsibility for the operations, rules and regulations developed by BX Equities, as well as their enforcement, and that actions taken by BX Equities pursuant to delegated authority remain subject to review, approval or rejection by the Exchange's Board in accordance with the procedures established by the Board). *See also* BX Equities Approval Order at 80470.

[8] *See* Section 4.1, Operating Agreement (stating that as sole manager of BX Equities, the Exchange shall have the power to do any and all acts necessary, convenient or incidental to or for the furtherance of the purposes described in the Operating Agreement, and that the Exchange has the authority to bind BX Equities).

[9] *See* BX Equities Approval Order at 80470.

[10] *See* Section 4.13(c) of the Exchange's By-Laws. BX Equities does not have a separate ROC.

[11] *See supra* note 7 [sic]. *See also* Section 5.1, Operating Agreement (stating that officers of BX Equities must also be officers of the Exchange).

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(1).

equities market of ensuring the fulfillment of its statutory and self-regulatory obligations. As stated above, the independent ROC of the Exchange's Board would continue to oversee the Exchange's regulatory and self-regulatory organization responsibilities with regards to both the equities and options markets, and the Exchange's regulatory department would continue to carry out its regulatory functions with respect to both markets under the oversight of the ROC.[14] For the same reasons, the Exchange believes that its proposal to remove BX Equities' Operating Agreement from the Exchange's rules in connection with the proposed termination of the Delegation Agreement is also consistent with Section 6(b)(1) of the Act.

The Exchange also believes that this filing furthers the objectives of Section 6(b)(5) of the Act,[15] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. The Exchange believes that the deletion of the Delegation Agreement and Operating Agreement from the Exchange's rules, and related conforming Exchange rule amendments, each as discussed above, is consistent with Section 6(b)(5) of the Act because the proposed changes would add clarity and transparency to the Exchange's Rulebook, ensuring that persons subject to the Exchange's jurisdiction, regulators, and the investing public can more easily navigate and understand the Exchange's rules.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not designed to address any competitive issues but rather is concerned solely with the corporate structure of the Exchange and the administration and function of its corporate governance structures.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

[14] *See supra* note 9 [sic].

[15] 15 U.S.C. 78f(b)(5).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BX–2021–051 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–BX–2021–051. 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–BX–2021–051 and should be submitted on or before November 30, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24413 Filed 11–8–21; 8:45 am]

BILLING CODE 8011–01–P

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93512; File No. SR–ICEEU–2021–021]

Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Amendments to the ICE Clear Europe Clearing Rules

November 3, 2021.

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 20, 2021, ICE Clear Europe Limited (''ICE Clear Europe'' or the ''Clearing House'') 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 primarily 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)(4) thereunder,[4] such that the proposed rule change was immediately 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

(a) The principal purpose of the proposed amendments is for ICE Clear Europe to add a new Part 24 to the ICE

[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)(4).

Clear Europe Clearing Rules (the ''Rules'') which would set out certain procedures relating to LIBOR transition for affected interest rate futures and option contracts cleared by the Clearing House (such Part 24, the ''LIBOR Transition Rules''). The LIBOR Transition Rules would address certain matters occurring in advance of the transition of Sterling and Swiss Franc LIBOR to other replacement rates, with impacts on the existing ICE Futures Europe Three Month Sterling LIBOR Contracts, Three Month EuroSwiss Contracts and Options on Three Month Sterling LIBOR Contracts.[5]

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICE Clear Europe 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. 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

(a) Purpose

ICE Clear Europe is proposing to adopt the LIBOR Transition Rules in advance of the expected transition of Sterling and Swiss Franc LIBOR rates, which are currently referenced in certain ICE Futures Europe interest rate futures and option contracts cleared by the Clearing House, to other replacement rates. As has been widely publicized, the UK Financial Conduct Authority (the ''FCA'') in July 2017 announced that it would no longer compel LIBOR panel banks to make LIBOR submissions after December 31, 2021. Since July 2017, the FCA, other regulators in various jurisdictions, industry groups and market participants have worked to develop and adopt various risk-free rates as alternatives to LIBOR, including the Sterling Over Night Index Average, or ''SONIA,'' for Sterling, and the Swiss Average Rate Overnight, or ''SARON,'' for Swiss Francs. In the derivative markets, industry groups and market participants have generally concluded that LIBOR-based contracts should be converted into contracts referencing a new risk-free rate, with a fallback spread adjustment reflecting the deemed difference in value between the relevant LIBOR rate and the replacement risk free rate. On March 5, 2021, following further consultations, the FCA announced the cessation dates for all LIBOR panels, which will be December 31, 2021 for the Sterling and Swiss Franc LIBORs underlying the relevant ICE Futures Europe interest rate futures and options. In the wake of that announcement, industry groups have established the fallback spreads expected to be used for transitioning derivatives contracts referencing such rates, which have been widely disseminated.[6] In light of these developments, the Clearing House has determined to transition the Three Month Sterling LIBOR Contracts, Three Month EuroSwiss Contracts and Options on Three Month Sterling LIBOR Contracts to replacement rates ahead of the cessation dates for the Sterling and Swiss Franc LIBOR panels.

ICE Futures Europe has already launched trading of new futures and option contracts referencing SONIA and SARON, which are already cleared by ICE Clear Europe. Market participants may currently trade in such contracts alongside contracts referencing LIBOR. Accordingly, it is possible for market participants, on a voluntary basis, to close out of positions in LIBOR-referencing contracts and enter into new positions in SONIA or SARON-referencing contracts through market transactions under ICE Futures Europe rules. ICE Clear Europe is proposing to adopt new Part 24 of the Rules, which would provide for the mandatory conversion or (in certain circumstances) cash settlement of any remaining LIBOR-referencing contracts that have not been voluntarily closed out as of a specified date in advance of the cessation of LIBOR publication of the Sterling and Swiss Franc LIBOR panels, as discussed in further detail herein.

Specifically, the proposed amendments would provide, upon a defined LIBOR Transition Time to be determined and communicated by Circular by the Clearing House, for (i) the amendment and restatement of Transitioning Three Month Sterling LIBOR Contracts into three-month SONIA contracts, (ii) the amendment and restatement of Transitioning Three Month EuroSwiss Contracts into three-month SARON contracts, and (iii) the amendment and restatement of options on Transitioning Three Month Sterling LIBOR Contracts into options on three-month SONIA contracts.

LIBOR Transition Rules

Rule 2401 would provide an introduction to the LIBOR Transition Rules and a general description of the LIBOR Transition Rules and their purpose. The introduction would clarify that the LIBOR Transition Rules would prevail in the event of any conflict with the remainder of the ICE Clear Europe Clearing Rules on matters to which the LIBOR Transition Rules relate.

Rule 2402 would provide the key additional definitions used in the LIBOR Transition Rules, including ''LIBOR Settlement Time'' and ''LIBOR Transition Time,'' ''Transitioning Three Month Sterling Contracts,'' ''Transitioning Three Month Euro Swiss Contracts,'' ''SONIA Contracts,'' ''SARON Contracts'', as discussed in further detail below.

Rule 2403 would provide that nothing in the LIBOR Transition Rules would prevent or restrict ICE Futures Europe or the Clearing House from clarifying or providing guidance on the application of the LIBOR Transition Rules or any related Circular.

LIBOR Settlement Time and LIBOR Transition Time

As set out in Rule 2403, the Clearing House would designate and communicate by Circular a LIBOR Settlement Time and LIBOR Transition Time for purposes of the settlement and transition of the Three Month Sterling LIBOR Contracts, Three Month EuroSwiss Contracts and Options on Three Month Sterling LIBOR Contracts. The LIBOR Settlement Time will be the time as of which the final pre-transition end-of-day settlement will be calculated (as discussed below in connection with Rule 2404) and will also be used to determine the contracts subject to transition. Pursuant to Rule 2403(b), contracts that are still open at the LIBOR Settlement Time but which are scheduled to expire on a later date will be transitioned under the LIBOR Transition Rules; those contracts that expire before the LIBOR Settlement Time will not be subject to the LIBOR Transition Rules, since they will already have settled in accordance with their existing terms. This wording would also exclude from the LIBOR Transition any LIBOR Contacts that have been the subject of a voluntary close out. The LIBOR Transition Time would be the time as of which the amendment and restatement of remaining transitioning contracts into SONIA Contracts, SARON Contracts or Options on SONIA Contracts will occur. It is expected that

[5] Capitalized terms used but not defined herein have the meanings specified in the Rules.

[6] See Bloomberg, IBOR Fallbacks (5 March 2021), available at *https://assets.bbhub.io/professional/sites/10/IBOR-Fallbacks-LIBOR-Cessation_Announcement_20210305.pdf.*

the LIBOR Transition Time and the LIBOR Settlement Time would both occur after the market has closed on a business day and prior to market opening the next business day. The Clearing House would be entitled to delay either such time (or to unwind the LIBOR Transition) at any time prior to the regular Margin call on the Business Day following the scheduled LIBOR Transition Time. Any such delays would be communicated to Clearing Members by Circular.

Pursuant to proposed Rule 2403(c), Options referencing Three Month Sterling LIBOR Contracts that expire prior to the LIBOR Settlement Time would expire and be exercised or abandoned and settle in the ordinary way, without being affected by the LIBOR Transition Rules. However, where such Contracts would be exercised prior to the LIBOR Settlement Time into Three Month Sterling LIBOR Contracts that expire after the LIBOR Settlement Time, transition would occur under the LIBOR Transition Rules for the resulting Three Month Sterling LIBOR Contracts.

LIBOR Transition Settlement Prices

Rule 2404 would describe the procedure for determining and using LIBOR Transition Settlement Prices. Following the LIBOR Settlement Time, the LIBOR Transition Settlement Prices would be used for calculating the regular end of day Margin call in respect of any Set of Three Month Sterling LIBOR Contracts, Three Month EuroSwiss Contracts or Options on the Three Month Sterling LIBOR Contracts.

Rule 2404 would also describe the manner in which the LIBOR Transition Settlement Prices would be determined for each Set of Three Month Sterling LIBOR Contracts, each Set of Three Month EuroSwiss Contracts, and each Option on the Three Month Sterling LIBOR Contracts of a particular Set. For the transitioning futures contracts, the LIBOR Transition Settlement Price would be the applicable daily settlement price for the corresponding SONIA or SARON contract, minus the applicable fallback spread. For the transitioning option contracts, the transition settlement price would be the settlement price of the corresponding SONIA option contract for the same delivery month and with a flex strike price equal to the strike price for the transitioning LIBOR contract plus the applicable fallback spread.

In addition, in relation to Options on the Three Month Sterling LIBOR Contracts for which the corresponding Option on the SONIA Contracts has a different expiry date, Rule 2404(c) would provide that the Clearing House would direct that a one-off irreversible payment be paid to the Clearing Member by the Clearing House or *vice versa* in order to address the change in value resulting from the change in expiry date.[7] The amount of such payment would be calculated as at the LIBOR Settlement Time by the Clearing House and included within the next regular Margin call or payment following the LIBOR Transition Time, unless otherwise directed by the Clearing House. Rule 2404 includes an acknowledgment that the methodology for calculating the LIBOR Transition Settlement Prices (including the Three Month Sterling LIBOR Spread and Three Month Swiss Franc LIBOR Spread) and the use of such prices as the Exchange Delivery Settlement Price are matters of which the market as a whole has had sufficient notice (in light of the extensive market consultation and discussion around LIBOR transition issues, including with respect to the fallback spread methodology and calculation).

Amendment and Restatement of Transition Three Month Sterling LIBOR Contracts

Rule 2405 would describe the process for the amendment and restatement of Transitioning Three Month Sterling LIBOR Contracts into SONIA Contracts. Because two lots of a Sterling LIBOR Contract will convert into a single lot of a SONIA contract in order to deal with differences in the sizes of lots under such contracts, Rule 2405(a) would provide for rounding down of odd numbers of lots in the conversion to the nearest even number of lots, with the remaining portion to be excluded from the transition and terminated with cash settlement in accordance with the Rule. A similar process to exclude, terminate and cash settle transactions in lieu of transition would be used as necessary to balance the number of buy and sell positions in transitioning contracts following the rounding of odd lots as described above.

Rule 2405(b) would provide that, at the LIBOR Transition Time, in respect of each Account of each Clearing Member, every two lots of a Set of Transitioning Three Month Sterling LIBOR Contracts (which are not otherwise excluded from the Sterling LIBOR Transition and terminated and cash settled as discussed above) would be amended and restated as a single lot of a SONIA Contract with an identical delivery month. Such SONIA Contracts would be treated as being of the same Set as any other SONIA Contracts of the same delivery month held by the Clearing Member at the Transition Time, and if they are in the same Account may be subject to netting pursuant to Rule 406, thereby creating fungibility between all SONIA Contacts, whether resulting from prior trading or from the LIBOR Transition. The Rule would also clarify that such SONIA Contracts would also remain ICE Futures Europe Contracts to bolster this outcome. Finally, open Contract Positions in respect of any Set of Transitioning Three Month Sterling LIBOR Contracts that would be excluded from the Sterling LIBOR Transition pursuant to Rule 2405(a) (as described above) would be terminated and cash settled at the relevant LIBOR Transition Futures Settlement Price announced by the Clearing House pursuant to Rule 2404(b)(i).

Rule 2405(c) would state that the Clearing House would not provide for any one-off payment in respect of the amendment and restatement of Transitioning Three Month Sterling LIBOR Contracts contemplated by these LIBOR Transition Rules. The Rule would include an acknowledgment that the proposed transition arrangements would be matters of which the market as a whole would have sufficient notice, in light of the extensive market consultation and discussion around LIBOR transition issues, including with respect to the fallback spread methodology and calculation, and in light of the ability of market participants to voluntarily close out of positions prior to the LIBOR Transition Time.

Rule 2405(d) would also clarify certain matters that apply in respect of Transitioning Three Month Sterling LIBOR Contracts following the LIBOR Transition Time. After such time, the Clearing House would be able to apply contractual netting of offsetting SONIA Contracts of the same Set that are recorded in the same Account in accordance with the ordinary Rules applicable to netting. The Rule would also provide that there may be additional *ad hoc* or regular Margin payments or calls including related to the amendment and restatement of Transitioning Three Month Sterling LIBOR Contracts subject to Sterling LIBOR Transition as SONIA Contracts or any consequent netting and increase or decrease in Open Contract Positions or changes in valuations. The Clearing House would also reserve the right to correct or amend an Exchange Delivery

[7] The Clearing House may direct such a payment under its existing powers pursuant to Rule 109(k) when changes to the contract terms ''materially affects'' the Exchange Delivery Settlement Price, as is considered to be the case in respect of this element of the LIBOR Transition Rules.

Settlement Price under Part 7 of the Rules.

Amendment and Restatement of Transitioning Three Month EuroSwiss Contracts

Rule 2406 would provide substantially similar procedures for the amendment and restatement of Transitioning Three Month EuroSwiss Contracts into SARON Contracts (with the exception that each single lot of a Transitioning Three Month EuroSwiss Contract would become a single lot of the corresponding SARON Contract, and accordingly no rounding or similar adjustment to open positions or payments in respect of odd lots or balanced positions which are excluded from the LIBOR Transition will be required).

Amendment and Restatement of Options on Transitioning Three Month Sterling LIBOR Contracts

Rule 2407 would set out the process for the amendment and restatement of Options on Transitioning Three Month Sterling LIBOR Contracts. As with the underlying Three Month Sterling Contract, in the transition, two lots of Options on Transitioning Three month Sterling LIBOR Contracts would be converted into a single lot of SONIA Options. As a result, Rule 2407(a) would set out a procedure for rounding odd numbered positions and balancing the remaining buy and sell positions (with termination and cash settlement for any positions excluded from the transition), similar to the procedure in Rule 2405(a) as discussed above.

Rule 2407(b) would set out the transition arrangements for Options on Transitioning Three Month Sterling LIBOR Contracts at the LIBOR Transition Time. Specifically, in respect of each Account of each Clearing Member, every two lots of Options on any Transitioning Three Month Sterling LIBOR Contract (which are not excluded from the Sterling LIBOR Transition as described above) would be amended and restated as a single lot of an Option on a SONIA Contract where the relevant Three Month Sterling LIBOR Contract and SONIA Contract have an identical delivery month. This amendment and restatement would result in the adjustment of the expiry date of certain Options on Transitioning Three Month Sterling LIBOR Contracts to the Friday prior to the third Wednesday of the expiry month, consistent with the existing convention for SONIA Contracts. The Strike Price of each Option on a SONIA Contract arising under Rule 2407 would be amended and restated as the Strike Price for the Option on the Transitioning Three Month Sterling LIBOR Contract plus the Three Month Sterling LIBOR Spread. Rule 2407 would clarify that Options on SONIA Contracts arising under Rule 2407 would remain ICE Futures Europe Contracts. Any Open Contract Position in respect of any Set of Options on any Transitioning Three Month Sterling LIBOR Contracts that is excluded from the Sterling LIBOR Transition pursuant to Rule 2407 would be terminated and cash settled at the relevant LIBOR Transition Options Settlement Price previously published by the Clearing House pursuant to Rule 2404(b)(iii).

Rule 2407(c) would provide that, other than the payment described above under Rule 2404(c), the Clearing House would not require any one-off payment in respect of the amendment and restatement of Options on any Transitioning Three Month Sterling LIBOR Contracts under Rule 2407. The Rule would include an acknowledgment, similar to those described above, that market participants have had sufficient notice of the transition terms.

Finally, Rule 2407(d) would address certain matters that would apply following the LIBOR Transition Time. After such time, the Clearing House would be able to apply contractual netting of offsetting Options on SONIA Contracts of the same Set that are recorded in the same Account, in accordance with Rule 406(a). SONIA Contracts (*i.e.,* SONIA Futures) that would arise upon exercise of any Options converted under Rule 2407 would be treated as being of the same Set as any other SONIA Contracts of the same delivery month held by the Clearing Member at the LIBOR Transition Time, and if they are in the same Account may be subject to netting pursuant to Rule 406. The Clearing House would clarify that additional *ad hoc* or regular Margin payments or calls could be made, including related to the amendment and restatement of the Options on Transitioning Three Month Sterling LIBOR Contracts as Options on SONIA Contracts or any consequent netting and increase or decrease in Open Contract Positions or changes in valuations. The Clearing House would also reserve its rights under Part 8 to correct or amend an Exchange Delivery Settlement Price under Part 8 of the Rules.

(b) Statutory Basis

ICE Clear Europe believes that LIBOR Transition Rules are consistent with the requirements of Section 17A of the Act[8] and the regulations thereunder applicable to it, including the standards under Rule 17Ad–22.[9] In particular, Section 17A(b)(3)(F) of the Act[10] requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts, and transactions, the safeguarding of securities and funds in the custody or control of the clearing agency or for which it is responsible, and the protection of investors and the public interest. The amendments in the LIBOR Transition Rules are intended to facilitate the transition of certain contracts in advance of the cessation of the Sterling and Swiss Franc LIBOR panels on 31 December 2021, consistent with ongoing discussions among regulators, industry groups and market participants more generally. The addition of the LIBOR Transition Rules will provide a procedure for the transition of Sterling and Swiss Franc LIBOR futures and options that would otherwise expire after the expected LIBOR cessation into SONIA and SARON Contracts, including applicable adjustments as appropriate. ICE Clear Europe also notes that prior to the transition, market participants are able on a voluntary basis to close out of Sterling and Swiss Franc LIBOR contracts, and/or enter into SONIA or SARON Contracts, through market transactions. The amendments thus provide a fallback to the extent market participants have not voluntarily adjusted their positions as of the transition time. As such, the amendments will facilitate continued clearing by the Clearing House of the transitioning contracts notwithstanding the cessation of the Sterling and Swiss Franc LIBOR panels, and avoid the disruption to the market that might otherwise occur upon LIBOR cessation. The amendments are also consistent with, and support, the overall market transition away from LIBOR-based contracts, which has been supported and indeed initiated and required by regulators and market participants, both in the UK and the US. In ICE Clear Europe's view, the amendments will thus promote the prompt and accurate clearance and settlement of transactions and the protections of investors within the meaning of Section 17A(b)(3)(F) of the Act. In facilitating the transition away from LIBOR-based contracts, consistent with the approach throughout the derivatives, securities

[8] 15 U.S.C. 78q–1.

[9] 17 CFR 240.17Ad–22.

[10] 15 U.S.C. 78q–1(b)(3)(F).

and other markets, the amendments will also further the public interest, within the meaning of that section. (ICE Clear Europe does not believe the amendments would affect the safeguarding of securities and funds in the custody or control of the clearing agency or for which it is responsible, within the meaning of that section.)

For similar reasons, the LIBOR Transition Rules also are consistent with relevant requirements of Rule 17Ad–22. Rule 17Ad–22(e)(3)(i) [11] requires clearing agencies to maintain a sound risk management framework that identifies, measures, monitors and manages the range of risks that it faces. The LIBOR Transition Rules will provide for the transition of existing LIBOR-based contracts into SONIA and SARON Contracts that are currently cleared by the Clearing House. As such, the contracts, upon transition, will be subject to the existing risk management framework and procedures of the Clearing House applicable to SONIA and SARON Contracts. The LIBOR Transition Rules also contain certain other arrangements to facilitate the transition, including addressing odd lots of existing contracts or unbalanced books via appropriate cash settlement at market value under a pre-determined methodology, and providing for a one-time adjustment payment to reflect the change in value resulting from a change in the expiration date of some option contracts. Taken together, these arrangements further the Clearing House's ability to manage the risk of the LIBOR transition, and as such are consistent with the requirements of Rule 17Ad–22(e)(3).[12]

Rule 17Ad–22(e)(21) requires that a clearing agency ''be efficient and effective in meeting the requirements of its participants and the markets it serves, and have the covered clearing agency's management regularly review the efficiency and effectiveness of its . . . scope of products cleared or settled.'' [13] The amendments are intended to be consistent with, and facilitate, the market-wide transition away from LIBOR-based contracts to so-called ''risk-free'' rates such as SONIA and SARON, in light of the expressed positions of relevant regulators and the commitments made by industry groups and market participants. The amendments, which have already been consulted upon and give effect to the output of broader consultations which have been undertaken by the ICE Futures Europe exchange, will provide market participants notice of the effect of the LIBOR Transition Rules on their contracts, in the event they have not otherwise taken steps in the market to address such contracts. As such, the amendments are, in ICE Clear Europe's view, consistent with the requirements of its participants and the markets it serves in light of the LIBOR transition, and will facilitate compliance with Rule 17Ad–22(e)(21).

(B) Clearing Agency's Statement on Burden on Competition

ICE Clear Europe does not believe the proposed amendments would have any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the purposes of the Act. The LIBOR Transition Rules are intended to update the Clearing House's instructions and practices with respect to certain Sterling and Swiss Franc futures and option contracts that reference LIBOR, to address the cessation of the Sterling and Swiss Franc LIBOR panels. (Although the LIBOR Transition Rules will result in market participants ceasing to be able to clear the Sterling and Swiss Franc LIBOR contracts, that is the result of the de-listing of the contracts at the exchange level, and is consistent with the movement of the broader market away from LIBOR-based contracts given the anticipated cessation of publication.) The amendments will provide for transition of remaining Sterling and Swiss Franc LIBOR futures and options contracts as of the transition date to SONIA or SARON contracts as applicable (contracts that are already cleared by the Clearing House). Such changes are thus not intended to impose new requirements on Clearing Members. As a result, ICE Clear Europe does not expect that the proposed changes will adversely affect access to clearing or the ability of Clearing Members, their customers or other market participants to continue to clear contracts. ICE Clear Europe also does not believe the amendments would materially affect the cost of clearing or otherwise impact competition among Clearing Members or other market participants or limit market participants' choices for selecting clearing services. The LIBOR Transition Rules provide for a one-off irreversible payment resulting from the change of value due to the change of the expiry date upon the conversion of certain options. Otherwise, as set forth above, the Clearing House does not believe that the amendments require any additional compensation payments to be made to any party to a transitioning contract, as the methodology for spread adjustment that is being used has been the subject of extensive industry consultation and discussion, and given that market participants are able to close out and replace positions themselves prior to the transition. Accordingly, ICE Clear Europe does not believe the amendments would impose any burden on competition not necessary or appropriate in furtherance of the purpose of the Act.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

ICE Clear Europe conducted a 14-day public consultation with respect to the LIBOR Transition Rules on 27 September 2021 pursuant to ICE Clear Europe Circular no. C21113.[14] Written comments relating to the proposed amendments have not been received by ICE Clear Europe. ICE Clear Europe will notify the Commission of any written comments received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [15] and paragraph (f) of Rule 19b–4 [16] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

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–ICEEU–2021–021 on the subject line.

[11] 17 CFR 240.17Ad–22(e)(3)(i).

[12] 17 CFR 240.17 Ad–22(e)(3)(i).

[13] 17 CFR 240.17Ad–22(e)(21)(iii).

[14] ICE Clear Europe Circular C21/113 (27 Sept. 2021), available at *https://www.theice.com/publicdocs/clear_europe/circulars/C21113.pdf.* Prior to such LIBOR Transition Rules being developed, a LIBOR transition plan was published by ICE Futures Europe on 22 March 2021 and distributed to its members.

[15] 15 U.S.C. 78s(b)(3)(A).

[16] 17 CFR 240.19b–4(f).

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–2021–021. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such 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-credit/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–2021–021 and should be submitted on or before November 30, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24414 Filed 11–8–21; 8:45 am]

BILLING CODE 8011–01–P

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93514; File No. SR–BX–2021–050]

Self-Regulatory Organizations; Nasdaq BX, Inc.; Notice of Filing of Proposed Rule Change To Amend the BX Equities LLC Operating Agreement

November 3, 2021.

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 22, 2021, Nasdaq BX, Inc. (''BX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its rules to reflect that Nasdaq, Inc. (''Nasdaq HoldCo''), the Exchange's sole stockholder, will transfer its entire ownership interest in the Exchange's subsidiary Nasdaq BX Equities LLC (''BX Equities'') to the Exchange, thereby resulting in the Exchange becoming the 100% direct owner and sole LLC member of BX Equities.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/bx/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Exchange's rules to reflect that Nasdaq HoldCo, the Exchange's sole stockholder, will transfer its entire ownership interest in the Exchange's subsidiary BX Equities to the Exchange (the ''Transfer''), thereby resulting in the Exchange becoming the 100% direct owner and sole LLC member of BX Equities. The Exchange notes that the proposed Transfer is the first part of a two-step process, the second part of which is the upstream merger of BX Equities with and into the Exchange (the ''Merger'' and together with the Transfer, the ''Transactions'').[3] The Transactions will ultimately result in the elimination of BX Equities. The Transactions are designed to simplify the corporate structure of Nasdaq HoldCo's subsidiaries, specifically the Exchange and BX Equities. The Transactions will not have any effect on Nasdaq HoldCo's direct ownership of the Exchange.

Background

BX Equities was acquired by Nasdaq HoldCo in 2008,[4] and established as a facility of and controlled subsidiary owned and operated by the Exchange for the listing and trading of cash equity securities.[5] Today, Nasdaq HoldCo directly owns 100% of the Exchange. The Exchange directly owns 53.21% of BX Equities, and Nasdaq HoldCo directly owns the remaining 46.79% of

[3] The proposed Merger is the subject of a separate rule filing to be filed by the Exchange with the Commission concurrent with this filing. Specifically, the Transfer filing would amend the BX Equities Operating Agreement to reflect Nasdaq HoldCo's transfer of ownership interest in BX Equities to the Exchange. The Merger filing would then delete the BX Equities Operating Agreement that was amended in the Transfer filing and delete the Delegation Agreement to reflect the Merger. *See* SR–BX–2021–051 (not yet published).

[4] *See* Securities Exchange Act Release No. 58324 (August 7, 2008), 73 FR 46936 (August 12, 2008) (SR–BSE–2008–02; –23; –25; SR–BSECC–2008–01) (''2008 Acquisition Approval Order''). At the time of the acquisition, the Exchange already owned 53.21% of BX Equities, with the remaining 46.79% owned by several investors. Following the 2008 Acquisition Approval Order, Nasdaq HoldCo purchased and as a result, became the direct owner of the 46.79% interest in BX Equities that was previously held by those investors. *See* 2008 Acquisition Approval Order at 46950.

[5] *See* Securities Exchange Act Release No. 59154 (December 23, 2008), 73 FR 80468 (December 31, 2008) (SR–BSE–2008–48) (''BX Equities Approval Order''). The NASDAQ OMX Group, Inc. (as referenced in both the 2008 Acquisition Approval Order and the BX Equities Approval Order) is now Nasdaq, Inc.

BX Equities.[6] The Fifth Amended and Restated Operating Agreement of BX Equities (''Operating Agreement'') reflects that the Exchange and Nasdaq HoldCo are the only owners and LLC members of BX Equities. Under Section 8.1 of the Operating Agreement, the Exchange must obtain Commission approval for transfers of ownership interests in BX Equities, including the proposed Transfer. Subject to the Commission's approval of this proposed rule change, the Exchange and Nasdaq HoldCo will enter into a contribution and assignment agreement (''Contribution Agreement'') pursuant to which Nasdaq HoldCo will transfer its entire 46.79% ownership interest in BX Equities to the Exchange. As a result of the Transfer, the Exchange will directly own 100% of BX Equities. In addition, the Exchange will continue to be 100% owned by Nasdaq HoldCo.

Proposal

As discussed above, BX Equities is currently governed by the Operating Agreement, which provides that the Exchange and Nasdaq HoldCo are the only owners and LLC members of BX Equities. Management of BX Equities, however, is vested solely in the Exchange. Nasdaq HoldCo has no direct management role in the operation of the entity, with the exception of its limited role as ''tax matters Member'' under Sections 10.9 and 12.6 and in the definitions of ''Capital Account'' and ''Tax Amount,'' and its limited rights with regard to dissolution of the entity under Article 11 and capital contributions under Section 7.4.[7]

To effectuate the proposed Transfer, the Exchange and Nasdaq HoldCo will enter into the Contribution Agreement pursuant to which Nasdaq HoldCo will transfer its entire ownership interest in BX Equities, and all of its other rights and obligations arising thereunder (including, without limitation, as tax matters Member of BX Equities), to the Exchange. Accordingly, the Exchange proposes to amend the Operating Agreement to reflect the foregoing, and to remove references throughout to Nasdaq HoldCo. Notably, the Exchange is proposing to make the following amendments:

- The introductory paragraphs, the definition of ''Agreement'' in Section 1.1, and Section 2.8(e) will be amended to reflect the most recent version of the Operating Agreement.
- The recitals will also be amended to add language regarding the Contribution Agreement.
- The definitions of ''Capital Account'' and ''Tax Amount'' in Section 1.1, and Sections 10.9 and 12.6 will be amended to replace Nasdaq HoldCo with the Exchange in order to reflect that Nasdaq HoldCo will no longer be the tax matters Member of BX Equities.
- Section 7.4 will be amended to reflect that Nasdaq HoldCo will no longer have limited rights with respect to capital contributions in BX Equities. The Exchange will also correct a typo in this section.
- Section 11.1(a)(i) will be amended to reflect that Nasdaq HoldCo will no longer have limited rights regarding the dissolution of BX Equities. The Exchange will also correct a typo in this section.
- Section 18.6(a), which relates to oversight pursuant to the Exchange Act over the books, records, premises, officers, directors, agents, and employees of Nasdaq HoldCo, will be deleted in its entirety and Section 18.6 will be renumbered accordingly. Section 18.6(a) will no longer be necessary upon Nasdaq HoldCo's withdrawal as an LLC member of BX Equities. Furthermore, Nasdaq HoldCo's By-Laws at Section 12.1(c) currently also contain similar oversight provisions.
- Lastly, the introductory paragraphs, the definition of ''Member'' in Section 1.1, Section 7.2, Schedule 1, and Schedule 2 will be amended to remove references to Nasdaq HoldCo as an LLC member of BX Equities.

Subject to Commission approval, the amended Operating Agreement will be operative immediately upon the Transfer. As noted above, the Exchange is concurrently filing a separate rule change to further amend the Operating Agreement by deleting it in its entirety upon the Merger and elimination of BX Equities.[8] The Exchange intends to implement the Transactions by the end of Q4 2021. The Exchange anticipates that the Merger will occur immediately after the Transfer.

2. Statutory Basis

The Exchange believes that this proposal is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Section 6(b)(1) of the Act,[10] in particular, in that it enables the Exchange to be so organized as to have the capacity to be able to carry out the purposes of the Act and to comply, and to enforce compliance by its exchange members and persons associated with its exchange members, with the provisions of the Act, the rules and regulations thereunder, and the rules of the Exchange. The proposed rule change merely seeks to simplify the corporate structure of BX Equities, and the Exchange will operate in a substantially similar manner following the Transfer as it operates today, with the addition of the Exchange's role as the tax matters Member of BX Equities. This is a corporate change, and will have no impact on how the Exchange operates its equities market.

The Exchange also believes that its proposal furthers the objectives of Section 6(b)(5) of the Act,[11] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. Specifically, the proposed rule change would result in the Operating Agreement correctly reflecting the ownership structure of its subsidiary BX Equities upon completion of the Transfer. The Exchange reiterates that it will continue to operate its equities market in the same manner as today following the Transfer.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not designed to address any competitive issues but rather is concerned solely with the corporate structure of BX Equities.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which

[6] *See supra* note 4.

[7] As stated in the BX Equities Approval Order, Nasdaq HoldCo remained an LLC member of BX Equities to avoid certain adverse tax consequences that would be associated with contributing its ownership interest to the Exchange. *See* BX Equities Approval Order at 80469–70. Those tax considerations have since expired.

[8] *See supra* note 3.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(1).

[11] 15 U.S.C. 78f(b)(5).

the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BX–2021–050 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–BX–2021–050. 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–BX–2021–050 and should be submitted on or before November 30, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24412 Filed 11–8–21; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[OMB Control No. 3235–0627]

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 17g–4

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (''PRA''), the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in Rule 17g–4 (17 CFR 240.17g–4) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) (''Exchange Act''). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

The Credit Rating Agency Reform Act of 2006 added a new section 15E, ''Registration of Nationally Recognized Statistical Rating Organizations,'' [1] to the Exchange Act. Pursuant to the authority granted under section 15E of the Exchange Act, the Commission adopted Rule 17g–4, which requires that a nationally recognized statistical rating organization (''NRSRO'') establish, maintain, and enforce written policies and procedures to prevent the misuse of material nonpublic information, including policies and procedures reasonably designed to prevent: (a) The inappropriate dissemination of material nonpublic information obtained in connection with the performance of credit rating services; (b) a person within the NRSRO from trading on material nonpublic information; and (c) the inappropriate dissemination of a pending credit rating action.[2]

There are 9 credit rating agencies registered with the Commission as NRSROs under section 15E of the Exchange Act, which have already established the policies and procedures required by Rule 17g–4. Based on staff experience, an NRSRO is estimated to spend an average of approximately 10 hours per year reviewing its policies and procedures regarding material nonpublic information and updating them (if necessary), resulting in an average industry-wide annual hour burden of approximately 90 hours.[3]

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 shall have practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information on respondents; 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.

The Commission may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

Please direct your written comments to: Dave Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John R. Pezzullo, 100 F St. NE, Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.*

Dated: November 3, 2021.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24424 Filed 11–8–21; 8:45 am]

BILLING CODE 8011–01–P

[12] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78o–7.

[2] *See* 17 CFR 240.17g–4; Release No. 34–55231 (Feb. 2, 2007), 72 FR 6378 (Feb. 9, 2007); Release No. 34–55857 (June 5, 2007), 72 FR 33564 (June 18, 2007).

[3] 9 currently registered NRSROs × 10 hours = 90 hours.

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–264, OMB Control No. 3235–0341]

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 17Ad–4(b) & (c)

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (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 the following rule: Rule 17Ad–4(b) & (c) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) (''Exchange Act''). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 17Ad–4(b) & (c) (17 CFR 240.17Ad–4) is used to document when transfer agents are exempt, or no longer exempt, from the minimum performance standards and certain recordkeeping provisions of the Commission's transfer agent rules. Pursuant to Rule 17Ad–4(b), if the Commission or the Office of the Comptroller of the Currency (''OCC'') is the appropriate regulatory authority (''ARA'') for an exempt transfer agent, that transfer agent is required to prepare and maintain in its possession a notice certifying that it is exempt from certain performance standards and recordkeeping and record retention provisions of the Commission's transfer agent rules. This notice need not be filed with the Commission or OCC. If the Board of Governors of the Federal Reserve System (''Fed'') or the Federal Deposit Insurance Corporation (''FDIC'') is the transfer agent's ARA, that transfer agent must prepare a notice and file it with the Fed or FDIC.

Rule 17Ad–4(c) sets forth the conditions under which a registered transfer agent loses its exempt status. Once the conditions for exemption no longer exist, the transfer agent, to keep the appropriate ARA apprised of its current status, must prepare, and file if the ARA for the transfer agent is the Fed or the FDIC, a notice of loss of exempt status under paragraph (c). The transfer agent then cannot claim exempt status under Rule 17Ad–4(b) again until it remains subject to the minimum performance standards for non-exempt transfer agents for six consecutive months.

ARAs use the information contained in the notices required by Rules 17Ad–4(b) and 17Ad–4(c) to determine whether a registered transfer agent qualifies for the exemption, to determine when a registered transfer agent no longer qualifies for the exemption, and to determine the extent to which that transfer agent is subject to regulation.

The Commission estimates that approximately 10 registered transfer agents each year prepare or file notices in compliance with Rules 17Ad–4(b) and 17Ad–4(c). The Commission estimates that each such registered transfer agent spends approximately 1.5 hours to prepare or file such notices for an aggregate total annual burden of 15 hours (1.5 hours times 10 transfer agents).

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 shall have practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information on respondents; 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: David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John R. Pezzullo, 100 F Street NE, Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

Dated: November 3, 2021.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24426 Filed 11–8–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–029, OMB Control No. 3235–0037]

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 17f–1(c) and Form X–17F–1A

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 17f–1(c) (17 CFR 240.17f–1(c) and Form X–17F–1A (17 CFR 249.100) under the Securities Exchange Act of 1934 (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 17f–1(c) requires approximately 10,100 entities in the securities industry to report lost, stolen, missing, or counterfeit securities certificates to the Commission or its designee, to a registered transfer agent for the issue, and, when criminal activity is suspected, to the Federal Bureau of Investigation. Such entities are required to use Form X–17F–1A to make such reports. Filing these reports fulfills a statutory requirement that reporting institutions report and inquire about missing, lost, counterfeit, or stolen securities. Since these reports are compiled in a central database, the rule facilitates reporting institutions to access the database that stores information for the Lost and Stolen Securities Program.

We estimate that 10,100 reporting institutions will report that securities are either missing, lost, counterfeit, or stolen annually and that each reporting institution will submit this report 30 times each year. The staff estimates that the average amount of time necessary to comply with Rule 17f–1(c) and Form X–17F–1A is five minutes. The total burden is approximately 25,250 hours annually for all respondents (10,100 times 30 times 5 divided by 60).

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 shall have practical utility; (b) the accuracy of the Commission's

estimates of the burden of the proposed collection of information; (c) 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: David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John R. Pezzullo, 100 F Street NE, Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24425 Filed 11–8–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–642, OMB Control No. 3235–0696]

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:

Rules 15Fb1–1 through 15Fb6–2 and Forms SBSE, SBSE–A, SBSE–BD, SBSE–C and SBSE–W

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 Rules 15Fb1–1 through 15Fb6–2 and Forms SBSE, SBSE–A, SBSE–BD, SBSE–C and SBSE–W (17 CFR 240.15Fb1–1 through 240.15Fb6–2, and 17 CFR 249.1600, 249.1600a, 249.1600b, 249.1600c and 249.1601), under the Securities Exchange Act of 1934 (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.

The Commission adopted Rules 15Fb1–1 through 15Fb6–2 and Forms SBSE, SBSE–A, SBSE–BD, SBSE–C and SBSE–W on August 5, 2015 to create a process to register SBS Entities. Forms SBSE, SBSE–A, and SBSE–BD and SBSE–C were designed to elicit certain information from applicants. The Commission uses the information disclosed by applicants through the SBS Entity registration rules and forms to: (1) Determine whether an applicant meets the standards for registration set forth in the provisions of the Exchange Act; and (2) develop an information resource regarding SBS Entities where members of the public may obtain relevant, up-to-date information about SBS Entities, and where the Commission may obtain information for examination and enforcement purposes. Without the information provided through these SBS Entity registration rules and forms, the Commission could not effectively determine whether the applicant meets the standards for registration or implement policy objectives of the Exchange Act.

The information collected pursuant to Rule 15Fb3–2 and Form SBSE–W allows the Commission to determine whether it is appropriate to allow an SBS Entity to withdraw from registration and to facilitate that withdrawal. Without this information, the Commission would be unable to effectively determine whether it was appropriate to allow an SBS Entity to withdraw. In addition, it would be more difficult for the Commission to properly regulate SBS Entities if it were unable to quickly identify those that have withdrawn from the security-based swap business.

In 2017 there were approximately 55 entities that may need to register as SBS Entities. That number has not changed. The Commission estimates that these Entities likely would incur a total burden of 9,825 hours per year to comply with Rules 15Fb1–1 through 15Fb6–2 and Forms SBSE, SBSE–A, SBSE–BD, SBSE–C and SBSE–W.

In addition, Rules 15Fb1–1 through 15Fb6–2 and Forms SBSE, SBSE–A, SBSE–BD, SBSE–C and SBSE–W may impose certain costs on non-resident persons that apply to be registered with the Commission as SBS Entities, including an initial and ongoing costs associated with obtaining an opinion of counsel indicating that it can, as a matter of law, provide the Commission with access to its books and records and submit to Commission examinations, and an ongoing cost associated with establishing and maintaining a relationship with a U.S. agent for service of process.

The staff estimates, based on internet research,[1] that it would cost each nonresident SBS Entity approximately $191 annually to appoint and maintain a relationship with a U.S. agent for service of process. Consequently, the total cost for all nonresident SBS Entities to appoint and maintain relationships with U.S. agents for service of process is approximately $4,202 per year.

Non-resident SBS Entities also would incur outside legal costs associated with obtaining an opinion of counsel. The staff estimates that each of the estimated 22 non-resident persons that likely will apply to register as SBS Entities with the Commission would incur, on average, approximately $25,000 in outside legal costs to obtain the opinion of counsel necessary to register, and that the total annualized cost for all nonresident SBS Entities to obtain this opinion of counsel would be approximately $183,333. Nonresident SBS Entities would also need to obtain a revised opinion of counsel after any changes in the legal or regulatory framework that would impact the SBS Entity's ability to provide, or manner in which it provides, the Commission with prompt access to its books and records or that impacts the Commission's ability to inspect and examine the SBS Entity. We do not believe this would occur frequently, and therefore estimate that one non-resident entity may need to recertify annually. Thus, the total ongoing cost associated with obtaining a revised opinion of counsel regarding the new regulatory regime would be approximately $25,000 annually. Consequently, the total annualized cost burden associated with Rules 15Fb1–1 through 15Fb6–2 and Forms SBSE, SBSE–A, SBSE–BD, SBSE–C and SBSE–W would be approximately $212,205 per year.

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 shall have practical utility; (b) the accuracy of the Commission's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity

[1] *See, e.g., https://www.incorp.com/registered-agent-services/* (as of October 15, 2021, $129 per year), *https://www.wolterskluwer.com/en/solutions/ct-corporation/registered-agent-services-solutions* (as of October 15, 2021, $305 per year), and *https://www.ailcorp.com/services/registered-agent* (as of October 15, 2021, $149 per year). The staff sought websites that provided pricing information and a comprehensive description of their registered agent services. We calculated our estimate by averaging the costs provided on these three websites – ($129 + $305 + $149) ÷ 3 = $191.

of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted 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: David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John R. Pezzullo, 100 F Street NE, Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

Dated: November 3, 2021.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24429 Filed 11–8–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–034, OMB Control No. 3235–0034]

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 17f–2(a)

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 17f–2(a) (17 CFR 240.17f–2(a)), under the Securities Exchange Act of 1934 (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 17f–2(a) (Fingerprinting Requirements for Securities Professionals) requires that securities professionals be fingerprinted. This requirement serves to identify security-risk personnel, to allow an employer to make fully informed employment decisions, and to deter possible wrongdoers from seeking employment in the securities industry. Partners, directors, officers, and employees of exchanges, brokers, dealers, transfer agents, and clearing agencies are included.

The Commission staff estimates that approximately 4,480 respondents will submit an aggregate total of 289,780 new fingerprint cards each year or approximately 65 fingerprint cards per year per registrant. The staff estimates that the average number of hours necessary to complete a fingerprint card is one-half hour. Thus, the total estimated annual burden is 144,890 hours for all respondents (289,780 times one-half hour). The average internal cost of compliance per hour is approximately $283. Therefore, the total estimated annual internal cost of compliance for all respondents is $41,003,870 (144,890 times $283).

This rule does not involve the collection of confidential information.

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 shall have practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) 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: David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John R. Pezzullo, 100 F Street NE, Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

Dated: November 3, 2021.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24423 Filed 11–8–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–517, OMB Control No. 3235–0575]

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:
Regulation AC

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 Regulation Analyst Certification (''Regulation AC'') (17 CFR 242.500–505, under the Securities Exchange Act of 1934 (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.

Regulation AC requires that research reports published, circulated, or provided by a broker or dealer or covered person contain a statement attesting that the views expressed in each research report accurately reflect the analyst's personal views and whether or not the research analyst received or will receive any compensation in connection with the views or recommendations expressed in the research report. Regulation AC also requires broker-dealers to, on a quarterly basis, make, keep, and maintain records of research analyst statements regarding whether the views expressed in public appearances accurately reflected the analyst's personal views, and whether any part of the analyst's compensation is related to the specific recommendations or views expressed in the public appearance. Regulation AC also requires that research prepared by foreign persons be presented to U.S. persons pursuant to Securities Exchange Act Rule 15a–6 and that broker-dealers notify associated persons if they would be covered by the regulation. Regulation AC excludes the news media from its coverage.

The Commission estimates that Regulation AC imposes an aggregate annual time burden of approximately 40,806 hours. The Commission estimates that the total annual internal cost of compliance for the 40,806 hours is approximately $20,923,582.

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 shall have practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) 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: David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John R. Pezzullo, 100 F Street NE, Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

Dated: November 3, 2021.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24428 Filed 11–8–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–442, OMB Control No. 3235–0498]

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 17a–12/Form X–17A–5 Part II

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 17a–12 (17 CFR 240.17a–12) and Part II of Form X–17A–5 (17 CFR 249.617) under the Securities Exchange Act of 1934 (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 17a–12 is the reporting rule tailored specifically for over-the-counter (''OTC'') derivatives dealers registered with the Commission, and Part II of Form X–17A–5, the Financial and Operational Combined Uniform Single (''FOCUS'') Report, is the basic document for reporting the financial and operational condition of OTC derivatives dealers. Rule 17a–12 requires registered OTC derivatives dealers to file Part II of the FOCUS Report quarterly. Rule 17a–12 also requires that OTC derivatives dealers file audited financial statements (''audited report'') annually.

The reports required under Rule 17a–12 provide the Commission with information used to monitor the operations of OTC derivatives dealers and to enforce their compliance with the Commission's rules. These reports also enable the Commission to review the business activities of OTC derivatives dealers and to anticipate, where possible, how these dealers may be affected by significant economic events.

There are currently five registered OTC derivatives dealers. The staff expects that three of those firms will register as Security-Based Swap Dealers within the next three years and therefore will no longer be subject to Rule 17a–12. Thus, only two OTC derivatives dealers will be subject to the requirements of Rule 17a–12. The staff estimates that the average amount of time necessary to prepare and file the quarterly reports required by the rule is eighty hours per OTC derivatives dealer [1] per year and that the average amount of time to prepare and file the annual audited report is 100 hours per OTC derivatives dealer per year, for a total reporting burden of 180 hours per OTC derivatives dealer annually. Thus the staff estimates that the total industry-wide time burden to comply with the requirements of Rule 17a–12 is 360 hours per year (180×2). The Commission estimates that the average annual cost per OTC derivatives dealer for an independent public accountant to examine the financial statements is approximately $46,300 per OTC derivatives dealer. Thus, the total industry-wide annual cost burden is approximately $92,600 ($46,300 $\times$ 2).

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 shall have practical utility; (b) the accuracy of the Commission'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. 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 unless it displays a currently valid OMB control number.

Please direct your written comments to: David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John R. Pezzullo, 100 F Street NE, Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

Dated: November 3, 2021.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24427 Filed 11–8–21; 8:45 am]

BILLING CODE 8011–01–P

[1] Based upon an average of 4 responses per year and an average of 20 hours spent preparing each response.

DEPARTMENT OF THE TREASURY

Community Development Financial Institutions Fund

Funding Opportunities: Bank Enterprise Award (BEA) Program; FY 2021 Funding Round; Correction

AGENCY: Community Development Financial Institutions Fund, Department of the Treasury.

ACTION: Notice; correction.

SUMMARY: The Community Development Financial Institutions Fund (CDFI Fund) published a document in the **Federal Register** of October 14, 2021, concerning the Notice of Funds Availability (NOFA) inviting Applications for the Fiscal Year (FY) 2021 Funding Round of the Bank Enterprise Award Program (BEA Program). On page 57256, in Table 2—Eligibility Requirements for Applicants, under the Criteria header for CDFI Applicant, under the Description header, it incorrectly states that an eligible Certified CDFI Applicant is an Insured Depository Institution that must be certified as a CDFI as of December 31, 2020 when in fact an eligible Certified CDFI Applicant is an Insured Depository Institution that is certified or has submitted a Certification application by December 31, 2020, has been Certified as a CDFI as of the October 14, 2021 publication date of this NOFA in the **Federal Register**, and

maintains its status as a Certified CDFI at the time BEA Program Awards are announced. Processing this Action will correct the misinformation that was published.

FOR FURTHER INFORMATION CONTACT: Tanya McInnis, Program Manager, Depository Institutions Initiatives, Bank Enterprise Award and Small Dollar Loan Programs, CDFI Fund; (202) 653–0309 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of October 14, 2021, in FR Vol. 86, No. 196, on page 57256, in Table 2—Eligibility Requirements for Applicants, under the Criteria header for CDFI Applicant, under the Description header, correct the first sentence to read:

For the FY 2021 funding round, an eligible Certified CDFI Applicant is: An Insured Depository Institution that is certified or has submitted its Certification application by December 31, 2020; was Certified as a CDFI as of the publication date of this NOFA in the **Federal Register**, which was on October 14, 2021; and maintains its status as a Certified CDFI at the time BEA Program Awards are announced under this NOFA.

Executive Summary: This notice announces the correction that eligible Certified CDFI Applicants must be Certified as a CDFI *or* have submitted an application for Certification by December 31, 2020 in order for the Application to receive priority funding consideration under the BEA Program NOFA.

Capitalized terms in this correction to the NOFA are defined in the authorizing statute, the Interim Rule, this NOFA, the Application, or the Uniform Requirements. Details regarding Application content requirements are found in the Application and related materials. Application materials can be found on *Grants.gov* and the CDFI Fund's website at *www.cdfifund.gov/bea.*

All other information and requirements set forth in the NOFA published on October 14, 2021, shall remain effective, as published.

Jodie L. Harris,

Director, Community Development Financial Institutions Fund.

[FR Doc. 2021–24542 Filed 11–5–21; 4:15 pm]

BILLING CODE P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service (IRS), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Guidance Regarding the Treatment of Certain Contingent Payment Debt Instructions with one or more Payments that are Denominated in, or Determined by Reference to, a Nonfunctional Currency.

DATES: Written comments should be received on or before January 10, 2022 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulation should be directed to Martha R. Brinson, at (202) 317–5753, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *Martha.R.Brinson@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Guidance Regarding the Treatment of Certain Contingent Payment Debt Instructions with one or more Payments that are Denominated in, or Determined by Reference to, a Nonfunctional Currency.

OMB Number: 1545–1831.

Regulation Project Number: TD 9157.

Abstract: This document contains final regulations regarding the treatment of contingent payment debt instruments for which one or more payments are denominated in, or determined by reference to, a currency other than the taxpayer's functional currency. These regulations are necessary because current regulations do not provide guidance concerning the tax treatment of such instruments. The regulations affect issuers and holders of such instruments.

Current Actions: There are no changes being made to the regulation at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other-for-profit organizations, Farms.

Estimated Number of Respondents: 250.

Estimated Time per Respondent: 24 mins.

Estimated Total Annual Burden Hours: 100.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments will be of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: November 3, 2021.

Martha R. Brinson,

Tax Analyst.

[FR Doc. 2021–24463 Filed 11–8–21; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service (IRS), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and

other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Guidance on Passive Foreign Company (PFIC) Purging Elections.

DATES: Written comments should be received on or before January 10, 2022 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulation should be directed to Martha R. Brinson, at (202) 317–5753, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *Martha.R.Brinson@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Guidance on Passive Foreign Investment Company (PFIC) Purging Elections.

OMB Number: 1545–1965.

Regulation Project Number: TD 9360.

Abstract: The IRS needs the information to substantiate the taxpayer's computation of the taxpayer's share of the PFIC's post-1986 earning and profits.

Current Actions: There are no changes being made to the regulation at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other-for-profit organizations and individuals.

Estimated Number of Respondents: 250.

Estimated Time per Respondent: 1 hour.

Estimated Total Annual Burden Hours: 250.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments will be of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: November 3, 2021.

Martha R. Brinson,

Tax Analyst.

[FR Doc. 2021–24462 Filed 11–8–21; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–NEW]

Agency Information Collection Activity Under OMB Review: Election To Waive, Retain, or Re-Elect Due Process Rights if in Receipt of Concurrent Active Duty Service Pay and Disability Compensation Pay

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Refer to ''OMB Control No. 2900–NEW''.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 1717 H Street NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–NEW'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: 38 U.S.C. 501, 5101(a), and 5304(c).

Title: Election to Waive, Retain, or Re-Elect Due Process Rights if in Receipt of Concurrent Active Duty Service Pay and Disability Compensation Pay (VA Form 21–10213).

OMB Control Number: 2900–NEW.

Type of Review: New collection.

Abstract: VA Form 21–10213, will be used to determine whether an election to waive due process rights is acknowledged, re-elected, or cancelled when a veteran is in receipt of concurrent active duty service pay and disability compensation pay. Without this collection of information, determination of election would not be possible.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 86 FR 166 on August 31, 2021, pages 48819 and 48820.

Affected Public: Individuals or Households.

Estimated Annual Burden: 8,333.

Estimated Average Burden per Respondent: 5 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 100,000.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration, Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2021–24420 Filed 11–8–21; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0156]

Agency Information Collection Activity Under OMB Review: Notice of Change in Student Status

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the

Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Refer to ''OMB Control No. 2900–0156''.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 1717 H Street NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0156'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: 38 U.S.C. 3020, 3034(a), 3241, 3323(a), 3474, 3524, 3680(a), 3684(a); 10 U.S.C. 510, and 16136. 38 Code of Federal Regulations 21.4203, 21.5200(d), 21.5292(e)(2), 21.5812, 21.7156, 21.7656, 21.9720, and 21.9725.

Title: Notice of Change in Student Status.

OMB Control Number: 2900–0156.

Type of Review: Revision of a currently approved collection.

Abstract: VA uses the information collected to determine whether the beneficiaries' educational benefits should be increased, decreased, or terminated, and the effective date of the change, if applicable. Without this information, VA might underpay or overpay benefits. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 86 FR 77 on September 3, 2021, page 49600.

Affected Public: Individuals or Households.

Estimated Annual Burden: 1,124,027 hours.

Estimated Average Burden per Respondent: 10 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 6,744,167.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration, Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2021–24409 Filed 11–8–21; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 424, 483, et al.

Medicare and Medicaid Programs; CY 2022 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model Requirements and Model Expansion; Home Health and Other Quality Reporting Program Requirements; Home Infusion Therapy Services Requirements; Survey and Enforcement Requirements for Hospice Programs; Medicare Provider Enrollment Requirements; and COVID–19 Reporting Requirements for Long-Term Care Facilities; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 424, 483, 484, 488, 489 and 498

[CMS–1747–F and CMS–5531–F]

RIN 0938–AU37 and 0938–AU32

Medicare and Medicaid Programs; CY 2022 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model Requirements and Model Expansion; Home Health and Other Quality Reporting Program Requirements; Home Infusion Therapy Services Requirements; Survey and Enforcement Requirements for Hospice Programs; Medicare Provider Enrollment Requirements; and COVID–19 Reporting Requirements for Long-Term Care Facilities

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule updates the home health and home infusion therapy services payment rates for calendar year (CY) 2022 in accordance with existing statutory and regulatory requirements. This rule also finalizes recalibration of the case-mix weights and updates the functional impairment levels, and comorbidity adjustment subgroups while maintaining the current low utilization payment adjustment (LUPA) thresholds for CY 2022. Additionally, this rule finalizes a policy to utilize the physical therapy LUPA add-on factor to establish the occupational therapy add-on factor for the LUPA add-on payment amounts and makes conforming regulations text changes to reflect that allowed practitioners are able to establish and review the plan of care. It also finalizes proposed changes to the Home Health Quality Reporting Program (QRP) including finalizing proposed measure removals and adoptions, public reporting, and modification of effective dates. It also finalizes proposed modifications to the effective date for the reporting of measures and certain standardized patient assessment data in the Inpatient Rehabilitation Facility (IRF) QRP and Long-Term Care Hospital (LTCH) QRP. In addition, this final rule codifies certain Medicare provider and supplier enrollment policies. It also makes permanent selected regulatory blanket waivers related to home health aide supervision that were issued to Medicare participating home health agencies during the COVID–19 public health emergency (PHE), and updates the home health conditions of participation regarding occupational therapists assessment completion to implement provisions of the Consolidated Appropriations Act, 2021 (CAA 2021). This final rule also finalizes proposals to expand the Home Health Value-Based Purchasing (HHVBP) Model and to end the original HHVBP Model one year early. Lastly, it establishes survey and enforcement requirements for hospice programs as set forth in the CAA 2021; and finalizes revisions to the infection control requirements for long-term care (LTC) facilities (Medicaid nursing facilities and Medicare skilled nursing facilities, also collectively known as ''nursing homes'') that will extend the mandatory COVID–19 reporting requirements beyond the current COVID–19 PHE until December 31, 2024.

DATES: These regulations are effective on January 1, 2022.

FOR FURTHER INFORMATION CONTACT: Brian Slater, (410) 786–5229, for home health and home infusion therapy payment inquiries.

For general information about home infusion payment, send your inquiry via email to *HomeInfusionPolicy@cms.hhs.gov*.

For general information about the Home Health Prospective Payment System (HH PPS), send your inquiry via email to *HomeHealthPolicy@cms.hhs.gov*.

For more information about the Home Health Value-Based Purchasing Model, *https://share.cms.gov/center/CCSQ/CSG/DIQS/LTC/LTCCOVIDReportingfinalrule/* please visit the HHVBP Model Expansion webpage at *https://innovation.cms.gov/innovation-models/home-health-value-based-purchasing-model*.

For information about the Home Health Quality Reporting Program (HH QRP), send your inquiry via email to *HHQRPquestions@cms.hhs.gov*.

For information about the home health conditions of participation, contact Mary Rossi-Coajou at: *mary.rossicoajou@cms.hhs.gov*, James Cowher at *james.cower@cms.hhs.gov,* or Jeannine Cramer at *Jeannine.cramer@cms.hhs.gov*.

For provider and supplier enrollment process inquiries: Frank Whelan, (410) 786–1302.

For information about the survey and enforcement requirements for hospice programs, send your inquiry via email to *QSOG_Hospice@cms.hhs.gov*.

For information about the LTC facility requirements for participation, contact Molly Anderson at: *Molly.Anderson@cms.hhs.gov,* Diane Corning at *Diane.Corning@cms.hhs.gov,* Kim Roche at *Kim.Roche@cms.hhs.gov,* or Alpha-Banu Wilson at *Alphabanu.Wilson@cms.hhs.gov*.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose

1. Home Health Prospective Payment System (HH PPS)

This final rule updates the payment rates for home health agencies (HHAs) for CY 2022, as required under section 1895(b) of the Social Security Act (the Act). This rule also finalizes recalibration of the case-mix weights under sections 1895(b)(4)(A)(i) and 1895(b)(4)(B) of the Act for 30-day periods of care in CY 2022 while maintaining the CY 2021 LUPA thresholds. This final rule updates the CY 2022 fixed-dollar loss ratio (FDL) for outlier payments (outlier payments as a percentage of estimated total payments are not to exceed 2.5 percent, as required by section 1895(b)(5)(A) of the Act). Finally, this rule uses the physical therapy (PT) add-on factor to establish the occupational therapy (OT) LUPA add-on factor and finalizes conforming regulations text changes at § 409.43, ensuring the regulations reflect that allowed practitioners, in addition to physicians, may establish and periodically review the home health plan of care.

2. Home Health Value Based Purchasing (HHVBP) Model

In this rule, we expand the Home Health Value-Based Purchasing (HHVBP) Model to all Medicare-certified HHAs in the 50 States, Territories, and the District of Columbia beginning January 1, 2022 with CY 2022 as a pre-implementation year. We are finalizing that CY 2023 will be the first performance year and CY 2025 the first payment year, based on HHA performance in CY 2023. We are also finalizing our proposal to end the original HHVBP Model one year early for the HHAs in the nine original Model States, such that CY 2020 performance data would not be used to calculate a payment adjustment for CY 2022.

3. Home Health (HH) Quality Reporting Program (HH QRP), Inpatient Rehabilitation Facility (IRF) QRP and Long-Term Care Hospital (LTCH) QRP

This rule finalizes proposals under the HH QRP, including removal of an Outcome and Assessment Information Set (OASIS)-based measure, the Drug Education on All Medications Provided to Patient/Caregiver During All Episodes of Care measure, under measure removal factor 1: Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made. This rule also finalizes our proposal to replace the Acute Care Hospitalization During the First 60 Days of Home Health (NQF #0171) measure and Emergency Department Use Without Hospitalization During the First 60 Days of Home Health (NQF #0173) measure with the Home Health Within Stay Potentially Preventable measure, and also finalizes our proposal to begin public reporting of the Percent of Residents Experiencing One or More Major Falls with Injury measure and 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) measure beginning in April 2022. Finally, this rule finalizes proposed revisions to certain HH QRP reporting requirements.

This rule also finalizes similar compliance dates for certain IRF QRP and LTCH QRP requirements.

4. Changes to the Home Health Conditions of Participation

In this rule, we are finalizing our proposed changes to make permanent selected regulatory blanket waivers related to home health aide supervision that we extended to Medicare participating home health agencies during the COVID–19 PHE. Blanket waivers to Medicare requirements were issued to provide flexibilities to make sure beneficiaries continue to have access to the health care they need while reducing burden to HHAs. In addition, Division CC, section 115 of CAA 2021 requires the Secretary of Health and Human Services (the Secretary) to permit an occupational therapist to conduct the initial assessment visit and complete the comprehensive assessment under the Medicare program, but only when occupational therapy is on the home health plan of care with either physical therapy or speech therapy, and skilled nursing services are not initially on the plan of care. Therefore, we are finalizing our proposed changes: (1) To the home health aide supervision requirements; and (2) that allow occupational therapists to complete the initial and comprehensive assessments for patients.

5. Medicare Coverage of Home Infusion Therapy

This final rule updates the home infusion therapy services payment rates for CY 2022, as required by section 1834(u) of the Act.

6. Provider and Supplier Enrollment Processes

In this final rule, we address a number of provisions regarding Medicare provider and supplier enrollment. Most of these provisions involve the finalization of the proposed codification of certain subregulatory policies. These policies related to: (1) The effective date of billing privileges for certain provider and supplier types and certain provider enrollment transactions; and (2) the deactivation of a provider or supplier's billing privileges. We are also finalizing two regulatory clarifications related to HHA changes of ownership and HHA capitalization requirements.

7. Survey and Enforcement Requirements for Hospice Programs

In this final rule, we are finalizing changes to increase and improve transparency, oversight, and enforcement for hospice programs in addition to implementing the provisions of Division CC, section 407(b) of CAA 2021. We continue to review and revise our health and safety requirements and survey processes to ensure that they are effective in driving quality of care for hospice programs.

8. COVID–19 Reporting Requirements for Long Term Care Facilities

This final rule revises the infection control requirements that LTC facilities must meet to participate in the Medicare and Medicaid programs. By doing so, LTC facilities will be required to continue the COVID–19 reporting requirements published in the Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency interim final rule with comment period, published on May 8, 2020 (85 FR 27550) and the interim final rule, COVID–19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals With

Intellectual Disabilities (ICFs-IID) Residents, Clients, published on May 13, 2021 (86 FR 26306). LTC facilities will be required to continue to report on a weekly basis to the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN), suspected and confirmed COVID–19 infections, total deaths and COVID–19 deaths, personal protective equipment (PPE) and hand hygiene supplies, ventilator capacity and supplies, resident beds and census, access to COVID–19 testing, staffing shortages, therapeutics administered to residents for the treatment of COVID–19 requirements until December 31, 2024, with the possibility of reduced frequency of reporting and modified or limited data elements that are required in the future at the discretion of the Secretary. They will also be required to report the COVID–19 vaccination status of residents and staff, including total numbers of residents and staff, numbers of residents and staff vaccinated, numbers of each dose of COVID–19 vaccine received, and COVID–19 vaccination adverse events.

B. Summary of the Provisions of This Rule

1. Home Health Prospective Payment System (HH PPS)

In the CY 2022 proposed rule (86 FR 35874) we included discussions of preliminary Patient-Driven Groupings Model (PDGM) monitoring data and analyses on home health utilization; LUPAs; the distribution of the case-mix methodology as determined by clinical groupings, admission source and timing, functional status, and comorbidities; and therapy visits. Additionally, we provided preliminary analysis on HHA expenditures as reported on 2019 cost reports to estimate the difference between Medicare payments and HHAs' costs. We also provided a description and solicited comments on a potential repricing methodology for determining the difference between assumed versus actual behavior change on estimated aggregate expenditures for home health payments. In section II.B.1. and 2. of this final rule, we provide a summary of comments on these topics.

In section II.B.3. of this rule, we are finalizing the recalibration of the PDGM case-mix weights, functional levels, and comorbidity adjustment subgroups while maintaining the CY 2021 LUPA thresholds for CY 2022.

In section II.B.4. of this rule, we update the home health wage index, and we also update the CY 2022 national, standardized 30-day period payment rates and the CY 2022 national per-visit payment amounts by the home health payment update percentage. The home health payment update percentage for CY 2022 is 2.6 percent. Additionally, this rule finalizes the FDL ratio at 0.40 for CY 2022, in order to ensure that aggregate outlier payments do not exceed 2.5 percent of the total aggregate payments, as required by section 1895(b)(5)(A) of the Act.

In section II.B.4.c.(5). of this final rule, we finalize changes to utilize the physical therapy (PT) LUPA add-on factor to establish the OT add-on factor for the LUPA add-on payment amounts with respect to the initial patient assessments newly permitted under Division CC, section 115 of CAA 2021 that revised § 484.55(a)(2) and (b)(3).

Section II.B.6. of this final rule finalizes conforming regulations text changes at § 409.43 to reflect new statutory provisions that allow practitioners in addition to physicians to establish and periodically review the home health plan of care. These changes are in accordance with section 3708 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136, March 27, 2020).

2. Home Health Value Based Purchasing (HHVBP) Model

In section III.A. of this final rule, we are finalizing our proposal to expand the HHVBP Model to all Medicare-certified HHAs in the 50 States, territories, and District of Columbia beginning January 1, 2022. However, we are designating CY 2022 as a pre-implementation year in response to a number of comments we received. CY 2023 will be the first performance year and CY 2025 the first payment year, with a maximum payment adjustment, upward or downward, of 5 percent. We are finalizing that the expanded Model would generally use benchmarks, achievement thresholds, and improvement thresholds based on CY 2019 data to assess achievement or improvement of HHA performance on applicable quality measures and that HHAs would compete nationally in their applicable size cohort, smaller-volume HHAs or larger-volume HHAs, as defined by the number of complete unique beneficiary episodes for each HHA in the year prior to the performance year. All HHAs certified to participate in the Medicare program prior to January 1, 2022, would be required to participate and would be eligible to receive an annual Total Performance Score based on their CY 2023 performance. We are finalizing the applicable measure set for the expanded Model, as well as policies related to the removal, modification, and suspension of quality measures, and the addition of new measures and the form, manner and timing of the OASIS-based, Home Health Consumer Assessment of Healthcare Providers and Systems (HHCAHPS) survey-based, and claims-based measures submission in the applicable measure set beginning CY 2022 and subsequent years. We are also finalizing our proposals for an appeals process, an extraordinary circumstances exception policy, and public reporting of annual performance data under the expanded Model.

In section III.B. of this final rule, we are finalizing our proposal to end the original HHVBP Model one year early. We are finalizing that we will not use CY 2020 performance data for the HHAs in the nine original Model States to apply payment adjustments for the CY 2022 payment year. We also are finalizing that we will not publicly report CY 2020 (performance year 5) annual performance data under the original HHVBP Model.

3. HH QRP

In section IV.C. of this final rule, we are finalizing the proposed updates to the HH QRP including: The removal of one OASIS-based measure, replacement of two claims-based measures with one claims-based quality measure; public reporting of two measures; revising the compliance date for certain reporting requirements for certain HH QRP reporting requirements; and summarizing comments received on our requests for information regarding digital quality measures and health equity.

4. Changes to the Home Health Conditions of Participation

In this section IV.D. of this rule, we finalize our proposal to make permanent selected regulatory blanket waivers related to home health aide supervision that we extended to Medicare-participating home health agencies during the COVID–19 PHE. In addition, we are revising our regulations to reflect Division CC, section 115 of CAA 2021. This provision requires CMS to permit an occupational therapist to conduct a home health initial assessment visit and complete a comprehensive assessment under the Medicare program, but only when occupational therapy is on the home health plan of care, with either physical therapy or speech therapy, and when skilled nursing services are *not* initially in the plan of care.

We are finalizing proposed changes to the home health aide supervision requirements at § 484.80(h)(1) and (2) and conforming regulation text changes at § 484.55(a)(2) and (b)(3), respectively,

to allow occupational therapists to complete the initial and comprehensive assessments for patients in accordance with changes in the law.

We are also making a technical correction at § 484.50(d)(5).

5. Medicare Coverage of Home Infusion Therapy

In section V. of this final rule, we discuss the home infusion therapy services payment categories, as finalized in the CYs 2019 and 2020 HH PPS final rules with comment period (83 FR 56406, 84 FR 60611). Additionally, we discuss the home infusion therapy services payment adjustments including finalizing the proposal to update the geographic adjustment factors (GAFs) used for wage adjustment and finalizing the proposal to maintain the percentages finalized for the initial and subsequent visit policy. In this section we also discuss updates to the home infusion therapy services payment rates for CY 2022, as required by section 1834(u) of the Act.

6. Provider and Supplier Enrollment Processes

In section VI. of this final rule, we addressed a number of provisions regarding Medicare provider and supplier enrollment. Most of these provisions involve the incorporation into 42 CFR part 424, subpart P, of certain sub-regulatory policies. These are addressed in section VI.B. of this final rule and include, for example, policies related to: (1) The effective date of billing privileges for certain provider and supplier types and the effective date of certain provider enrollment transactions; and (2) the deactivation of a provider's or supplier's billing privileges.

In addition, we finalized in section VI.C. of this final rule two regulatory clarifications related to HHA changes of ownership and HHA capitalization requirements.

7. Survey and Enforcement Requirements for Hospice Programs

In section VII. of this final rule, there are a number of provisions related to Division CC, section 407 of CAA 2021. These provisions enhance the hospice program survey process by requiring the use of multidisciplinary survey teams, prohibiting surveyor conflicts of interest, expanding CMS-based surveyor training to accrediting organizations (AOs), and requiring AOs with CMS-approved hospice programs to begin use of the Form CMS–2567. Additionally, we are finalizing our proposed provisions to establish a hospice program complaint hotline. Lastly, the finalized provisions create the authority for imposing enforcement remedies for noncompliant hospice programs including the development and implementation of a range of remedies as well as procedures for appealing determinations regarding these remedies. The Special Focus Program will be considered in future rulemaking.

Section 1865(a) of the Act provides that CMS may recognize and approve national AO Medicare accreditation programs which demonstrate that their health and safety standards and survey and oversight processes meet or exceed those used by CMS to determine compliance with applicable requirements. When a CMS-approved AO program accredits a provider, CMS ''deems'' the provider to have complied with applicable Medicare conditions or requirements. The CAA 2021 provisions expanding requirements for AOs will apply to AOs with CMS-approved accreditation programs, and currently there are three such AOs: Accreditation Commission for Health Care (ACHC), Community Health Accreditation Partner (CHAP), and The Joint Commission (TJC). Half of all the Medicare-certified hospices have been deemed by these AOs.

We described and solicited comments on all aspects of the proposed survey and enforcement provisions for hospice programs.

8. Inpatient Rehabilitation Facility (IRF) Quality Reporting Program

In section IX.A. of this final rule, we are finalizing our proposal to modify the compliance date for certain reporting requirements in the IRF QRP.

9. Long Term Care Hospital (LTCH) Quality Reporting Program

In section IX.B. of this final rule, we are finalizing our proposal to modify the compliance date for certain reporting requirements in the LTCH QRP.

10. COVID–19 Reporting Requirements for Long-Term Care (LTC) Facilities

In section X.C of this final rule, we finalize our COVID–19 reporting requirements with the following modifications:

- Reporting frequency is modified to no more than weekly, and may be reduced, at the discretion of the Secretary;
- The possibility of modified or limited data elements that are required in the future, contingent on the state of the pandemic and at the discretion of the Secretary.
- The addition of a sunset date of December 31, 2024, for all reporting requirements, with the exclusion of the reporting requirements at § 483.80(g)(1)(viii).

C. Summary of Costs, Transfers, and Benefits

TABLE 1: SUMMARY OF COSTS, TRANSFERS, AND BENEFITS

Provision Description	Costs and Cost Savings	Transfers	Benefits
CY 2022 HH PPS Payment Rate Update		The overall economic impact of the HH PPS payment rate update is an estimated $570 million (3.2 percent) in increased payments to HHAs in CY 2022.	To ensure home health payments are consistent with statutory payment authority for CY 2022.
HHVBP		The overall economic impact of the expanded HHVBP Model for CYs 2023 through 2027 is an estimated $3.376 billion in total savings to FFS Medicare from a reduction in unnecessary hospitalizations and skilled nursing facility (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.	
HH QRP	The total savings beginning in CY 2023 is an estimated $2,762,277 based upon the removal of one OASIS-based measure, item M2016.		
Changes to the Home Health Conditions of Participation	We do not anticipate any costs or cost savings associated with our proposed Conditions of Participation provisions.		
Medicare Coverage of Home Infusion Therapy		The overall economic impact of the statutorily-required HIT payment rate updates is an estimated increase in payments to HIT suppliers of 5.1 percent ($300,000) for CY 2022.	To ensure that payment for home infusion therapy services are consistent with statutory authority for CY 2022.
Provider and Supplier Enrollment Processes	We do not anticipate any costs or cost savings associated with our Medicare provider and supplier enrollment provisions.	The overall impact of our provider enrollment provisions will be a transfer of $54,145,000 from providers/suppliers to the Federal Government. This will result from our provision prohibiting payment for services and items furnished by a deactivated provider or supplier.	
Survey and Enforcement Requirements for Hospice Programs	We estimate that the provisions that we present in the preamble of this final rule to implement Division CC, section 407 of CAA 2021 will result in an estimated cost of approximately $5.5 million from FY 2021 through FY 2022.	We do not anticipate any transfers associated with our Medicare survey and enforcement requirements for hospice programs.	To ensure a comprehensive strategy to enhance the hospice program survey process, increase accountability for hospice programs, and provide increased transparency to the public.
COVID-19 Reporting Requirements for Long Term Care Facilities	The total estimated continuing cost for the LTC reporting requirements finalized in this rule is $2,171,571.		These changes will extend the benefits of COVID-19 reporting for LTC facilities beyond the PHE and will provide LTC facilities with more flexibility and eliminate unnecessary burden.

II. Home Health Prospective Payment System

A. Overview of the Home Health Prospective Payment System

1. Statutory Background

Section 1895(b)(1) of the Act requires the Secretary to establish a Home Health Prospective Payment System (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.

In accordance with the statute, as amended by the Balanced Budget Act of 1997 (BBA), (Pub. L. 105–33, enacted August 5, 1997) we published a final rule in the July 3, 2000 **Federal Register** (65 FR 41128) to implement the HH PPS legislation. Section 4603(a) of the BBA allowed the Secretary to consider an appropriate unit of service and at such time, a 60-day unit of payment was established. 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). 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, 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 home health agencies (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.

Section 51001(a)(1)(B) of the Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123) amended section 1895(b) of the Act to require a change to the home health unit of payment to 30-day periods beginning 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.

Additionally, section 1895(b)(3)(A)(iv) of the Act 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).

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, section 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 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. 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. Current System for Payment of Home Health Services Beginning in CY 2020 and Subsequent Years

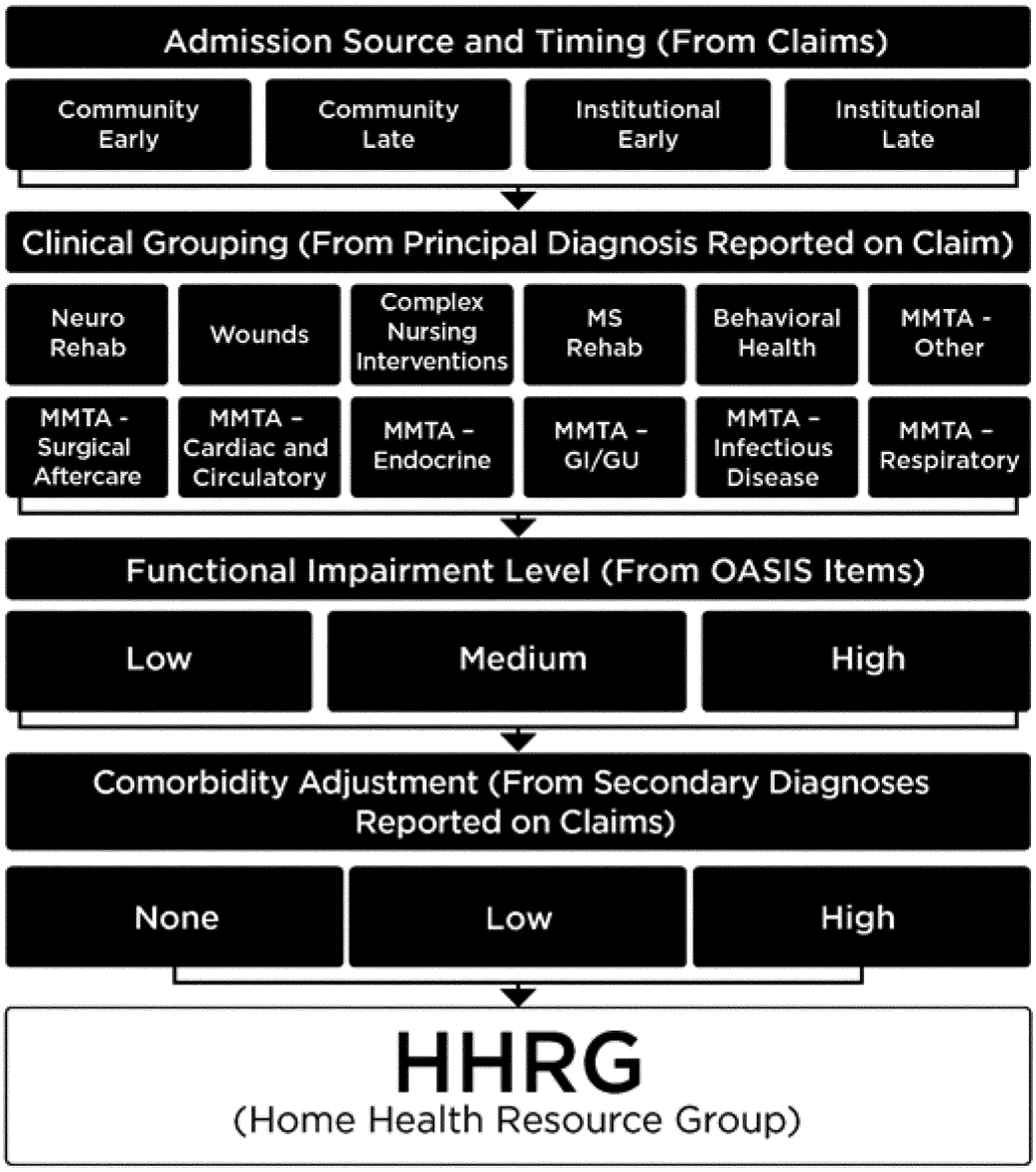
For home health periods of care beginning on or after January 1, 2020, Medicare makes payment under the HH PPS on the basis of a national, standardized 30-day period payment rate that is adjusted for case-mix and area wage differences in accordance with section 51001(a)(1)(B) of the BBA of 2018. The national, standardized 30-day period payment rate includes payment for 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 now also part of the national, standardized 30-day period rate. Durable medical equipment provided as a home health service, as defined in section 1861(m) of the Act, is paid the fee schedule amount or is paid through the competitive bidding program and such payment is not included in the national, standardized 30-day period payment amount.

To better align payment with patient care needs and to 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 Patient-Driven Groupings Model (PDGM) for home health periods of care beginning on or after January 1, 2020. The PDGM did not change eligibility or coverage criteria for Medicare home health services, and as long as the individual meets the criteria for home health services as described at 42 CFR 409.42, the individual can receive Medicare home health services, including therapy services. For more information about the role of therapy services under the PDGM, we refer readers to the Medicare Learning Network (MLN) Matters article SE2000 available at *https://www.cms.gov/regulations-and-guidanceguidance transmittals2020-transmittals/se20005*. To adjust for case-mix for 30-day periods of care beginning on and after January 1, 2020, the HH PPS uses a 432-category case mix classification system to assign patients to a home health resource group (HHRG) using patient characteristics and other clinical information from Medicare claims and the Outcome and Assessment Information Set (OASIS) assessment instrument. These 432 HHRGs represent the different payment groups based on five main case-mix categories under the PDGM, as shown in Figure 1. Each HHRG has an associated case-mix weight that is used in calculating the payment for a 30-day period of care. For periods of care with visits less than the low-utilization payment adjustment (LUPA) threshold for the HHRG, Medicare pays national per-visit rates based on the discipline(s) providing the services. Medicare also adjusts the national standardized 30-day period payment rate for certain intervening events that are subject to a partial payment adjustment (PEP). For certain cases that exceed a specific cost

threshold, an outlier adjustment may also be available.

Under this 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 (admission source, timing clinical grouping, functional impairment level, and comorbidity adjustment) using a fixed effects model. A detailed description of each of the case-mix variables under the PDGM have been described previously, and we refer readers to the CY 2021 HH PPS final rule (85 FR 70303, 70305).

FIGURE 1: CASE-MIX VARIABLES IN THE PDGM



B. Provisions of the Final Rule

1. PDGM Monitoring

The PDGM made several changes to the HH PPS, including replacing 60-day episodes of care with 30-day periods of care, removing therapy volume from directly determining payment, and developing 432 case-mix adjusted payment groups in place of the previous 153 groups. In the CY 2022 HH PPS proposed rule (86 FR 35880), we provided preliminary data analyses on the PDGM including: Overall home health utilization, clinical groupings and comorbidities, admission source and timing, functional impairment levels, and therapy visits. We also provided data analysis on the 2019 HHA Medicare cost reports. We solicited comments on the preliminary PDGM data and cost analyses, along with other factors CMS should be monitoring. These comments and our responses are summarized in this section of the rule.

Comment: Many commenters viewed the overall decrease in utilization as more likely related to the COVID–19 PHE, rather than the implementation of the PDGM. One industry association stated that the COVID–19 PHE brought extensive changes in patient mix, home health patient census, significant practice changes and changes in admission source referrals. Commenters also stated because of the COVID–19 PHE, patients were often unwilling to allow home health clinicians into their

homes to receive needed care. Commenters also indicated that half of HHAs provided services to actively infected COVID–19 patients. We received several comments regarding the increase of LUPAs in CY 2020. Commenters remarked that the increase of LUPAs is more attributable to pandemic-related factors rather than HHAs taking advantage of the PDGM. Commenters also stated that the use of telehealth for the provision of home health visits contributed to the increase in LUPAs in CY 2020 because of safety concerns and patient refusal to allow for in-person visits. Other commenters stated because telehealth services are not reported as home health visits, utilization of home health services is not fully captured. Additionally, several commenters recommended that CMS examine CY 2020 data at a more granular level due to the COVID–19 PHE, including, but not limited to, geographical differences and seasonal trends.

Response: CMS appreciates all of the comments received regarding CY 2020 utilization trends and the impact of the COVID–19 PHE on the provision of home health services. We acknowledge commenter statements and concerns as to how the COVID–19 PHE affected the types of home health patients served and how HHAs had to adjust care practices in response. We also understand that the COVID–19 PHE has presented unique challenges for all providers who have had to develop and institute new protocols and processes to ensure the health and safety of home health staff and beneficiaries. CMS instituted maximum flexibilities and implemented waivers to assist providers in navigating the COVID–19 PHE and to safeguard the continued provision of Medicare home health services.[1]

In the CY 2021 HH PPS final rule (85 FR 70298), CMS finalized changes to § 409.43(a) as implemented in the March, 2020 COVID–19 interim final rule with comment (IFC) (85 FR 19230), to allow the use of telecommunications technology more broadly, even outside of the COVID–19 PHE. If HHAs use telecommunications technology in the provision of home health care, the regulations state that the plan of care must include any provision of remote patient monitoring or other services furnished via a telecommunications system and that these services cannot substitute for a home visit ordered as part of the plan of care and cannot be considered a home visit for the purposes of patient eligibility or payment, in accordance with section 1895(e)(1)(A) of the Act. Such changes were made to provide flexibility in the provision of care during the COVID–19 PHE and beyond as we recognize telecommunication services, at times, may be in the best interest of the patient and support the overall care of beneficiaries. However, since the law does not consider services furnished via a telecommunications system a home visit, these encounters, while allowed, are not included in utilization analysis.

We also understand the interest in monitoring the impact of the COVID–19 PHE on home health services. While we continue to conduct analyses on home health utilization and other metrics, including the effects of COVID–19, we note that the PHE is ongoing and as such, patterns and trends may change over time. We will continue to examine the effects of the ongoing COVID–19 PHE on home health utilization and will determine when and how best to provide this information. We note that CMS does publish COVID–19 data and statistics, which provides information on how the COVID–19 PHE is affecting the Medicare population and aims to better inform individual and public policy healthcare decisions to address the impact of COVID–19.[2]

Comment: Several commenters requested additional detailed analyses of the impact of the PDGM on home health utilization. Some examples of suggested additional analyses included demographic data, social determinants of health, Program for Evaluating Payment Patterns Electronic Report (PEPPER reports), and HHA provider types, such as profit versus non-profit. A commenter recommended that CMS should supplement its analysis of utilization data with additional data and monitoring tools, such as survey data. Another commenter supports CMS' plans to assess the relationship of the OASIS GG items to resource use and their correlation to the current OASIS M1800–1860 items that address functional status. We received several comments stating that the level of data provided in the proposed rule did not reflect whether the home health services furnished were appropriate. Commenters also suggested that CMS examine patient outcomes and patient experiences in future rulemaking. Other commenters raised concerns about HHA admission practices. Commenters expressed concern that some HHAs exclude eligible beneficiaries with longer-term, chronic conditions, prematurely discharge patients, ''cherry-pick'' patients to admit to home health, and decrease necessary home health aide services. Several commenters requested that CMS continue to closely review and monitor therapy utilization data under the PDGM to evaluate for unintended consequences, and if, appropriate implement safeguards as needed. Specifically, commenters stated that the removal of therapy thresholds for payment have resulted in decreases in therapy utilization, termination of therapy staff, and increased use of algorithms, rather than clinical judgment, to determine the appropriate number of therapy visits.

Response: We thank commenters for the additional suggestions for more detailed analyses on home health utilization and other relevant trends and will consider such suggestions for future analyses. We appreciate the concerns by commenters regarding potential aberrant practices and quality of care issues. As we continue to analyze home health utilization, we will monitor for any emerging trends that may warrant any program integrity actions.

Regarding the concerns related to the removal of therapy thresholds, beginning in CY 2020, section 1895(b)(4)(B)(ii) of the Act, as added by section 51001 of the Bipartisan Budget Act of 2018 (BBA 2018) eliminated the use of therapy thresholds in calculating payments for CY 2020 and subsequent years. However, as with analysis of overall home health utilization, we will continue to monitor the provision of therapy visits, including by subspecialty. We remind commenters that all home health services, including therapy, must be provided in accordance with the Conditions of Participation at 42 CFR 484.60. Specifically, 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. The individualized plan of care must also specify the patient and caregiver education and training. Services must be furnished in accordance with accepted standards of practice.

Comment: We received several comments regarding our analysis on the CY 2019 Medicare home health cost reports. Specifically, commenters expressed concerns over the accuracy of

[1] Coronavirus waivers & flexibilities. *https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers.*

[2] Preliminary Medicare COVID–19 Data Snapshot. *https://www.cms.gov/research-statistics-data-systems/preliminary-medicare-covid-19-data-snapshot.*

cost report data. Commenters stated that the home health agency cost report data may not adequately reflect the home health industries' costs as providers vary in complexity, sophistication, size and resources.

Response: We appreciate the commenters' feedback on the CY 2019 cost report analysis provided in the proposed rule. We recognize that with the COVID–19 PHE, the CY 2019 data on the Medicare cost reports may not reflect the most recent changes such as increased telecommunications technology costs, increased PPE costs, and hazard pay. As we stated in the CY 2022 HH PPS proposed rule (86 FR 35884), when the CY 2020 cost reports become available, we will update the estimated 30-day period of care costs in CY 2020 in future rulemaking.

2. Comment Solicitation on the Annual Determination of the Impact of Differences Between Assumed Behavior Changes and Actual Behavior Changes on Estimated Aggregate Payment Expenditures Under the HH PPS

In the CY 2019 HH PPS final rule with comment period (83 FR 56455), we finalized the use of three behavior assumptions in order to calculate a 30-day budget-neutral payment amount for CY 2020 as required by section 1895(b)(3)(A)(iv) of the Act. These included the clinical coding, the comorbidity, and the LUPA behavior assumptions. In the CY 2020 HH PPS final rule with comment period (84 FR 60519), we finalized a −4.36 percent behavior assumption adjustment in order to calculate a national, standardized 30-day base payment rate, assuming that these behaviors would happen half as frequently during the first year of implementation of the PDGM and 30-day unit of payment. Section 1895(b)(3)(D)(i) of the Act requires CMS to annually determine the impact of the differences between assumed behavior changes and actual behavior changes on estimated aggregate expenditures beginning with 2020 and ending with 2026. In the CY 2020 final rule with comment period (84 FR 60513), we stated that we interpret actual behavior changes to encompass both behavior changes that were previously outlined, as assumed by CMS, and other behavior changes not identified at the time that the budget neutral 30-day payment for CY 2020 was determined. In the CY 2022 proposed rule (86 FR 35889), we solicited comments on a possible methodology where we would use actual CY 2020 30-day period claims data to simulate 60-day episodes to determine what CY 2020 payments would have been under the 153-group case-mix system and 60-day unit of payment. We also solicited comments on any potential alternative methods for determining the difference between assumed and actual behavior changes on estimated aggregate expenditures. We received comments on the methodology described in the proposed rule, comments regarding potential alternative methods, and comments on the previously finalized behavior assumptions which are summarized in this section of the rule.

Comment: We received several comments stating that an independent analysis of the actual versus assumed behavior changes show that CMS' assumptions on two of the three previously finalized behavior assumptions were inaccurate. These commenters stated that CMS overestimated the clinical group assumption and the LUPA assumption. These commenters stated that the magnitude of coding the highest paying clinical diagnosis was overstated and the actual change in coding practices did not manifest as CMS assumed. Commenters also stated that there was a significant increase in the frequency of LUPA periods of care, indicating that the LUPA assumption also was overestimated. That is, commenters stated that HHAs did not make 1–2 extra visits to meet or exceed the LUPA threshold to receive a full, case-mix adjusted 30-day period payment. Commenters recommended that we remove these behavior assumptions and the −4.36 percent payment adjustment for rate setting in CY 2022. Other comments stated that not only should the −4.36 percent adjustment be removed, but that we should further increase the 30-day payment in CY 2022.

A few commenters stated CMS does not have the authority to institute budget neutrality adjustments beyond those related to behavior changes. In addition, a few commenters stated we must utilize a PDGM budget neutrality methodology that is solely focused on assumed behavior changes that were incorporated into the original 2020 rate setting.

Many commenters noted, as projected, the reported comorbidity levels have increased. Some commenters state this change may be because HHAs are now comprehensively recording these secondary diagnoses on home health claims, thereby more accurately reflecting patient acuity. However, other commenters disagreed and believe there is a change in aggregate patient acuity due to the COVID–19 PHE. Several commenters stated that there have been noted increases in the functional impairment level. Many stated that an increase of patients into the high functional impairment category and a decrease in the low functional impairment category could be a direct result of the COVID–19 PHE, because HHAs had to accept higher acuity and more functionally impaired patients while elective surgeries were canceled and decreased the utilization in patients with lower functional impairment scores. The majority of commenters were supportive of foregoing any payment adjustment in CY 2022 based on the difference between assumed versus actual behavior change.

Response: We appreciate the commenters feedback and would like to remind commenters that section 1895(b)(3)(a)(iv) of the Act required CMS to make behavioral assumptions when calculating the budget-neutral 30-day payment rate. Section 1895(b)(3)(D) of the Act also requires CMS to annually determine the impact of differences between assumed behavior changes and actual behavior changes on estimated aggregate expenditures beginning with CY 2020 and ending with CY 2026. Therefore, we cannot simply remove a behavior change assumption; rather, we are required by law to annually determine the effects of behavior change on estimated aggregate expenditures. Furthermore, we stated in the CY 2019 HH PPS final rule with comment period (53 FR 56455), the CY 2020 HH PPS final rule with comment period (84 FR 60513), and the CY 2022 HH PPS proposed rule (86 FR 35890), that we interpret actual behavior changes to encompass both behavior changes that were previously outlined, as assumed by CMS, and other behavior changes not identified at the time that the budget neutral 30-day payment amount for CY 2020 was determined.

The law gives CMS the discretion to make temporary and permanent payment adjustments at a time and in a manner determined, by the Secretary, to be appropriate. As such, we did not propose any adjustment to the national, standardized 30-day payment rate in the CY 2022 HH PPS proposed rule based on any behavior assumptions. The law requires that we make any temporary and permanent payment adjustment based on the difference between assumed versus actual behavior change on estimated aggregate expenditures through notice and comment rulemaking.

Given some of the comments stating that CMS overestimated the behavior change, we wish to remind commenters that the CYs 2020 and 2021 LDS files

included two separate datasets; one uses claims with a ''full'' behavior assumption applied, using the initial proposed −8.389 percent adjustment, and the other uses claims with a ''no'' behavior assumption applied (no adjustment for changes in behavior). As stated previously in the CY 2020 HH PPS final rule with comment period (84 FR 60512), CMS applied the three behavioral assumptions to only half of the 30-day periods of care, randomly selected. The −4.36 percent behavior adjustment is not included in the CYs 2020 and 2021 LDS files given the 30-day periods to which the assumptions were applied were done so randomly. Therefore, any independent analysis conducted would need to include application of the behavior assumptions to only half of the 30-day periods in the LDS files.

Comment: The majority of commenters disagreed with the methodology set out in the proposed rule. Their concerns related to: The exclusions we applied to the data when simulating 60-day episodes claims from 30-day periods; the impact of the COVID–19 PHE; the lack of comparability between case-mix models (for example, the assertion that a case-mix of 1.0 is not the same across two systems); and the removal of payment incentives for therapy visits leading to a decline in therapy services furnished in CY 2020. Many commenters offered an alternative approach to compare CY 2018 60-day episodes converted to 30-day periods used for CY 2020 rate setting to actual CY 2020 30-day periods. Commenters stated such approach would more accurately determine the differences between assumed versus actual behavior changes on estimated aggregate expenditures, would be less biased, would eliminate the need to model other changes that occurred due to the implementation of the PDGM, and would avoid the impact of the COVID–19 PHE on therapy utilization. A few commenters also recommended to incorporate some analysis of evaluating ''real'' and ''nominal'' changes in the average case-mix weight.

However, MedPAC supported the method presented in the proposed rule for computing the budget-neutral amount stating the method was reasonable and would satisfy the requirement to reconcile payments based on the differences between assumed versus actual behavior change on estimated aggregate expenditures, as required by section 1895(a)(3)(D) of the Act.

Response: We appreciate the commenters' comprehensive review of the methodology described in the CY 2022 HH PPS proposed rule. We will consider all alternative approaches as we continue to develop and refine a methodology for annually determining the difference between assumed versus actual behavior changes on estimated aggregate expenditures. As stated previously, the methodology and any associated payment adjustment based on the difference between assumed versus actual behavior change on estimated aggregate expenditures will be made through future notice and comment rulemaking.

3. CY 2022 PDGM LUPA Thresholds and PDGM Case-Mix Weights

a. CY 2022 PDGM LUPA Thresholds

Under the HH PPS, LUPAs are paid when a certain visit threshold for a payment group during a 30-day period of care is not met. In the CY 2019 HH PPS final rule with comment period (83 FR 56492), we finalized our policy that the LUPA thresholds would be set at the 10th percentile 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. If the LUPA threshold for the payment group is met under the PDGM, the 30-day period of care is be paid the full 30-day period case-mix adjusted payment amount (subject to any PEP or outlier adjustments). If a 30-day period of care does not meet the PDGM LUPA visit threshold, then payment will be made using the CY 2022 per-visit payment amounts as described in section III. of this final rule. 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.

In the CY 2019 HH PPS final rule with comment period (83 FR 56492), we finalized our policy that the LUPA thresholds for each PDGM payment group would be reevaluated every year based on the most current utilization data available at the time of rulemaking. However, CY 2020 was the first year of the new case-mix adjustment methodology and we stated in the CY 2021 final rule (85 FR 70305, 70306) we would maintain the LUPA thresholds that were finalized and shown in Table 17 of the CY 2020 HH PPS final rule with comment period (84 FR 60522) for CY 2021 payment purposes. At that time, we did not have sufficient CY 2020 data to reevaluate the LUPA thresholds for CY 2021.

We have received anecdotal feedback from stakeholders that in CY 2020, HHAs billed more LUPAs because patients requested fewer in-person visits due the COVID–19 PHE. As discussed further in this section of this rule, we proposed to update the case-mix weights for CY 2022 using CY 2020 data as there are several factors that contribute to how the case-mix weight is set for a particular case-mix group (such as the number of visits, length of visits, types of disciplines providing visits, and non-routine supplies) and the case-mix weight is derived by comparing the average resource use for the case-mix group relative to the average resource use across all groups. CMS believes that the COVID–19 PHE would have impacted utilization within all case-mix groups similarly. Therefore, the impact of any reduction in resource use caused by the COVID–19 PHE on the calculation of the case-mix weight would be minimized since the impact would be accounted for both in the numerator and denominator of the formula used to calculate the case-mix weight. However, in contrast, the LUPA thresholds are based on the number of overall visits in a particular case-mix group (the threshold is the 10th percentile of visits or 2 visits, whichever is greater) instead of a relative value (like what is used to generate the case-mix weight) that would control for the impacts of the COVID–19 PHE. We note that visit patterns and some of the decrease in overall visits in CY 2020 may not be representative of visit patterns in CY 2022. If we had proposed to set the LUPA thresholds using CY 2020 data and then set the LUPA thresholds again for CY 2023 using data from CY 2021, it is likely that there would be an increase in these thresholds due to the lower number of visits that occurred in CY 2020. Therefore, to mitigate any potential future and significant short-term variability in the LUPA thresholds due to the COVID–19 PHE, we proposed to maintain the LUPA thresholds finalized and displayed in Table 17 in the CY 2020 HH PPS final rule with comment period (84 FR 60522) for CY 2022 payment purposes. We believe that maintaining the LUPA thresholds for CY 2022 was the best approach because it mitigates potential fluctuations in the thresholds caused by visit patterns changing from what we observed in CY 2020 potentially due to the COVID–19 PHE. The public comments on our proposal to maintain the CY 2021 LUPA thresholds for CY 2022 payment purposes and our responses are summarized in this section of the rule.

Comment: Some commenters expressed their support for the policy to maintain the CY 2020 LUPA thresholds for CY 2022 in order to mitigate potential fluctuations in the thresholds caused by changing visit patterns in CY 2020 potentially due to the COVID–19 PHE. One commenter recommended that CMS allow telehealth visits to be counted toward meeting LUPA thresholds. This commenter stated that in situations where virtual care visits can be equally as efficacious as an in-person meeting, and CMS should allow these visits to count within this payment framework.

Response: We thank the commenters for their support. As noted previously, the goal of maintaining the LUPA thresholds for CY 2022 is to mitigate any potential fluctuations in the thresholds resulting from any changes in visit patterns resulting from the COVID–19 PHE. While we understand that there are ways in which technology can be further utilized to improve patient care, better leverage advanced practice clinicians, and improve outcomes while potentially making the provision of home health care more efficient, we remind stakeholders that under current law, services furnished via a telecommunications system cannot be considered a home health visit for purposes of eligibility or payment. 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.

Final Decision: We are finalizing the proposal to maintain the LUPA thresholds for CY 2022. The LUPA thresholds for CY 2022 are located on the HHA Center webpage.[3]

b. CY 2022 Functional Impairment Levels

Under the PDGM, the functional impairment level is determined by responses to certain OASIS items associated with activities of daily living and risk of hospitalization; that is, responses to OASIS items M1800–M1860 and M1032. A home health period of care receives points based on each of the responses associated with these functional OASIS items, which are then converted into a table of points corresponding to increased resource use. The sum of all of these points results in a functional score which is used to group home health periods into a functional level with similar resource use. That is, the higher the points, the higher the response is associated with increased resource use. The sum of all of these points results in a functional impairment score which is used to group home health periods into one of three functional impairment levels with similar resource use. The three functional impairment levels of low, medium, and high were designed so that approximately ⅓ of home health periods from each of the clinical groups fall within each level. Home health periods in the low impairment level have responses for the functional OASIS items that are associated with the lowest resource use, on average. Home health periods in the high impairment level have responses for the functional OASIS items that are associated with the highest resource use on average.

For CY 2022, we proposed to use CY 2020 claims data to update the functional points and functional impairment levels by clinical group. The CY 2018 HH PPS proposed rule (82 FR 35320) and the Home Health Groupings Model (HHGM) technical report from December 2016 [4] provide a more detailed explanation as to the construction of these functional impairment levels using the OASIS items. We proposed to use this same methodology previously finalized to update the functional impairment levels for CY 2022. The updated OASIS functional points table and the table of functional impairment levels by clinical group for CY 2022 are listed in Tables 2 and 3, respectively.

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[3] Home Health Agency Center webpage. *https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.*

[4] Overview of the Home Health Groupings Model Technical Report. November 2016. *https://downloads.cms.gov/files/hhgm%20technical%20report%20120516%20sxf.pdf.*

TABLE 2: OASIS POINTS TABLE FOR THOSE ITEMS ASSOCIATED WITH INCREASED RESOURCE USE USING A REDUCED SET OF OASIS ITEMS, CY 2020

	Responses	Points (2020)	Percent of Periods in 2020 with this Response Category
M1800: Grooming	0 or 1	0	33.8%
	2 or 3	3	66.2%
M1810: Current Ability to Dress Upper Body	0 or 1	0	28.8%
	2 or 3	6	71.2%
M1820: Current Ability to Dress Lower Body	0 or 1	0	13.7%
	2	5	63.3%
	3	12	23.0%
M1830: Bathing	0 or 1	0	3.5%
	2	1	13.4%
	3 or 4	9	51.4%
	5 or 6	17	31.7%
M1840: Toilet Transferring	0 or 1	0	63.7%
	2, 3 or 4	5	36.3%
M1850: Transferring	0	0	2.0%
	1	3	24.4%
	2, 3, 4 or 5	7	73.6%
M1860: Ambulation/Locomotion	0 or 1	0	4.5%
	2	7	16.8%
	3	6	61.2%
	4, 5 or 6	19	17.5%
M1032: Risk of Hospitalization	Three or fewer items marked (Excluding responses 8, 9 or 10)	0	70.1%
	Four or more items marked (Excluding responses 8, 9 or 10)	12	29.9%

Source: CY 2020 Home Health Claims Data, Periods that begin and end in CY 2020 accessed on the Chronic Conditions Data Warehouse (CCW) July 12, 2021.

TABLE 3: THRESHOLDS FOR FUNCTIONAL LEVELS BY CLINICAL GROUP, CY 2020

Clinical Group	Level of Impairment	Points (2020)
MMTA – Other	Low	0-33
	Medium	34-48
	High	49+
Behavioral Health	Low	0-32
	Medium	33-48
	High	49+
Complex Nursing Interventions	Low	0-36
	Medium	37-56
	High	57+
Musculoskeletal Rehabilitation	Low	0-35
	Medium	36-48
	High	49+
Neuro Rehabilitation	Low	0-36
	Medium	37-55
	High	56+
Wound	Low	0-36
	Medium	37-54
	High	55+
MMTA - Surgical Aftercare	Low	0-34
	Medium	35-45
	High	46+
MMTA - Cardiac and Circulatory	Low	0-32
	Medium	33-47
	High	48+
MMTA – Endocrine	Low	0-30
	Medium	31-44
	High	45+
MMTA - Gastrointestinal tract and Genitourinary system	Low	0-36
	Medium	37-51
	High	52+
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	Low	0-33
	Medium	34-48
	High	49+
MMTA – Respiratory	Low	0-36
	Medium	37-48
	High	49+

Source: CY 2020 Home Health Claims Data, Periods that begin and end in CY 2020 accessed on the CCW July 12, 2021.

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The following is a summary of the comments received and our responses to comments on the proposal to update the functional points and the functional impairment levels by clinical group.

Comment: MedPAC was supportive of the proposal to update the functional points and functional impairment levels for CY 2022 and recommended that CMS to continue to update the functional categories in this manner in future payment years. MedPAC stated that the re-weighting CMS proposed for CY 2022 would reset the payment categories based on 2020 data, so that periods will again be evenly distributed across the three functional payment categories. MedPAC believes that maintaining this distribution helps to ensure the accuracy of Medicare payments.

Response: We thank the Commission for its support.

Final Decision: We are finalizing the proposal to update the functional points and functional impairment levels for CY 2022.

c. CY 2022 Comorbidity Subgroups

Thirty-day periods of care 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 diagnosis subgroups 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 receives no comorbidity adjustment if no secondary diagnoses exist or none meet the criteria for a low or high comorbidity adjustment.

In the CY 2019 HH PPS final rule with comment period (83 FR 56406), we stated that we would continue to examine the relationship of reported comorbidities on resource utilization and make the appropriate payment refinements so that payments align with the actual costs of providing care. For CY 2022, we proposed to use the same methodology used to establish the comorbidity subgroups to update the comorbidity subgroups using CY 2020 home health data.

For CY 2022, we proposed to update the comorbidity subgroups to include 20 low comorbidity adjustment subgroups and 85 high comorbidity adjustment interaction subgroups. To generate the final comorbidity subgroups, we used CY 2020 home health claims data with linked OASIS data (as of July 12, 2021). The tables later in this section have been revised to reflect the results using the updated data. The final comorbidity subgroups include 20 low comorbidity adjustment subgroups as identified in Table 4 and 87 high comorbidity subgroups as identified in Table 5.

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TABLE 4: LOW COMORBIDITY ADJUSTMENT SUBGROUPS FOR CY 2022

Low Comorbidity Subgroup	Subgroup Description
Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae
Circulatory 7	Atherosclerosis, includes Peripheral Vascular Disease, Aortic Aneurysms and Hypotension
Circulatory 9	Other Venous Embolism and Thrombosis
Circulatory 10	Varicose Veins and Lymphedema
Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease
Heart 10	Dysrhythmias, includes Atrial Fibrillation and Atrial Flutter
Heart 11	Heart Failure
Musculoskeletal 1	Lupus
Musculoskeletal 2	Rheumatoid Arthritis
Neoplasms 1	Malignant Neoplasms of Lip, Oral Cavity and Pharynx, includes Head and Neck Cancers
Neoplasms 2	Malignant Neoplasms of Digestive Organs, includes Gastrointestinal Cancers
Neoplasms 18	Secondary Neoplasms of Urinary and Reproductive Systems, Skin, Brain, and Bone
Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
Neurological 10	Diabetes with Neuropathy
Neurological 11	Diabetic Retinopathy and Macular Edema
Respiratory 9	Respiratory Failure and Atelectasis
Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
Skin 4	Stages Two through Four and Unstageable Pressure Ulcers by Site

TABLE 5: HIGH COMORBIDITY ADJUSTMENT INTERACTIONS FOR CY 2022

Comorbidity Subgroup Interaction	Comorbidity Group	Subgroup Description	Comorbidity Group	Subgroup Description
1	Behavioral 2	Mood Disorders, includes Depression and Bipolar Disorder	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
2	Behavioral 2	Mood Disorders, includes Depression and Bipolar Disorder	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
3	Behavioral 2	Mood Disorders, includes Depression and Bipolar Disorder	Skin 4	Stages Two through Four and Unstageable Pressure Ulcers by Site
4	Behavioral 4	Psychotic, major depressive, and dissociative disorders, includes unspecified dementia, eating disorder and intellectual disabilities	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
5	Behavioral 4	Psychotic, major depressive, and dissociative disorders, includes unspecified dementia, eating disorder and intellectual disabilities	Skin 4	Stages Two through Four and Unstageable Pressure Ulcers by Site
6	Behavioral 4	Psychotic, major depressive, and dissociative disorders, includes unspecified dementia, eating disorder and intellectual disabilities	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
7	Behavioral 5	Phobias, Other Anxiety and Obsessive Compulsive Disorders	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
8	Cerebral 1	Occlusion/Stenosis of Pre-cerebral/Cerebral Arteries without Cerebral Infarction	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae
9	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Neurological 10	Diabetes with Neuropathy

10	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Circulatory 2	Hemolytic, Aplastic, and Other Anemias
11	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Heart 11	Heart Failure
12	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
13	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
14	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Skin 4	Stages Two through Four and Unstageable Pressure Ulcers by Site
15	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Circulatory 7	Atherosclerosis, includes Peripheral Vascular Disease, Aortic Aneurysms and Hypotension
16	Circulatory 1	Nutritional, Enzymatic, and Other Heredity Anemias	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
17	Circulatory 1	Nutritional, Enzymatic, and Other Heredity Anemias	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
18	Circulatory 1	Nutritional, Enzymatic, and Other Heredity Anemias	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
19	Circulatory 1	Nutritional, Enzymatic, and Other Heredity Anemias	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
20	Circulatory 10	Varicose Veins and Lymphedema	Heart 9	Valve Disorders
21	Circulatory 10	Varicose Veins and Lymphedema	Musculoskeletal 3	Joint Pain
22	Circulatory 10	Varicose Veins and Lymphedema	Endocrine 1	Hypothyroidism
23	Circulatory 10	Varicose Veins and Lymphedema	Endocrine 3	Type 1, Type 2, and Other Specified Diabetes
24	Circulatory 10	Varicose Veins and Lymphedema	Respiratory 5	Chronic Obstructive Pulmonary Disease, and Asthma, and Bronchiectasis
25	Circulatory 10	Varicose Veins and Lymphedema	Heart 12	Other Heart Diseases
26	Circulatory 10	Varicose Veins and Lymphedema	Neurological 10	Diabetes with Neuropathy
27	Circulatory 10	Varicose Veins and Lymphedema	Heart 11	Heart Failure
28	Circulatory 10	Varicose Veins and Lymphedema	Endocrine 5	Obesity, and Disorders of Metabolism and Fluid Balance
29	Circulatory 10	Varicose Veins and Lymphedema	Heart 10	Dysrhythmias, includes Atrial Fibrillation and Atrial Flutter
30	Circulatory 10	Varicose Veins and Lymphedema	Neurological 11	Diabetic Retinopathy and Macular Edema
31	Circulatory 10	Varicose Veins and Lymphedema	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
32	Circulatory 2	Hemolytic, Aplastic, and Other Anemias	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
33	Circulatory 2	Hemolytic, Aplastic, and Other Anemias	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
34	Circulatory 2	Hemolytic, Aplastic, and Other Anemias	Skin 4	Stages Two through Four and Unstageable Pressure Ulcers by Site

35	Circulatory 4	Hypertensive Chronic Kidney Disease	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
36	Circulatory 4	Hypertensive Chronic Kidney Disease	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
37	Circulatory 7	Atherosclerosis, includes Peripheral Vascular Disease, Aortic Aneurysms and Hypotension	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
38	Circulatory 7	Atherosclerosis, includes Peripheral Vascular Disease, Aortic Aneurysms and Hypotension	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
39	Circulatory 9	Other Venous Embolism and Thrombosis	Neurological 10	Diabetes with Neuropathy
40	Circulatory 9	Other Venous Embolism and Thrombosis	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD
41	Circulatory 9	Other Venous Embolism and Thrombosis	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes Graft-Versus-Host-Disease
42	Endocrine 1	Hypothyroidism	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
43	Endocrine 1	Hypothyroidism	Skin 4	Stages Two through Four and Unstageable Pressure Ulcers by Site
44	Endocrine 3	Type 1, Type 2, and Other Specified Diabetes	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
45	Endocrine 3	Type 1, Type 2, and Other Specified Diabetes	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
46	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes Graft-Versus-Host-Disease	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
47	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes Graft-Versus-Host-Disease	Skin 4	Stages Two through Four and Unstageable Pressure Ulcers by Site
48	Endocrine 5	Obesity, and Disorders of Metabolism and Fluid Balance	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
49	Endocrine 5	Obesity, and Disorders of Metabolism and Fluid Balance	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
50	Endocrine 5	Obesity, and Disorders of Metabolism and Fluid Balance	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
51	Endocrine 5	Obesity, and Disorders of Metabolism and Fluid Balance	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
52	Heart 10	Dysrhythmias, includes Atrial Fibrillation and Atrial Flutter	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
53	Heart 10	Dysrhythmias, includes Atrial Fibrillation and Atrial Flutter	Skin 4	Stages Two through Four and Unstageable Pressure Ulcers by Site
54	Heart 11	Heart Failure	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
55	Heart 11	Heart Failure	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
56	Heart 11	Heart Failure	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
57	Heart 12	Other Heart Diseases	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers

58	Heart 8	Other Pulmonary Heart Diseases	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
59	Heart 9	Valve Disorders	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
60	Infectious 1	C-diff, MRSA, E-coli, Sepsis	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
61	Infectious 1	C-diff, MRSA, E-coli, Sepsis	Skin 4	Stages Two through Four and Unstageable Pressure Ulcers by Site
62	Musculoskeletal 2	Rheumatoid Arthritis	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
63	Musculoskeletal 3	Joint Pain	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
64	Musculoskeletal 3	Joint Pain	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
65	Musculoskeletal 3	Joint Pain	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
66	Musculoskeletal 4	Lumbar Spinal Stenosis	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
67	Musculoskeletal 4	Lumbar Spinal Stenosis	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
68	Neurological 10	Diabetes with Neuropathy	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
69	Neurological 10	Diabetes with Neuropathy	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
70	Neurological 10	Diabetes with Neuropathy	Skin 4	Stages Two through Four and Unstageable Pressure Ulcers by Site
71	Neurological 11	Diabetic Retinopathy and Macular Edema	Skin 4	Stages Two through Four and Unstageable Pressure Ulcers by Site
72	Neurological 4	Alzheimer's Disease and Related Dementias	Respiratory 9	Respiratory Failure and Atelectasis
73	Neurological 4	Alzheimer's Disease and Related Dementias	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
74	Neurological 4	Alzheimer's Disease and Related Dementias	Skin 4	Stages Two through Four and Unstageable Pressure Ulcers by Site
75	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD
76	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
77	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
78	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD
79	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia	Skin 4	Stages Two through Four and Unstageable Pressure Ulcers by Site
80	Renal 1	Chronic Kidney Disease and End Stage Renal Disease	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers

81	Renal 1	Chronic Kidney Disease and End Stage Renal Disease	Skin 4	Stages Two through Four and Unstageable Pressure Ulcers by Site
82	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD	Skin 4	Stages Two through Four and Unstageable Pressure Ulcers by Site
83	Respiratory 4	Bronchitis, Emphysema, and Interstitial Lung Disease	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
84	Respiratory 5	Chronic Obstructive Pulmonary Disease, and Asthma, and Bronchiectasis	Skin 4	Stages Two through Four and Unstageable Pressure Ulcers by Site
85	Respiratory 9	Respiratory Failure and Atelectasis	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
86	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
87	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers	Skin 4	Stages Two through Four and Unstageable Pressure Ulcers by Site

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In this section of the rule is a summary of the comments received and our response to those comments on the proposed updates to the low comorbidity adjustment subgroups and the high comorbidity adjustment subgroups for CY 2022.

Comment: A commenter requested that CMS reassign diseases and disorders, as well as specific ICD–10 CM diagnosis codes, to different clinical groups or comorbidity subgroups to align with codes representing either similar conditions or similar clinical manifestations. The commenter requested the following reassignments:

(1) Reassign dementia codes currently listed in the Behavioral Health clinical group to the Neuro Rehabilitation clinical group, due to the clinical similarities of Alzheimer's Disease and dementia, and to mirror the current classification of dementia within the neurological comorbidity subgroup

(2) Add musculoskeletal pain, M25.5XX codes to the Musculoskeletal Rehabilitation (MS-Rehab) clinical group when listed as a primary diagnosis, as 14 of 17 M25.5XX codes are included in the Musculoskeletal 3 comorbidity subgroup;

(3) Add the ''specified by organism'' sepsis codes A40.0 through A40.9 and A41.01 through A41.89 to the Infectious 1 comorbidity subgroup to align with current coding practices including A41.9 sepsis unspecified;

(4) Assign leukemia in relapse diagnosis subgroup codes, C92.4X, C92.5X, C92.6X, C92.AX to the Neoplasm 22 comorbidity subgroup, consistent with similar leukemia codes included in this comorbidity subgroup;

(5) Reassign the diagnosis subgroup diabetes with mononeuropathy codes, EXX.41, and the diagnosis subgroup diabetes with autonomic (poly)neuropathy, EXX.43, codes to the Neurological 10 comorbidity subgroup, as neuropathy is a neurological condition and the Neurological 10 comorbidity subgroup already contains diabetic polyneuropathy codes;

(6) Review the Neurological 11 comorbidity subgroup for a potential error since almost all the codes are related to vision issues except for the neuropathy diagnosis subgroup G62 codes. In addition, the commenter noted other types of hereditary and idiopathic neuropathy diagnosis subgroup G60 codes and inflammatory neuropathy diagnosis subgroup G61 codes are not assigned to a comorbidity subgroup when listed as a secondary diagnosis. The commenter requested reassigning the neuropathy diagnosis subgroup codes G60, G61, and G62 to the Neurological 10 comorbidity subgroup, which currently includes diabetic neuropathy;

(7) Assign rheumatic tricuspid valve disease diagnosis codes I08 to the Heart 9 comorbidity subgroup to align with other nonrheumatic valve disorders.

Response: We appreciate the commenter's review of these codes and suggested reassignments. As we stated in the CY 2020 final rule with comment period (84 FR 60510), and as described in the technical report ''Overview of the Home Health Groupings Model'',[5] the home health-specific comorbidity list is based on the principles of patient assessment by body systems and their associated diseases, conditions, and injuries. We used this process to develop categories of conditions that identify clinically relevant relationships associated with increased resource use. We understand the magnitude of clinical conditions and comorbidities, and the interactions that exist between them, in the Medicare home health population; however, we remind commenters that only those subgroups of diagnoses that represent more than 0.1 percent of periods of care and that have at least as high as the median resource use will receive a low comorbidity adjustment. We describe this method for determining statistical significance in the CY 2020 final rule with comment period (84 FR 60510). This is based on the knowledge that the average number of comorbidities in the aggregate becomes the standard within that population for the purpose of payment. However, because we still expect HHAs to report all secondary diagnoses that affect care planning, there will be comorbidity subgroups included in the home health-specific list that don't meet the criteria to receive an adjustment.

We reviewed each of the requested coding changes to determine if the reassignment to a certain clinical group or comorbidity subgroup was warranted.

1. Request for Dementia Codes To Be Reassigned From the Behavioral Health Clinical Group to the Neuro Rehabilitation Clinical Group

We determined there are only two dementia codes listed in the Behavioral Health clinical group with a Neurological 3 comorbidity subgroup; both of which are unspecified dementia codes. Because the commenter stated that reclassifying the dementia codes to a different clinical group would align with the current comorbidity subgroup Neurological 3, we expanded our review to include all ICD–10 CM diagnosis codes in the Neurological 3 comorbidity subgroup. Table 6 lists these codes, their

[5] Overview of the Home Health Groupings Model. November 18, 2016. *https://downloads.cms.gov/files/hhgm%20technical%20report%20120516%20sxf.pdf.*

description, their current assigned clinical group, and current assigned comorbidity subgroup.

TABLE 6: COMORBIDITY SUBGROUP NEUROLOGICAL_3 ICD-10 CM DIAGNOSIS CODES

ICD-10-CM Code	Code Description	Clinical Group Name	Comorbidity Subgroup
F02.80	Dementia in other diseases classified elsewhere without behavioral disturbance	N/A	Neurological_3
F02.81	Dementia in other diseases classified elsewhere with behavioral disturbance	N/A	Neurological_3
F03.90	Unspecified dementia without behavioral disturbance	Behavioral Health	Neurological_3
F03.91	Unspecified dementia with behavioral disturbance	Behavioral Health	Neurological_3
F04	Amnestic disorder due to known physiological condition	N/A	Neurological_3
F05	Delirium due to known physiological condition	N/A	Neurological_3
F06.1	Catatonic disorder due to known physiological condition	N/A	Neurological_3
F06.8	Other specified mental disorders due to known physiological condition	N/A	Neurological_3

Our clinical advisors determined that because the two dementia codes (F03.90 and F03.91) listed in the Behavioral Health clinical group are unspecified and the etiology is unknown, they are clinically appropriate to be in the Behavioral Health clinical group and would not warrant a change in clinical group assignment. Upon review of the comorbidity subgroup codes in Table 6, we determined that these codes are more appropriate in a behavioral health comorbidity subgroup. Additionally, assigning these codes to the Behavioral 4 comorbidity subgroup does not result in a change in the comorbidity adjustment for these codes.

2. Request for Musculoskeletal Pain Diagnosis Subgroup, M25.5X Codes To Be Reassigned to Musculoskeletal Rehab Clinical Group

We reviewed the ICD–10 CM diagnoses codes M25.5XX indicating musculoskeletal pain. Table 7 lists these codes, their description, their current assigned clinical group and current assigned comorbidity subgroup.

TABLE 7: MUSCULOSKELETAL PAIN ICD-10 CM DIAGNOSIS CODES

ICD-10-CM Code	Code Description	Clinical Group Name	Comorbidity Subgroup
M25.50	Pain in unspecified joint	N/A	No group
M25.511	Pain in right shoulder	N/A	Musculoskeletal_3
M25.512	Pain in left shoulder	N/A	Musculoskeletal_3
M25.519	Pain in unspecified shoulder	N/A	No group
M25.521	Pain in right elbow	N/A	Musculoskeletal_3
M25.522	Pain in left elbow	N/A	Musculoskeletal_3
M25.529	Pain in unspecified elbow	N/A	No group
M25.531	Pain in right wrist	N/A	Musculoskeletal_3
M25.532	Pain in left wrist	N/A	Musculoskeletal_3
M25.539	Pain in unspecified wrist	N/A	No group
M25.541	Pain in joints of right hand	N/A	Musculoskeletal_3
M25.542	Pain in joints of left hand	N/A	Musculoskeletal_3
M25.549	Pain in joints of unspecified hand	N/A	No group
M25.551	Pain in right hip	N/A	Musculoskeletal_3
M25.552	Pain in left hip	N/A	Musculoskeletal_3
M25.559	Pain in unspecified hip	N/A	No group
M25.561	Pain in right knee	N/A	Musculoskeletal_3
M25.562	Pain in left knee	N/A	Musculoskeletal_3
M25.569	Pain in unspecified knee	N/A	No group
M25.571	Pain in right ankle and joints of right foot	N/A	Musculoskeletal_3
M25.572	Pain in left ankle and joints of left foot	N/A	Musculoskeletal_3
M25.579	Pain in unspecified ankle and joints of unspecified foot	N/A	No group
M25.59	Pain in other specified joint	N/A	No group

Our clinical advisors reviewed the ICD–10 CM diagnoses codes M25.5XX for musculoskeletal pain and have determined that these codes lack the specificity to clearly support a rationale for skilled services. In the CY 2019 HH

PPS final rule with comment period (83 FR 56473), we stated that many of the codes that indicate pain or contractures as the primary diagnosis, for example M54.5 (low back pain) or M62.422 (contracture of muscle, right hand), although site specific, do not indicate the cause of the pain or contracture. We stated that we would expect a more definitive diagnosis indicating the cause of the pain or contracture, as the reason for the skilled care, in order to appropriately group the home health period. While we believe that 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 recognize that pain can significantly impact the patient's recovery and plan of care. Therefore, when musculoskeletal pain with a specific location is indicated as a secondary diagnosis, we believe these codes are appropriate to remain in the Musculoskeletal 3 comorbidity subgroup. We disagree with the comment that the ICD–10 CM diagnoses codes M25.5XX should be reassigned to the MS-Rehab clinical group.

3. Request for Sepsis, Specified by Organism Codes To Be Assigned to the Infectious 1 Comorbidity Subgroup

We reviewed sepsis, specified by organism, codes A40.0 through A40.9 and A41.01 through A41.89. Table 8 lists these codes, their description, their current assigned clinical group, and current assigned comorbidity subgroup.

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TABLE 8: SEPSIS SPECIFIED BY ORGANISM ICD-10 CM DIAGNOSIS CODES

ICD-10-CM Code	Code Description	Clinical Group Name	Comorbidity Subgroup
A40.0	Sepsis due to streptococcus, group A	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
A40.1	Sepsis due to streptococcus, group B	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
A40.3	Sepsis due to Streptococcus pneumoniae	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
A40.8	Other streptococcal sepsis	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
A40.9	Streptococcal sepsis, unspecified	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
A41.01	Sepsis due to Methicillin susceptible Staphylococcus aureus	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
A41.02	Sepsis due to Methicillin resistant Staphylococcus aureus	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
A41.1	Sepsis due to other specified staphylococcus	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
A41.2	Sepsis due to unspecified staphylococcus	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
A41.3	Sepsis due to Hemophilus influenzae	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
A41.4	Sepsis due to anaerobes	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
A41.50	Gram-negative sepsis, unspecified	MMTA – Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
A41.51	Sepsis due to Escherichia coli [E. coli]	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
A41.52	Sepsis due to Pseudomonas	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
A41.53	Sepsis due to Serratia	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
A41.59	Other Gram-negative sepsis	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
A41.81	Sepsis due to Enterococcus	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
A41.89	Other specified sepsis	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group

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Our clinical advisors reviewed the ICD–10–CM codes A40.0 through A40.9 and A41.01 through A41.89 and concur that clinically these codes are appropriate for inclusion in the Infectious 1 comorbidity subgroup when listed as a secondary diagnosis. We remind readers that ICD–10 CM codes A40.0 through A40.9 and A41.01 through A41.89 require the etiology code to be coded as primary, when applicable. When we reassigned the codes listed in Table 8 to Infectious 1, there was no change to the comorbidity adjustment for these codes (for example, no change in payment).

5. Request for Leukemia in Relapse Codes To Be Reassigned to the Neoplasm 22 Comorbidity Subgroup

We reviewed the ICD–10 CM codes indicating leukemia or histiocytosis with no comorbidity subgroup when listed as a secondary diagnosis. Table 9 lists these codes, their description, their current assigned clinical group, and current assigned comorbidity subgroup.

TABLE 9: LEUKEMIA AND HISTIOCYTOSIS ICD-10 CM DIAGNOSIS CODES

ICD-10-CM Code	Code Description	Clinical Group Name	Comorbidity Subgroup
C92.02	Acute myeloblastic leukemia, in relapse	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
C92.42	Acute promyelocytic leukemia, in relapse	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
C92.52	Acute myelomonocytic leukemia, in relapse	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
C92.62	Acute myeloid leukemia with 11q23-abnormality in relapse	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
C92.A2	Acute myeloid leukemia w multilineage dysplasia, in relapse	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
C94.40	Acute panmyelosis w myelofibrosis not achieve remission	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
C94.41	Acute panmyelosis with myelofibrosis, in remission	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
C94.42	Acute panmyelosis with myelofibrosis, in relapse	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
C94.6	Myelodysplastic disease, not classified	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
C96.5	Multifocal and unisystemic Langerhans-cell histiocytosis	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
C96.6	Unifocal Langerhans-cell histiocytosis	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group

Our clinical advisors reviewed the leukemia and histiocytosis codes listed in Table 9 and concur that these codes are appropriate for inclusion in the Neoplasm 22 comorbidity subgroup when listed as a secondary diagnosis code. When we reassigned the codes listed in Table 9 to Neoplasm 22, there was no change to the comorbidity adjustment for these codes (for example, no change in payment).

5. Request for Subgroup of Diabetes With Mononeuropathy and Autonomic (Poly) Neuropathy Be Reassigned to the Neurological 10 Comorbidity Subgroup

We reviewed the ICD–10 CM diagnosis codes, diabetes with mononeuropathy, EXX.41, and diabetes with autonomic (poly)neuropathy, EXX.43. Table 10 lists these codes, their description, their current assigned clinical group, and current assigned comorbidity subgroup.

TABLE 10: DIABETES WITH MONONEUROPATHY OR AUTONOMIC (POLY)NEUROPATHY ICD-10 CM DIAGNOSIS CODES

ICD-10-CM Code	Code Description	Clinical Group Name	Comorbidity Subgroup
E08.41	Diabetes mellitus due to underlying condition with diabetic mononeuropathy	N/A	Endocrine 2
E08.43	Diabetes mellitus due to underlying condition with diabetic autonomic (poly)neuropathy	N/A	Endocrine 2
E09.41	Drug or chemical induced diabetes mellitus with neurological complications with diabetic mononeuropathy	MMTA – Endocrine	Endocrine 2
E09.43	Drug or chemical induced diabetes mellitus with neurological complications with diabetic autonomic (poly)neuropathy	MMTA – Endocrine	Endocrine 2
E10.41	Type 1 diabetes mellitus with diabetic mononeuropathy	MMTA – Endocrine	Endocrine 3
E10.43	Type 1 diabetes mellitus with diabetic autonomic (poly)neuropathy	MMTA – Endocrine	Endocrine 3
E11.41	Type 2 diabetes mellitus with diabetic mononeuropathy	MMTA – Endocrine	Endocrine 3
E11.43	Type 2 diabetes mellitus with diabetic autonomic (poly)neuropathy	MMTA – Endocrine	Endocrine 3
E13.41	Other specified diabetes mellitus with diabetic mononeuropathy	MMTA – Endocrine	Endocrine 3
E13.43	Other specified diabetes mellitus with diabetic autonomic (poly)neuropathy	MMTA – Endocrine	Endocrine 3

Our clinical advisors first reviewed all of the current ICD–10 CM diagnoses currently listed in the Neurological 10 comorbidity subgroup. We determined that all of the codes listed in the Neurological 10 comorbidity subgroup are specific to diabetic unspecified neuropathy or diabetic polyneuropathy. The ICD–10 CM diagnosis codes EXX.41, diabetes with mononeuropathy, are different from diabetes with unspecified neuropathy or diabetic polyneuropathy in terms of clinical effects on the body system as a whole. Therefore, we disagree that the ICD–10 CM diagnosis codes EXX.41 should be reassigned to the Neurological 10 comorbidity subgroup. However, our clinical advisors agree that ICD–10 CM diagnosis subgroup EXX.43, diabetes with autonomic (poly)neuropathy, should be reassigned to the Neurological 10 comorbidity subgroup. The Endocrine 2 and Endocrine 3 comorbidity subgroups currently receive no comorbidity adjustment; whereas the Neurological 10 comorbidity subgroup currently receives a low comorbidity adjustment. Reassignment of the ICD–10 CM diagnosis subgroup EXX.43, diabetes with autonomic (poly)neuropathy, to Neurological 10 results in these codes receiving a low comorbidity adjustment when listed as a secondary diagnosis.

6. Request for Neuropathy Diagnosis Subgroup G60, G61, and G62 Codes To Be Reassigned to the Neurological 10 Comorbidity Subgroup

We reviewed the Neurological 11 comorbidity subgroup and concur with the commenter that almost all of the ICD–10 CM diagnosis codes listed are primarily related to eye diseases and disorders (for example, retinopathy and macular degeneration). As the commenter also noted that there are other types of hereditary, idiopathic, and inflammatory neuropathies with no neurological comorbidity subgroup assigned, we reviewed the diagnosis subgroup G codes indicating a specified neuropathy (mono or poly) or unspecified polyneuropathy. Table 11 lists these codes, their description, their current assigned clinical group, and comorbidity subgroup.

TABLE 10: OTHER SPECIFIED NEUROPATHY (MONO OR POLY) OR UNSPECIFIED POLYNEUROPATHY ICD-10 CM DIAGNOSIS CODES

ICD-10-CM Code	Code Description	Clinical Group Name	Comorbidity Subgroup
G13.0	Paraneoplastic neuromyopathy and neuropathy	N/A	No Group
G58.0	Intercostal neuropathy	N/A	No Group
G60.0	Hereditary motor and sensory neuropathy	Neurological Rehab	No Group
G60.2	Neuropathy in association with hereditary ataxia	Neurological Rehab	No Group
G60.3	Idiopathic progressive neuropathy	Neurological Rehab	No Group
G60.8	Other hereditary and idiopathic neuropathies	Neurological Rehab	No Group
G60.9	Hereditary and idiopathic neuropathy, unspecified	Neurological Rehab	No Group
G61.1	Serum neuropathy	Neurological Rehab	No Group
G61.82	Multifocal motor neuropathy	Neurological Rehab	No Group
G62.0	Drug-induced polyneuropathy	Neurological Rehab	Neurological 11
G62.1	Alcoholic polyneuropathy	Neurological Rehab	Neurological 11
G62.2	Polyneuropathy due to other toxic agents	N/A	Neurological 11
G62.81	Critical illness polyneuropathy	Neurological Rehab	Neurological 11
G62.82	Radiation-induced polyneuropathy	Neurological Rehab	Neurological 11
G62.89	Other specified polyneuropathies	Neurological Rehab	Neurological 11
G62.9	Polyneuropathy, unspecified	N/A	Neurological 11
G90.09	Other idiopathic peripheral autonomic neuropathy	Neurological Rehab	No Group
G99.0	Autonomic neuropathy in diseases classified elsewhere	N/A	No Group

We determined that all of the codes listed in the Neurological 10 comorbidity subgroup are specific to diabetic unspecified neuropathy or diabetic polyneuropathy and therefore disagree that the neuropathy diagnosis subgroup G60, G61, and G62 codes should be reassigned. Our clinical advisors reviewed all the current neurological comorbidity subgroups and determined that the Neurological 11 comorbidity subgroup clinically remains the most appropriate comorbidity subgroup for codes G60, G61, and G62. However, we may consider additional neurological comorbidity subgroups in the future and, if appropriate, will reassign ICD–10 CM diagnosis codes if needed.

7. Request for Rheumatic Tricuspid Valve Disease Diagnoses Subgroup, I08.– Codes To Be Assigned to the Heart 9 Comorbidity Subgroup

We reviewed the ICD–10 CM diagnosis subgroup I08.X, related to rheumatic disorders involving valves. Table 12 lists these codes, their description, their current assigned clinical group, and comorbidity subgroup.

TABLE 12: RHEUMATIC DISORDERS ICD-10 CM DIAGNOSIS CODES

ICD-10-CM Code	Code Description	Clinical Group Name	Comorbidity Subgroup
I08.0	Rheumatic disorders of both mitral and aortic valves	MMTA - Cardiac and Circulatory	No Group
I08.1	Rheumatic disorders of both mitral and tricuspid valves	MMTA - Cardiac and Circulatory	No Group
I08.2	Rheumatic disorders of both aortic and tricuspid valves	MMTA - Cardiac and Circulatory	No Group
I08.3	Combined rheumatic disorders of mitral, aortic and tricuspid valves	MMTA - Cardiac and Circulatory	No Group
I08.8	Other rheumatic multiple valve diseases	MMTA - Cardiac and Circulatory	No Group
I08.9	Rheumatic multiple valve disease, unspecified	MMTA - Cardiac and Circulatory	No Group

Our clinical advisors agree that these codes are clinically appropriate for inclusion in the Heart 9 comorbidity subgroup when listed as a secondary diagnosis. When we reassigned the codes listed in Table 12 to Heart 9, there was no change to the comorbidity adjustment for these codes (for example, no change in payment).

Final Decision: After reviewing the requested diseases and disorders for a clinical group or comorbidity subgroup reassignment, we are finalizing the reassignments of the following ICD–10 CM diagnosis codes: The ICD–10 CM diagnosis codes in the Neurological 3 comorbidity subgroup will be reassigned to the Behavioral 4 comorbidity subgroup; Sepsis, specified by organism, ICD–10 CM codes A40.0 through A40.9 and A41.01 through A41.89 will be assigned to the Infectious 1 comorbidity subgroup (note that while these codes will now be a part of the Infectious 1 comorbidity subgroup, we remind stakeholders that category A40 ''streptococcal sepsis'' and category A41 ''other sepsis'' have a code first note. If both the principal and secondary

diagnoses are from category A40 and A41, there will not be a comorbidity adjustment, as both are listed from the same diagnosis subchapter); Leukemia in relapse and histiocytosis ICD–10 CM diagnosis codes will be assigned to the Neoplasm 22 comorbidity subgroup; The EXX.43 ICD–10 CM diagnosis codes will be reassigned to the Neurological 10 comorbidity subgroup; The I08.X ICD–10 CM diagnosis codes will be assigned to the Heart 9 comorbidity subgroup. Table 13 in this section of the rule shows the final ICD–10 CM diagnosis code comorbidity subgroup reassignments. We did not reassign any clinical group for any ICD–10 CM diagnosis code. The final CY 2022 Clinical Group and Comorbidity Adjustment Diagnosis List is posted on the HHA Center webpage.[6]

TABLE 13: FINAL ICD-10 CM DIAGNOSIS CODES COMORBIDITY SUBGROUP REASSIGNMENTS

ICD-10-CM Codes	Current "Old" Comorbidity Subgroup	Reassigned "Final" Comorbidity Subgroup
F02.80, F02.81,F03.90, F03.91, F04, F05, F06.1, F06.8	Neurological 3	Behavioral 4
A40.0, A40.1, A40.3, A40.8, A40.9 A41.01 through A41.53, A41.59, A41.81, A41.89	No Group	Infectious 1
C92.02, C92.42, C92.52, C92.62, C92.A2, C94.40 through C94.42, C94.6, C96.5, C96.6	No Group	Neoplasm 22
E08.41, E09.41	Endocrine 2	Endocrine 2 (no change)
E08.43, E09.43	Endocrine 2	Neurological 10
E10.41, E11.41, E13.41	Endocrine 3	Endocrine 3 (no change)
E10.43, E11.43, E13.43	Endocrine 3	Neurological 10
G60, G61, and G62 subgroups	Neurological 11	Neurological 11 (no change)
I08.0 through I08.3, I08.8, I08.9	No Group	Heart 9
M25.50, M25.519, M25.529, M25.539, M25.549, M25.559, M25.569, M25.579, M25.59	No Group	No Group (no change)
M25.511, M25.512, M25.521, M25.522, M25.531, M25.532, M25.541, M25.542, M25.551, M25.552, M25.561, M25.562, M25.571, M25.572	Musculoskeletal 3	Musculoskeletal 3 (no change)

d. CY 2022 PDGM Case-Mix Weights

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 and other characteristics, such as timing, admission source, clinical grouping using the reported principal diagnosis, functional impairment level, and comorbid conditions. The PDGM case-mix methodology results in 432 unique case-mix groups called home health resource groups (HHRGs). In the CY 2019 HH PPS final rule with comment period (83 FR 56515), we finalized a policy to annually recalibrate the PDGM case-mix weights using a fixed effects model with the most recent and complete utilization data available at the time of annual rulemaking. Annual recalibration of the PDGM case-mix weights ensures that the case-mix weights reflect, as accurately as possible, current home health resource use and changes in utilization patterns. To generate the proposed recalibrated CY 2022 case-mix weights, we used CY 2020 home health claims data with linked OASIS data (as of March 30, 2021). To generate the final recalibrated CY 2022 case-mix weights, we used CY 2020 home health claims data with linked OASIS data (as of July 12, 2021). These data are the most current and complete data available at this time. The tables later in this section have been revised to reflect the results using the updated data.

In the CY 2022 HH PPS proposed rule (86 FR 35874), we stated that we believe that recalibrating the case-mix weights using data from CY 2020 would be more reflective of PDGM utilization and patient resource use than case-mix weights that were set using simulated claims data of 60-day episodes grouped under the old system. Using data from CY 2020 would begin to shift case-mix weights derived from data with 60-day episodes grouped under the old system to data from actual 30-day periods under the PDGM.

The claims data provide 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 following steps:

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 refer readers to Table 13 for further information on the OASIS items used for the functional impairment level under the PDGM. We measure resource use with the cost-per-minute + NRS approach that uses information from 2019 home health cost reports. We use 2019 home health cost report data because it is the most complete data available at the time of rulemaking. Other variables in the regression model include the 30-day period's admission source, clinical group, and 30-day period timing. We also include HHA 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

[6] HHA Center webpage: *https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.*

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: 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 0.05 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 0.05 or less), we assign the two comorbidities together to the high comorbidity adjustment.

Step 3: Hold the LUPA thresholds at their current thresholds as described previously in the proposed rule.

Step 4: 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 14 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 14: COEFFICIENT OF PAYMENT REGRESSION AND COEFFICIENT DIVIDED BY AVERAGE RESOURCE USE (LUPA THRESHOLDS HELD)

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	$168.35	1.1%	0.1169
MMTA - Other - High Functional	$323.27	0.9%	0.2245
MMTA - Surgical Aftercare - Low Functional	-$88.46	1.2%	-0.0614
MMTA - Surgical Aftercare - Medium Functional	$133.25	1.2%	0.0925
MMTA - Surgical Aftercare - High Functional	$369.37	1.1%	0.2565
MMTA - Cardiac and Circulatory - Low Functional	-$52.38	6.4%	-0.0364
MMTA - Cardiac and Circulatory - Medium Functional	$122.40	6.4%	0.0850
MMTA - Cardiac and Circulatory - High Functional	$282.64	6.5%	0.1963
MMTA - Endocrine - Low Functional	$279.06	2.4%	0.1938
MMTA - Endocrine - Medium Functional	$448.54	2.4%	0.3115
MMTA - Endocrine - High Functional	$554.37	2.4%	0.3850
MMTA - Gastrointestinal tract and Genitourinary system - Low Functional	-$78.08	1.8%	-0.0542
MMTA - Gastrointestinal tract and Genitourinary system - Medium Functional	$122.71	1.3%	0.0852
MMTA - Gastrointestinal tract and Genitourinary system - High Functional	$253.62	1.5%	0.1761
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - Low Functional	-$51.16	1.6%	-0.0355
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - Medium Functional	$123.72	1.7%	0.0859
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - High Functional	$313.29	1.5%	0.2175
MMTA - Respiratory - Low Functional	-$44.10	3.3%	-0.0306
MMTA - Respiratory - Medium Functional	$121.07	2.0%	0.0841
MMTA - Respiratory - High Functional	$275.31	2.5%	0.1912
Behavioral Health - Low Functional	-$123.45	0.8%	-0.0857
Behavioral Health - Medium Functional	$98.91	0.8%	0.0687
Behavioral Health - High Functional	$230.10	0.7%	0.1598
Complex - Low Functional	-$111.18	1.2%	-0.0772
Complex - Medium Functional	$91.71	0.9%	0.0637
Complex - High Functional	$48.10	1.0%	0.0334
MS Rehab - Low Functional	$99.47	6.5%	0.0691
MS Rehab - Medium Functional	$247.69	6.9%	0.1720

MS Rehab - High Functional	$480.42	6.1%	0.3336
Neuro - Low Functional	$255.82	3.5%	0.1776
Neuro - Medium Functional	$446.01	3.5%	0.3097
Neuro - High Functional	$625.61	3.5%	0.4344
Wound - Low Functional	$423.16	5.6%	0.2938
Wound - Medium Functional	$594.79	4.0%	0.4130
Wound - High Functional	$774.05	4.7%	0.5375
Admission Source with Timing (Community Early is excluded)			
Community - Late	-$566.96	62.8%	-0.3937
Institutional - Early	$306.83	19.5%	0.2131
Institutional - Late	$171.47	6.1%	0.1191
Comorbidity Adjustment (No Comorbidity Adjustment - is excluded)			
Comorbidity Adjustment - Has at least one comorbidity from comorbidity list, no interaction from interaction list	$92.66	48.8%	0.0643
Comorbidity Adjustment - Has at least one interaction from interaction list	$316.28	14.7%	0.2196
Constant	$1,368.54		
Average Resource Use	$1,440.10		
Number of 30-day Periods	7,590,683		
Adjusted R Squared	0.3290		

Source: CY 2020 Home Health Claims Data, Periods that begin and end in CY 2020 accessed on the CCW July 12, 2021.

The case-mix weights finalized for CY 2022 are listed in Table 15 and is posted on the HHA Center webpage.[7]

[7] HHA Center Webpage: *https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.*

TABLE 15—CASE-MIX WEIGHTS FOR EACH HHRG PAYMENT GROUP

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Final Recalibrated Weight for 2022	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
1FC11	Behavioral Health - High	Early - Community	0	1.1101	4
1FC21	Behavioral Health - High	Early - Community	1	1.1744	4
1FC31	Behavioral Health - High	Early - Community	2	1.3297	4
2FC11	Behavioral Health - High	Early - Institutional	0	1.3232	4
2FC21	Behavioral Health - High	Early - Institutional	1	1.3875	4
2FC31	Behavioral Health - High	Early - Institutional	2	1.5428	4
3FC11	Behavioral Health - High	Late - Community	0	0.7164	2
3FC21	Behavioral Health - High	Late - Community	1	0.7807	2
3FC31	Behavioral Health - High	Late - Community	2	0.9360	3
4FC11	Behavioral Health - High	Late - Institutional	0	1.2292	3
4FC21	Behavioral Health - High	Late - Institutional	1	1.2935	3
4FC31	Behavioral Health - High	Late - Institutional	2	1.4488	3
1FA11	Behavioral Health - Low	Early - Community	0	0.8646	3
1FA21	Behavioral Health - Low	Early - Community	1	0.9289	4
1FA31	Behavioral Health - Low	Early - Community	2	1.0842	3
2FA11	Behavioral Health - Low	Early - Institutional	0	1.0777	3
2FA21	Behavioral Health - Low	Early - Institutional	1	1.1420	3
2FA31	Behavioral Health - Low	Early - Institutional	2	1.2973	3
3FA11	Behavioral Health - Low	Late - Community	0	0.4709	2
3FA21	Behavioral Health - Low	Late - Community	1	0.5352	2
3FA31	Behavioral Health - Low	Late - Community	2	0.6905	2
4FA11	Behavioral Health - Low	Late - Institutional	0	0.9837	2
4FA21	Behavioral Health - Low	Late - Institutional	1	1.0480	2
4FA31	Behavioral Health - Low	Late - Institutional	2	1.2033	2
1FB11	Behavioral Health - Medium	Early - Community	0	1.0190	4
1FB21	Behavioral Health - Medium	Early - Community	1	1.0833	4
1FB31	Behavioral Health - Medium	Early - Community	2	1.2386	5
2FB11	Behavioral Health - Medium	Early - Institutional	0	1.2321	4
2FB21	Behavioral Health - Medium	Early - Institutional	1	1.2964	4
2FB31	Behavioral Health - Medium	Early - Institutional	2	1.4517	3
3FB11	Behavioral Health - Medium	Late - Community	0	0.6253	2
3FB21	Behavioral Health - Medium	Late - Community	1	0.6896	2
3FB31	Behavioral Health - Medium	Late - Community	2	0.8449	2
4FB11	Behavioral Health - Medium	Late - Institutional	0	1.1381	3
4FB21	Behavioral Health - Medium	Late - Institutional	1	1.2024	3
4FB31	Behavioral Health - Medium	Late - Institutional	2	1.3577	3
1DC11	Complex - High	Early - Community	0	0.9837	3

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Final Recalibrated Weight for 2022	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
1DC21	Complex - High	Early - Community	1	1.0481	2
1DC31	Complex - High	Early - Community	2	1.2033	2
2DC11	Complex - High	Early - Institutional	0	1.1968	4
2DC21	Complex - High	Early - Institutional	1	1.2611	4
2DC31	Complex - High	Early - Institutional	2	1.4164	4
3DC11	Complex - High	Late - Community	0	0.5900	2
3DC21	Complex - High	Late - Community	1	0.6544	2
3DC31	Complex - High	Late - Community	2	0.8096	2
4DC11	Complex - High	Late - Institutional	0	1.1028	3
4DC21	Complex - High	Late - Institutional	1	1.1671	3
4DC31	Complex - High	Late - Institutional	2	1.3224	3
1DA11	Complex - Low	Early - Community	0	0.8731	3
1DA21	Complex - Low	Early - Community	1	0.9374	3
1DA31	Complex - Low	Early - Community	2	1.0927	2
2DA11	Complex - Low	Early - Institutional	0	1.0862	3
2DA21	Complex - Low	Early - Institutional	1	1.1505	3
2DA31	Complex - Low	Early - Institutional	2	1.3058	3
3DA11	Complex - Low	Late - Community	0	0.4794	2
3DA21	Complex - Low	Late - Community	1	0.5438	2
3DA31	Complex - Low	Late - Community	2	0.6990	2
4DA11	Complex - Low	Late - Institutional	0	0.9922	2
4DA21	Complex - Low	Late - Institutional	1	1.0565	2
4DA31	Complex - Low	Late - Institutional	2	1.2118	2
1DB11	Complex - Medium	Early - Community	0	1.0140	3
1DB21	Complex - Medium	Early - Community	1	1.0783	3
1DB31	Complex - Medium	Early - Community	2	1.2336	2
2DB11	Complex - Medium	Early - Institutional	0	1.2271	4
2DB21	Complex - Medium	Early - Institutional	1	1.2914	4
2DB31	Complex - Medium	Early - Institutional	2	1.4467	4
3DB11	Complex - Medium	Late - Community	0	0.6203	2
3DB21	Complex - Medium	Late - Community	1	0.6846	2
3DB31	Complex - Medium	Late - Community	2	0.8399	2
4DB11	Complex - Medium	Late - Institutional	0	1.1331	3
4DB21	Complex - Medium	Late - Institutional	1	1.1974	3
4DB31	Complex - Medium	Late - Institutional	2	1.3527	3
1HC11	MMTA - Cardiac - High	Early - Community	0	1.1466	5
1HC21	MMTA - Cardiac - High	Early - Community	1	1.2109	5
1HC31	MMTA - Cardiac - High	Early - Community	2	1.3662	4
2HC11	MMTA - Cardiac - High	Early - Institutional	0	1.3596	4

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Final Recalibrated Weight for 2022	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
2HC21	MMTA - Cardiac - High	Early - Institutional	1	1.4240	4
2HC31	MMTA - Cardiac - High	Early - Institutional	2	1.5793	5
3HC11	MMTA - Cardiac - High	Late - Community	0	0.7529	2
3HC21	MMTA - Cardiac - High	Late - Community	1	0.8172	2
3HC31	MMTA - Cardiac - High	Late - Community	2	0.9725	3
4HC11	MMTA - Cardiac - High	Late - Institutional	0	1.2656	4
4HC21	MMTA - Cardiac - High	Late - Institutional	1	1.3300	3
4HC31	MMTA - Cardiac - High	Late - Institutional	2	1.4853	4
1HA11	MMTA - Cardiac - Low	Early - Community	0	0.9139	4
1HA21	MMTA - Cardiac - Low	Early - Community	1	0.9783	4
1HA31	MMTA - Cardiac - Low	Early - Community	2	1.1336	4
2HA11	MMTA - Cardiac - Low	Early - Institutional	0	1.1270	4
2HA21	MMTA - Cardiac - Low	Early - Institutional	1	1.1913	4
2HA31	MMTA - Cardiac - Low	Early - Institutional	2	1.3466	4
3HA11	MMTA - Cardiac - Low	Late - Community	0	0.5202	2
3HA21	MMTA - Cardiac - Low	Late - Community	1	0.5846	2
3HA31	MMTA - Cardiac - Low	Late - Community	2	0.7399	2
4HA11	MMTA - Cardiac - Low	Late - Institutional	0	1.0330	3
4HA21	MMTA - Cardiac - Low	Late - Institutional	1	1.0974	3
4HA31	MMTA - Cardiac - Low	Late - Institutional	2	1.2526	3
1HB11	MMTA - Cardiac - Medium	Early - Community	0	1.0353	5
1HB21	MMTA - Cardiac - Medium	Early - Community	1	1.0996	5
1HB31	MMTA - Cardiac - Medium	Early - Community	2	1.2549	5
2HB11	MMTA - Cardiac - Medium	Early - Institutional	0	1.2484	5
2HB21	MMTA - Cardiac - Medium	Early - Institutional	1	1.3127	4
2HB31	MMTA - Cardiac - Medium	Early - Institutional	2	1.4680	5
3HB11	MMTA - Cardiac - Medium	Late - Community	0	0.6416	2
3HB21	MMTA - Cardiac - Medium	Late - Community	1	0.7059	2
3HB31	MMTA - Cardiac - Medium	Late - Community	2	0.8612	3
4HB11	MMTA - Cardiac - Medium	Late - Institutional	0	1.1544	3
4HB21	MMTA - Cardiac - Medium	Late - Institutional	1	1.2187	3
4HB31	MMTA - Cardiac - Medium	Late - Institutional	2	1.3740	4
1IC11	MMTA - Endocrine - High	Early - Community	0	1.3353	5
1IC21	MMTA - Endocrine - High	Early - Community	1	1.3996	5
1IC31	MMTA - Endocrine - High	Early - Community	2	1.5549	5
2IC11	MMTA - Endocrine - High	Early - Institutional	0	1.5483	4
2IC21	MMTA - Endocrine - High	Early - Institutional	1	1.6127	4
2IC31	MMTA - Endocrine - High	Early - Institutional	2	1.7680	4
3IC11	MMTA - Endocrine - High	Late - Community	0	0.9416	3

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Final Recalibrated Weight for 2022	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
3IC21	MMTA - Endocrine - High	Late - Community	1	1.0059	3
3IC31	MMTA - Endocrine - High	Late - Community	2	1.1612	3
4IC11	MMTA - Endocrine - High	Late - Institutional	0	1.4543	4
4IC21	MMTA - Endocrine - High	Late - Institutional	1	1.5187	3
4IC31	MMTA - Endocrine - High	Late - Institutional	2	1.6740	3
1IA11	MMTA - Endocrine - Low	Early - Community	0	1.1441	4
1IA21	MMTA - Endocrine - Low	Early - Community	1	1.2084	4
1IA31	MMTA - Endocrine - Low	Early - Community	2	1.3637	4
2IA11	MMTA - Endocrine - Low	Early - Institutional	0	1.3572	3
2IA21	MMTA - Endocrine - Low	Early - Institutional	1	1.4215	3
2IA31	MMTA - Endocrine - Low	Early - Institutional	2	1.5768	4
3IA11	MMTA - Endocrine - Low	Late - Community	0	0.7504	2
3IA21	MMTA - Endocrine - Low	Late - Community	1	0.8147	2
3IA31	MMTA - Endocrine - Low	Late - Community	2	0.9700	3
4IA11	MMTA - Endocrine - Low	Late - Institutional	0	1.2632	3
4IA21	MMTA - Endocrine - Low	Late - Institutional	1	1.3275	3
4IA31	MMTA - Endocrine - Low	Late - Institutional	2	1.4828	3
1IB11	MMTA - Endocrine - Medium	Early - Community	0	1.2618	5
1IB21	MMTA - Endocrine - Medium	Early - Community	1	1.3261	5
1IB31	MMTA - Endocrine - Medium	Early - Community	2	1.4814	4
2IB11	MMTA - Endocrine - Medium	Early - Institutional	0	1.4748	5
2IB21	MMTA - Endocrine - Medium	Early - Institutional	1	1.5392	4
2IB31	MMTA - Endocrine - Medium	Early - Institutional	2	1.6945	5
3IB11	MMTA - Endocrine - Medium	Late - Community	0	0.8681	3
3IB21	MMTA - Endocrine - Medium	Late - Community	1	0.9324	3
3IB31	MMTA - Endocrine - Medium	Late - Community	2	1.0877	3
4IB11	MMTA - Endocrine - Medium	Late - Institutional	0	1.3808	3
4IB21	MMTA - Endocrine - Medium	Late - Institutional	1	1.4452	3
4IB31	MMTA - Endocrine - Medium	Late - Institutional	2	1.6005	4
1JC11	MMTA - GI/GU - High	Early - Community	0	1.1264	4
1JC21	MMTA - GI/GU - High	Early - Community	1	1.1908	3
1JC31	MMTA - GI/GU - High	Early - Community	2	1.3461	3
2JC11	MMTA - GI/GU - High	Early - Institutional	0	1.3395	4
2JC21	MMTA - GI/GU - High	Early - Institutional	1	1.4038	4
2JC31	MMTA - GI/GU - High	Early - Institutional	2	1.5591	4
3JC11	MMTA - GI/GU - High	Late - Community	0	0.7327	2
3JC21	MMTA - GI/GU - High	Late - Community	1	0.7971	2
3JC31	MMTA - GI/GU - High	Late - Community	2	0.9524	2
4JC11	MMTA - GI/GU - High	Late - Institutional	0	1.2455	3

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Final Recalibrated Weight for 2022	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
4JC21	MMTA - GI/GU - High	Late - Institutional	1	1.3098	3
4JC31	MMTA - GI/GU - High	Late - Institutional	2	1.4651	4
1JA11	MMTA - GI/GU - Low	Early - Community	0	0.8961	3
1JA21	MMTA - GI/GU - Low	Early - Community	1	0.9604	3
1JA31	MMTA - GI/GU - Low	Early - Community	2	1.1157	3
2JA11	MMTA - GI/GU - Low	Early - Institutional	0	1.1092	3
2JA21	MMTA - GI/GU - Low	Early - Institutional	1	1.1735	3
2JA31	MMTA - GI/GU - Low	Early - Institutional	2	1.3288	4
3JA11	MMTA - GI/GU - Low	Late - Community	0	0.5024	2
3JA21	MMTA - GI/GU - Low	Late - Community	1	0.5667	2
3JA31	MMTA - GI/GU - Low	Late - Community	2	0.7220	2
4JA11	MMTA - GI/GU - Low	Late - Institutional	0	1.0152	3
4JA21	MMTA - GI/GU - Low	Late - Institutional	1	1.0795	3
4JA31	MMTA - GI/GU - Low	Late - Institutional	2	1.2348	3
1JB11	MMTA - GI/GU - Medium	Early - Community	0	1.0355	4
1JB21	MMTA - GI/GU - Medium	Early - Community	1	1.0999	4
1JB31	MMTA - GI/GU - Medium	Early - Community	2	1.2551	4
2JB11	MMTA - GI/GU - Medium	Early - Institutional	0	1.2486	4
2JB21	MMTA - GI/GU - Medium	Early - Institutional	1	1.3129	4
2JB31	MMTA - GI/GU - Medium	Early - Institutional	2	1.4682	4
3JB11	MMTA - GI/GU - Medium	Late - Community	0	0.6418	2
3JB21	MMTA - GI/GU - Medium	Late - Community	1	0.7062	2
3JB31	MMTA - GI/GU - Medium	Late - Community	2	0.8615	2
4JB11	MMTA - GI/GU - Medium	Late - Institutional	0	1.1546	3
4JB21	MMTA - GI/GU - Medium	Late - Institutional	1	1.2189	3
4JB31	MMTA - GI/GU - Medium	Late - Institutional	2	1.3742	4
1KC11	MMTA - Infectious - High	Early - Community	0	1.1679	3
1KC21	MMTA - Infectious - High	Early - Community	1	1.2322	3
1KC31	MMTA - Infectious - High	Early - Community	2	1.3875	3
2KC11	MMTA - Infectious - High	Early - Institutional	0	1.3809	3
2KC21	MMTA - Infectious - High	Early - Institutional	1	1.4453	3
2KC31	MMTA - Infectious - High	Early - Institutional	2	1.6005	4
3KC11	MMTA - Infectious - High	Late - Community	0	0.7742	2
3KC21	MMTA - Infectious - High	Late - Community	1	0.8385	2
3KC31	MMTA - Infectious - High	Late - Community	2	0.9938	2
4KC11	MMTA - Infectious - High	Late - Institutional	0	1.2869	3
4KC21	MMTA - Infectious - High	Late - Institutional	1	1.3513	3
4KC31	MMTA - Infectious - High	Late - Institutional	2	1.5066	3
1KA11	MMTA - Infectious - Low	Early - Community	0	0.9148	3

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Final Recalibrated Weight for 2022	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
1KA21	MMTA - Infectious - Low	Early - Community	1	0.9791	3
1KA31	MMTA - Infectious - Low	Early - Community	2	1.1344	3
2KA11	MMTA - Infectious - Low	Early - Institutional	0	1.1278	3
2KA21	MMTA - Infectious - Low	Early - Institutional	1	1.1922	3
2KA31	MMTA - Infectious - Low	Early - Institutional	2	1.3475	4
3KA11	MMTA - Infectious - Low	Late - Community	0	0.5211	2
3KA21	MMTA - Infectious - Low	Late - Community	1	0.5854	2
3KA31	MMTA - Infectious - Low	Late - Community	2	0.7407	2
4KA11	MMTA - Infectious - Low	Late - Institutional	0	1.0339	2
4KA21	MMTA - Infectious - Low	Late - Institutional	1	1.0982	3
4KA31	MMTA - Infectious - Low	Late - Institutional	2	1.2535	3
1KB11	MMTA - Infectious - Medium	Early - Community	0	1.0362	3
1KB21	MMTA - Infectious - Medium	Early - Community	1	1.1006	3
1KB31	MMTA - Infectious - Medium	Early - Community	2	1.2558	4
2KB11	MMTA - Infectious - Medium	Early - Institutional	0	1.2493	3
2KB21	MMTA - Infectious - Medium	Early - Institutional	1	1.3136	4
2KB31	MMTA - Infectious - Medium	Early - Institutional	2	1.4689	4
3KB11	MMTA - Infectious - Medium	Late - Community	0	0.6425	2
3KB21	MMTA - Infectious - Medium	Late - Community	1	0.7069	2
3KB31	MMTA - Infectious - Medium	Late - Community	2	0.8622	2
4KB11	MMTA - Infectious - Medium	Late - Institutional	0	1.1553	3
4KB21	MMTA - Infectious - Medium	Late - Institutional	1	1.2196	3
4KB31	MMTA - Infectious - Medium	Late - Institutional	2	1.3749	4
1AC11	MMTA - Other - High	Early - Community	0	1.1748	4
1AC21	MMTA - Other - High	Early - Community	1	1.2391	4
1AC31	MMTA - Other - High	Early - Community	2	1.3944	4
2AC11	MMTA - Other - High	Early - Institutional	0	1.3879	4
2AC21	MMTA - Other - High	Early - Institutional	1	1.4522	4
2AC31	MMTA - Other - High	Early - Institutional	2	1.6075	5
3AC11	MMTA - Other - High	Late - Community	0	0.7811	2
3AC21	MMTA - Other - High	Late - Community	1	0.8454	2
3AC31	MMTA - Other - High	Late - Community	2	1.0007	2
4AC11	MMTA - Other - High	Late - Institutional	0	1.2939	3
4AC21	MMTA - Other - High	Late - Institutional	1	1.3582	3
4AC31	MMTA - Other - High	Late - Institutional	2	1.5135	3
1AA11	MMTA - Other - Low	Early - Community	0	0.9503	4
1AA21	MMTA - Other - Low	Early - Community	1	1.0147	4
1AA31	MMTA - Other - Low	Early - Community	2	1.1699	4
2AA11	MMTA - Other - Low	Early - Institutional	0	1.1634	3

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Final Recalibrated Weight for 2022	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
2AA21	MMTA - Other - Low	Early - Institutional	1	1.2277	3
2AA31	MMTA - Other - Low	Early - Institutional	2	1.3830	3
3AA11	MMTA - Other - Low	Late - Community	0	0.5566	2
3AA21	MMTA - Other - Low	Late - Community	1	0.6210	2
3AA31	MMTA - Other - Low	Late - Community	2	0.7762	2
4AA11	MMTA - Other - Low	Late - Institutional	0	1.0694	3
4AA21	MMTA - Other - Low	Late - Institutional	1	1.1337	3
4AA31	MMTA - Other - Low	Late - Institutional	2	1.2890	3
1AB11	MMTA - Other - Medium	Early - Community	0	1.0672	5
1AB21	MMTA - Other - Medium	Early - Community	1	1.1316	5
1AB31	MMTA - Other - Medium	Early - Community	2	1.2868	4
2AB11	MMTA - Other - Medium	Early - Institutional	0	1.2803	4
2AB21	MMTA - Other - Medium	Early - Institutional	1	1.3446	4
2AB31	MMTA - Other - Medium	Early - Institutional	2	1.4999	5
3AB11	MMTA - Other - Medium	Late - Community	0	0.6735	2
3AB21	MMTA - Other - Medium	Late - Community	1	0.7379	2
3AB31	MMTA - Other - Medium	Late - Community	2	0.8931	3
4AB11	MMTA - Other - Medium	Late - Institutional	0	1.1863	3
4AB21	MMTA - Other - Medium	Late - Institutional	1	1.2506	3
4AB31	MMTA - Other - Medium	Late - Institutional	2	1.4059	4
1LC11	MMTA - Respiratory - High	Early - Community	0	1.1415	4
1LC21	MMTA - Respiratory - High	Early - Community	1	1.2058	4
1LC31	MMTA - Respiratory - High	Early - Community	2	1.3611	4
2LC11	MMTA - Respiratory - High	Early - Institutional	0	1.3546	4
2LC21	MMTA - Respiratory - High	Early - Institutional	1	1.4189	4
2LC31	MMTA - Respiratory - High	Early - Institutional	2	1.5742	4
3LC11	MMTA - Respiratory - High	Late - Community	0	0.7478	2
3LC21	MMTA - Respiratory - High	Late - Community	1	0.8121	2
3LC31	MMTA - Respiratory - High	Late - Community	2	0.9674	3
4LC11	MMTA - Respiratory - High	Late - Institutional	0	1.2606	3
4LC21	MMTA - Respiratory - High	Late - Institutional	1	1.3249	3
4LC31	MMTA - Respiratory - High	Late - Institutional	2	1.4802	3
1LA11	MMTA - Respiratory - Low	Early - Community	0	0.9197	4
1LA21	MMTA - Respiratory - Low	Early - Community	1	0.9840	4
1LA31	MMTA - Respiratory - Low	Early - Community	2	1.1393	4
2LA11	MMTA - Respiratory - Low	Early - Institutional	0	1.1327	4
2LA21	MMTA - Respiratory - Low	Early - Institutional	1	1.1971	4
2LA31	MMTA - Respiratory - Low	Early - Institutional	2	1.3524	4
3LA11	MMTA - Respiratory - Low	Late - Community	0	0.5260	2

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3LA21	MMTA - Respiratory - Low	Late - Community	1	0.5903	2
3LA31	MMTA - Respiratory - Low	Late - Community	2	0.7456	2
4LA11	MMTA - Respiratory - Low	Late - Institutional	0	1.0388	3
4LA21	MMTA - Respiratory - Low	Late - Institutional	1	1.1031	3
4LA31	MMTA - Respiratory - Low	Late - Institutional	2	1.2584	3
1LB11	MMTA - Respiratory - Medium	Early - Community	0	1.0344	4
1LB21	MMTA - Respiratory - Medium	Early - Community	1	1.0987	5
1LB31	MMTA - Respiratory - Medium	Early - Community	2	1.2540	5
2LB11	MMTA - Respiratory - Medium	Early - Institutional	0	1.2474	4
2LB21	MMTA - Respiratory - Medium	Early - Institutional	1	1.3118	4
2LB31	MMTA - Respiratory - Medium	Early - Institutional	2	1.4671	5
3LB11	MMTA - Respiratory - Medium	Late - Community	0	0.6407	2
3LB21	MMTA - Respiratory - Medium	Late - Community	1	0.7050	2
3LB31	MMTA - Respiratory - Medium	Late - Community	2	0.8603	2
4LB11	MMTA - Respiratory - Medium	Late - Institutional	0	1.1535	3
4LB21	MMTA - Respiratory - Medium	Late - Institutional	1	1.2178	3
4LB31	MMTA - Respiratory - Medium	Late - Institutional	2	1.3731	4
1GC11	MMTA - Surgical Aftercare - High	Early - Community	0	1.2068	4
1GC21	MMTA - Surgical Aftercare - High	Early - Community	1	1.2711	5
1GC31	MMTA - Surgical Aftercare - High	Early - Community	2	1.4264	4
2GC11	MMTA - Surgical Aftercare - High	Early - Institutional	0	1.4199	5
2GC21	MMTA - Surgical Aftercare - High	Early - Institutional	1	1.4842	5
2GC31	MMTA - Surgical Aftercare - High	Early - Institutional	2	1.6395	5
3GC11	MMTA - Surgical Aftercare - High	Late - Community	0	0.8131	2
3GC21	MMTA - Surgical Aftercare - High	Late - Community	1	0.8774	2
3GC31	MMTA - Surgical Aftercare - High	Late - Community	2	1.0327	2
4GC11	MMTA - Surgical Aftercare - High	Late - Institutional	0	1.3259	4
4GC21	MMTA - Surgical Aftercare - High	Late - Institutional	1	1.3902	4
4GC31	MMTA - Surgical Aftercare - High	Late - Institutional	2	1.5455	4
1GA11	MMTA - Surgical Aftercare - Low	Early - Community	0	0.8889	3
1GA21	MMTA - Surgical Aftercare - Low	Early - Community	1	0.9532	3
1GA31	MMTA - Surgical Aftercare - Low	Early - Community	2	1.1085	4
2GA11	MMTA - Surgical Aftercare - Low	Early - Institutional	0	1.1019	3
2GA21	MMTA - Surgical Aftercare - Low	Early - Institutional	1	1.1663	4
2GA31	MMTA - Surgical Aftercare - Low	Early - Institutional	2	1.3216	4
3GA11	MMTA - Surgical Aftercare - Low	Late - Community	0	0.4952	2
3GA21	MMTA - Surgical Aftercare - Low	Late - Community	1	0.5595	2
3GA31	MMTA - Surgical Aftercare - Low	Late - Community	2	0.7148	2
4GA11	MMTA - Surgical Aftercare - Low	Late - Institutional	0	1.0080	3

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Final Recalibrated Weight for 2022	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
4GA21	MMTA - Surgical Aftercare - Low	Late - Institutional	1	1.0723	3
4GA31	MMTA - Surgical Aftercare - Low	Late - Institutional	2	1.2276	4
1GB11	MMTA - Surgical Aftercare - Medium	Early - Community	0	1.0428	4
1GB21	MMTA - Surgical Aftercare - Medium	Early - Community	1	1.1072	4
1GB31	MMTA - Surgical Aftercare - Medium	Early - Community	2	1.2625	5
2GB11	MMTA - Surgical Aftercare - Medium	Early - Institutional	0	1.2559	4
2GB21	MMTA - Surgical Aftercare - Medium	Early - Institutional	1	1.3202	5
2GB31	MMTA - Surgical Aftercare - Medium	Early - Institutional	2	1.4755	5
3GB11	MMTA - Surgical Aftercare - Medium	Late - Community	0	0.6491	2
3GB21	MMTA - Surgical Aftercare - Medium	Late - Community	1	0.7135	2
3GB31	MMTA - Surgical Aftercare - Medium	Late - Community	2	0.8688	2
4GB11	MMTA - Surgical Aftercare - Medium	Late - Institutional	0	1.1619	3
4GB21	MMTA - Surgical Aftercare - Medium	Late - Institutional	1	1.2262	4
4GB31	MMTA - Surgical Aftercare - Medium	Late - Institutional	2	1.3815	4
1EC11	MS Rehab - High	Early - Community	0	1.2839	5
1EC21	MS Rehab - High	Early - Community	1	1.3483	5
1EC31	MS Rehab - High	Early - Community	2	1.5035	5
2EC11	MS Rehab - High	Early - Institutional	0	1.4970	6
2EC21	MS Rehab - High	Early - Institutional	1	1.5613	6
2EC31	MS Rehab - High	Early - Institutional	2	1.7166	6
3EC11	MS Rehab - High	Late - Community	0	0.8902	2
3EC21	MS Rehab - High	Late - Community	1	0.9546	2
3EC31	MS Rehab - High	Late - Community	2	1.1098	3
4EC11	MS Rehab - High	Late - Institutional	0	1.4030	4
4EC21	MS Rehab - High	Late - Institutional	1	1.4673	4
4EC31	MS Rehab - High	Late - Institutional	2	1.6226	5
1EA11	MS Rehab - Low	Early - Community	0	1.0194	5
1EA21	MS Rehab - Low	Early - Community	1	1.0837	5
1EA31	MS Rehab - Low	Early - Community	2	1.2390	5
2EA11	MS Rehab - Low	Early - Institutional	0	1.2324	5
2EA21	MS Rehab - Low	Early - Institutional	1	1.2968	5
2EA31	MS Rehab - Low	Early - Institutional	2	1.4521	5
3EA11	MS Rehab - Low	Late - Community	0	0.6257	2
3EA21	MS Rehab - Low	Late - Community	1	0.6900	2
3EA31	MS Rehab - Low	Late - Community	2	0.8453	2
4EA11	MS Rehab - Low	Late - Institutional	0	1.1385	4
4EA21	MS Rehab - Low	Late - Institutional	1	1.2028	3
4EA31	MS Rehab - Low	Late - Institutional	2	1.3581	4
1EB11	MS Rehab - Medium	Early - Community	0	1.1223	5

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Final Recalibrated Weight for 2022	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
1EB21	MS Rehab - Medium	Early - Community	1	1.1867	5
1EB31	MS Rehab - Medium	Early - Community	2	1.3419	5
2EB11	MS Rehab - Medium	Early - Institutional	0	1.3354	5
2EB21	MS Rehab - Medium	Early - Institutional	1	1.3997	6
2EB31	MS Rehab - Medium	Early - Institutional	2	1.5550	6
3EB11	MS Rehab - Medium	Late - Community	0	0.7286	2
3EB21	MS Rehab - Medium	Late - Community	1	0.7930	2
3EB31	MS Rehab - Medium	Late - Community	2	0.9482	3
4EB11	MS Rehab - Medium	Late - Institutional	0	1.2414	4
4EB21	MS Rehab - Medium	Late - Institutional	1	1.3057	4
4EB31	MS Rehab - Medium	Late - Institutional	2	1.4610	4
1BC11	Neuro - High	Early - Community	0	1.3847	5
1BC21	Neuro - High	Early - Community	1	1.4491	5
1BC31	Neuro - High	Early - Community	2	1.6044	5
2BC11	Neuro - High	Early - Institutional	0	1.5978	5
2BC21	Neuro - High	Early - Institutional	1	1.6621	5
2BC31	Neuro - High	Early - Institutional	2	1.8174	5
3BC11	Neuro - High	Late - Community	0	0.9910	2
3BC21	Neuro - High	Late - Community	1	1.0554	3
3BC31	Neuro - High	Late - Community	2	1.2107	3
4BC11	Neuro - High	Late - Institutional	0	1.5038	4
4BC21	Neuro - High	Late - Institutional	1	1.5681	4
4BC31	Neuro - High	Late - Institutional	2	1.7234	4
1BA11	Neuro - Low	Early - Community	0	1.1280	5
1BA21	Neuro - Low	Early - Community	1	1.1923	5
1BA31	Neuro - Low	Early - Community	2	1.3476	4
2BA11	Neuro - Low	Early - Institutional	0	1.3410	5
2BA21	Neuro - Low	Early - Institutional	1	1.4054	5
2BA31	Neuro - Low	Early - Institutional	2	1.5606	5
3BA11	Neuro - Low	Late - Community	0	0.7343	2
3BA21	Neuro - Low	Late - Community	1	0.7986	2
3BA31	Neuro - Low	Late - Community	2	0.9539	2
4BA11	Neuro - Low	Late - Institutional	0	1.2470	3
4BA21	Neuro - Low	Late - Institutional	1	1.3114	4
4BA31	Neuro - Low	Late - Institutional	2	1.4666	4
1BB11	Neuro - Medium	Early - Community	0	1.2600	5
1BB21	Neuro - Medium	Early - Community	1	1.3244	5
1BB31	Neuro - Medium	Early - Community	2	1.4796	5
2BB11	Neuro - Medium	Early - Institutional	0	1.4731	6

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Final Recalibrated Weight for 2022	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
2BB21	Neuro - Medium	Early - Institutional	1	1.5374	6
2BB31	Neuro - Medium	Early - Institutional	2	1.6927	6
3BB11	Neuro - Medium	Late - Community	0	0.8663	2
3BB21	Neuro - Medium	Late - Community	1	0.9307	2
3BB31	Neuro - Medium	Late - Community	2	1.0860	3
4BB11	Neuro - Medium	Late - Institutional	0	1.3791	4
4BB21	Neuro - Medium	Late - Institutional	1	1.4434	4
4BB31	Neuro - Medium	Late - Institutional	2	1.5987	5
1CC11	Wound - High	Early - Community	0	1.4878	5
1CC21	Wound - High	Early - Community	1	1.5521	5
1CC31	Wound - High	Early - Community	2	1.7074	5
2CC11	Wound - High	Early - Institutional	0	1.7009	5
2CC21	Wound - High	Early - Institutional	1	1.7652	5
2CC31	Wound - High	Early - Institutional	2	1.9205	5
3CC11	Wound - High	Late - Community	0	1.0941	3
3CC21	Wound - High	Late - Community	1	1.1585	3
3CC31	Wound - High	Late - Community	2	1.3137	3
4CC11	Wound - High	Late - Institutional	0	1.6069	4
4CC21	Wound - High	Late - Institutional	1	1.6712	4
4CC31	Wound - High	Late - Institutional	2	1.8265	4
1CA11	Wound - Low	Early - Community	0	1.2442	5
1CA21	Wound - Low	Early - Community	1	1.3085	4
1CA31	Wound - Low	Early - Community	2	1.4638	4
2CA11	Wound - Low	Early - Institutional	0	1.4572	4
2CA21	Wound - Low	Early - Institutional	1	1.5216	4
2CA31	Wound - Low	Early - Institutional	2	1.6768	4
3CA11	Wound - Low	Late - Community	0	0.8505	2
3CA21	Wound - Low	Late - Community	1	0.9148	3
3CA31	Wound - Low	Late - Community	2	1.0701	3
4CA11	Wound - Low	Late - Institutional	0	1.3632	3
4CA21	Wound - Low	Late - Institutional	1	1.4276	3
4CA31	Wound - Low	Late - Institutional	2	1.5829	3
1CB11	Wound - Medium	Early - Community	0	1.3633	5
1CB21	Wound - Medium	Early - Community	1	1.4277	5
1CB31	Wound - Medium	Early - Community	2	1.5830	5
2CB11	Wound - Medium	Early - Institutional	0	1.5764	5
2CB21	Wound - Medium	Early - Institutional	1	1.6407	5
2CB31	Wound - Medium	Early - Institutional	2	1.7960	5
3CB11	Wound - Medium	Late - Community	0	0.9696	3

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Final Recalibrated Weight for 2022	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
3CB21	Wound - Medium	Late - Community	1	1.0340	3
3CB31	Wound - Medium	Late - Community	2	1.1893	3
4CB11	Wound - Medium	Late - Institutional	0	1.4824	4
4CB21	Wound - Medium	Late - Institutional	1	1.5467	4
4CB31	Wound - Medium	Late - Institutional	2	1.7020	4

Source: CY 2020 Home Health Claims Data, Periods that begin and end in CY 2020 accessed from the CCW July 12 , 2021.

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To ensure the changes to the PDGM case-mix weights are implemented in a budget neutral manner, we then apply a case-mix budget neutrality factor to the CY 2022 national, standardized 30-day period payment rate. Typically, the case-mix weight budget neutrality factor is calculated using the most recent, complete home health claims data available. However, due to the COVID–19 PHE, we looked at using the previous calendar year's home health claims data (CY 2019) to determine if there were significant differences between utilizing CY 2019 and CY 2020 claims data. We noted that CY 2020 is the first year of actual PDGM utilization data, therefore, if we were to use CY 2019 data due to the COVID–19 PHE we would need to simulate 30-day periods from 60-day episodes under the old system. We believe that using CY 2020 utilization data is more appropriate than using CY 2019 utilization data because it is actual PDGM utilization data. The case-mix budget neutrality factor is calculated as the ratio of 30-day base payment rates such that total payments when the CY 2022 PDGM case-mix weights (developed using CY 2020 home health claims data) are applied to CY 2020 utilization (claims) data are equal to total payments when CY 2021 PDGM case-mix weights (developed using CY 2018 home health claims data) are applied to CY 2020 utilization data. This produces a case-mix budget neutrality factor for CY 2022 of 1.0396. For reasons described previously, CY 2020 utilization data was used to calculate the case-mix weight budget neutrality factor because it is the most recent complete data we have at the time of this rulemaking.

We invited comments on the CY 2022 proposed case-mix weights and proposed case-mix weight budget neutrality factor and comments are summarized later in this section.

Comment: MedPAC supports CMS' proposal to use CY 2020 data to recalibrate the PDGM case-mix weights for CY 2022.

Response: We thank MedPAC for its support.

Comment: Many commenters were generally opposed to the proposal to recalibrate the PDGM case-mix weights for CY 2022. These commenters expressed concerns about the influence of the COVID–19 PHE on the types of patients receiving home health care, and the use of CY 2020 data. These commenters believe that CY 2020 utilization will likely not be representative of utilization patterns in CY 2022. One commenter stated that the trends seen in 2020 and 2021 will not hold permanently, and therefore data from these periods would be skewed if used in modifying the PDGM rate structure or case-mix weight recalibration. Another commenter cautioned against the use of CY 2020 data for recalibration and stated that the COVID–19 PHE directly led to shifts in referral sources, and increases in the severity of cases. One commenter expressed concern by what they describe as ''the inconsistency in the usage of CY 2020 data, when both case-mix weights and LUPAs rates are dependent upon utilization and care patterns.'' Another commenter stated that while annual recalibration of case-mix weights is generally appropriate to ensure that that case-mix weights reflect recent trends in utilization and resource, the COVID–19 PHE has had significant effects on home health utilization and overall case-mix severity in CY 2020. Several commenters recommended that CMS maintain the structure and design of the PDGM for CY 2022.

Response: We acknowledge commenter statements and concerns as to how the COVID–19 PHE affected home health utilization in CY 2020 as well as potential impact to CY 2021 utilization. However, we continue to believe that it is important to base the PDGM case-mix weights on actual PDGM utilization data and patient resource and shift away from the use of data prior to the implementation of the PDGM, where utilization was influenced by different incentives, such as the therapy thresholds used in case-mix adjustment prior to the PDGM. As stated in the CY 2022 HH PPS proposed rule (86 FR 35892), there are several factors that contribute to how the case-mix weight is set for a particular case-mix group (such as the number of visits, length of visits, types of disciplines providing visits, and non-routine supplies) and the case-mix weight is derived by comparing the average resource use for the case-mix group relative to the average resource use across all groups. CMS believes that the COVID–19 PHE would have impacted utilization within all case-mix groups similarly. Therefore, the impact of any reduction in resource use caused by the COVID–19 PHE on the calculation of the case-mix weight would be minimized since the impact would be accounted for both in the numerator and denominator of the formula used to calculate the case-mix weight. However, the LUPA thresholds are based on the number of overall visits in a particular case-mix group (the threshold is the 10th percentile of visits or 2 visits, whichever is greater) instead of a relative value (like what is used to generate the case-mix weight). Finally, we note that if we chose not to recalibrate for CY 2022, it would be the third calendar year without an update to the case-mix weights. We believe that prolonging recalibration could lead to more significant variation in the case-mix weights than what is observed using CY 2020 utilization data.

Comment: One commenter expressed concern with the frequency of case-mix weight recalibration. This commenter

believes that CMS should not recalibrate the case-mix weights for CY 2022 because annual changes are too frequent. This commenter recommended that CMS change the frequency of recalibration from annually to no more often than every three years.

Response: We thank the commenter for the recommendation. In the CY 2019 HH PPS final rule, we finalized our proposal to annually recalibrate the PDGM case-mix weights (83 FR 56515) to reflect the most recent utilization data available at the time of rulemaking. We stated that 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. Any changes to the frequency of the recalibration of the case-mix weights would need to be proposed through notice and comment rulemaking.

Final Decision: We are finalizing the recalibration of the HH PPS case-mix weights as proposed for CY 2022. We are also finalizing the proposal to implement the changes to the PDGM case-mix weights in a budget neutral manner by applying a case-mix budget neutrality factor to the CY 2022 national, standardized 30-day period payment rate. As stated previously, the final case-mix budget neutrality factor for CY 2022 will be 1.0396.

4. CY 2022 Home Health Payment Rate Updates

a. CY 2022 Home Health Market Basket Update for HHAs

Section 1895(b)(3)(B) of the Act requires that the standard prospective payment amounts for home health 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 cost report data. As such, based on the rebased 2016–based home health market basket, we finalized our policy that the labor share is 76.1 percent and the non-labor 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, 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 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 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, calendar year, cost reporting period, or other annual period). The Bureau of Labor Statistics (BLS) is the agency that publishes the official measure of private nonfarm business MFP. Please visit *http://www.bls.gov/mfp*, to obtain the BLS historical published MFP data.

The home health update percentage for CY 2022 is based on the estimated home health market basket update, specified at section 1895(b)(3)(B)(iii) of the Act. In the CY 2022 HH PPS proposed rule, we proposed a market basket update of 2.4 percent (based on IHS Global Inc.'s first-quarter 2021 forecast with historical data through fourth-quarter 2020) (86 FR 35909). The CY 2022 proposed home health market basket update of 2.4 percent was then reduced by a productivity adjustment, as mandated by the section 3401 of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111–148), of 0.6 percentage point for CY 2022. In effect, the proposed home health payment update percentage for CY 2022 was a 1.8 percent increase. 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 2022, the proposed home health payment update was −0.2 percent (1.8 percent minus 2 percentage points). We also proposed that if more recent data became available after the publication of the proposed rule and before the publication of the final rule (for example, more recent estimates of the home health market basket update and productivity adjustment), we would use such data, if appropriate, to determine the home health payment update percentage for CY 2022 in the final rule (86 FR 35909).

Comment: Several commenters had concerns with the market basket update factor. The commenters noted that the HH PPS market basket update factor has recently declined from 3.0 percent in CY 2019 to 2.4 percent in CY 2022. They stated this is likely because the market basket price indices do not reflect the pandemic-driven inflation in large part because the market basket composite index is determined on a 4-quarter rolling average basis and reflect general cost changes across the healthcare industry—failing to account for home health specific price changes on a real-time and industry specific basis.

They also stated that the COVID–19 PHE in CY 2020 has in some part affected the supply of and demand for certain inputs, including home health labor leading to a general increase in labor and other input prices. For example, the pandemic intensified staffing shortages for HHAs as home health workers left their jobs due to fear of exposure to the virus. As such, HHAs had to raise wages to attract adequate staff. Additionally, the commenters stated that the CMS HH PPS market basket price indexes and cost weight categories may not capture increased telehealth and personal protective equipment (PPE) costs that HHAs faced as a result of the pandemic. The commenters provided an example of data from a Partnership for Quality Home Healthcare (PQHH) member HHA that suggested that in March and April of CY 2020, average pricing for masks and gowns approximately increased 8 and 6 times, respectively.

The commenters also noted that in CY 2020, some portion of home health visits were shifted to telehealth during the COVID–19 PHE. The commenters stated that HHAs can report costs of telehealth on the HHA cost report, but incompletely, which implies that cost weights and price proxies in CY 2020 and future years fail to accurately account for telehealth use.

One commenter also constructed an estimated market basket index using results from the 2021 PQHH Labor Cost Survey related to the three largest components of the market basket index (wages and salaries, benefits, and administrative and general expenses). Based on this analysis, the commenter determined that the home health specific market basket update factor should have increased by approximately 1.1 percentage points between CY 2019 and CY 2020 and by approximately 1.2 percentage points between CY 2020 and CY 2021. The commenter noted that these results were in stark contrast to CMS HH PPS market basket update factors that decreased by 0.1 percentage point between CY 2019 and CY 2020, and further by 0.6 percentage point between CY 2020 to CY 2021.

The commenter noted that CMS' indicated in the CY 2021 final rule that the lower update (2.3 percent) for CY 2021 was ''primarily driven by slower anticipated compensation growth for both health-related and other occupations as labor markets were expected to be significantly impacted during the recession that started in February 2020 and throughout the anticipated recovery.'' In contrast, their results showed that HHA wages grew at a slightly higher rate between 2019 and 2021, although underlying data shows that therapy professions primarily those in urban areas experienced a decline in wage growth in 2020. In addition, the commenter stated that the significant increase in benefits costs and administrative, general, and other costs seem to influence a large part of their increase in the estimated market basket constructed from the survey data. The commenter noted that these results reflect that the COVID–19 pandemic in 2020 likely resulted in price inflation for most HHA inputs as opposed to a recession and highlight the need for CMS to consider using price proxies that accurately reflect trends in the home health industry.

Response: We appreciate the comment and the commenter's analysis of home health agency costs. The 2016-based home health market basket is a fixed-weight, Laspeyres-type price index that measures the change in price, over time, of the same mix of goods and services purchased in the base period. The effects on total costs resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured.

Any increase in costs as a result of the COVID–19 PHE (to the extent they differ from the price increase of the 2016-based home health market basket) would not be reflected in the market basket update factor. Changes in costs would be reflected when the market basket cost weights are updated to incorporate more recent home health agency cost data.

The current HHA market basket cost weights are based on Medicare cost report data from 2016. Typically, a market basket is rebased every four to five years. However, we continually monitor the cost weights in the market baskets to ensure they are reflecting the mix of inputs used in providing services. We do not yet have cost report data available to determine the impact of the COVID–19 PHE on HHA cost structures. When the data becomes available, we will review the 2020 Medicare cost report data to evaluate the impact of the COVID–19 PHE as well as implementation of the PDGM and determine whether a rebasing of the market basket cost weights is appropriate. Any future rebasing or revising of the HHA market basket will be proposed and subject to public comments in future rulemaking.

We disagree with the commenter that the price proxies used in the HHA market basket do not accurately reflect trends in the home health industry. The price proxies used in the market basket represent the price indices that correspond with the relevant cost categories (which were determined using HHA Medicare cost report data and Bureau of Economic Analysis Benchmark Input-Output data for NAICS 621600, Home Health Care Services), capturing the overall inflation of these products or services. Specifically, the aggregate compensation price proxy reflects the occupational composition of the home health industry (healthcare and nonhealthcare) published by the BLS Office of Occupational Employment Statistics. About 25 percent of the home health market basket is proxied by the Employment Cost Index (ECI) for Wages and Salaries and ECI for Benefits for civilian hospital workers, reflecting the price increases for compensation for skilled healthcare workers that are also employed by HHAs. Another 27 percent of the home health market basket is proxied by the ECI for Wages and Salaries and ECI for Benefits for healthcare social assistance workers, reflecting the price increases for compensation for overall healthcare workers such as home health aides and nursing aides. A description of the detailed methodology used to develop the 2016-based HHA market basket can be found in the CY 2019 final rule (83 FR 56427).

For this final rule, based on IHS Global Inc.'s (IGI's) third quarter 2021 forecast, the CY 2022 increase in the 2016-based home health market basket is 3.1 percent (compared to the proposed rule of 2.4 percent), which is primarily due to forecasted higher compensation prices. The revised higher forecast for compensation prices for CY 2022 reflects the recent faster historical trends, lower projected labor-force participation, and higher anticipated overall inflation as compared to IGI's first quarter 2021 forecast.

We understand the commenter's concern for adequate price increase and payment for Medicare services. As noted in the previous comment by the Medicare Payment Advisory Commission, Medicare margins are estimated to be roughly 15 percent in 2019. In addition, we would note that the increase in the home health market basket used for the HHS PPS (that is based on a forecast) over the CY 2010 to CY 2020 time period has exceeded the resulting actual increase in the home health market basket by an average of 0.5 percentage point each year.

Comment: Several commenters supported CMS' proposal to increase aggregate payments in CY 2022 by 1.8 percent; however, they stated that due to the increased demand on the home health industry as a result of the COVID–19 PHE as well as the lack of coverage for home health services delivered remotely, they strongly encouraged CMS to implement a larger increase.

The commenters stated that annual increases to the home health payment rates have not kept pace with recent increases in home health providers' staffing and other costs, and that CMS should consider rising labor costs in particular when finalizing rates for CY 2022. They noted that patients are safest at home during a pandemic, and home health providers risk their own safety to ensure that these patients continue to receive quality care with minimum exposure. Therefore, they believed HHAs should be adequately reimbursed.

Several commenters recommended that CMS establish a process and methodology to modify home health agency payment systems and rates during a PHE to address new costs triggered by the COVID–19 PHE or unpredicted limitations in payment models. They stated that CMS modified both the market basket increase and productivity adjustment in other sectors in final rules that take effect on October 1, 2021; however, they believe neither those changes in other sectors, nor the proposed 2022 rate adjustment in home health services adequately accounts for the increased costs of care in 2021 that are highly likely to continue in 2022.

The commenters stated that foremost among the cost increases not adequately represented in the market basket increase are personal protective equipment and other infection control costs. They stated that the market basket index reflects increases in the cost of goods and labor, but it does not address new costs or volume increases in the use of such items as PPE. While the end of the COVID–19 PHE is unfortunately not known, commenters stated that they believe it is reasonable and fair to conclude that the use of PPE will be maintained at levels comparable to 2020 throughout 2021 and into 2022. As such, the commenters stated that the increased cost of care, as experienced in 2020–2021, as it relates to PPE will continue in 2022. They stated that CMS could include a PPE cost add-on to the

2022 payment episodic and per visit payment rates. The commenters stated that conceptually, an add-on has been used in Medicare home health services previously to reflect the administrative costs of OASIS and other administrative activities for LUPA-only patient care.

Response: We appreciate the commenters' support for the use of the productivity-adjusted market basket to annually update HH PPS payments. As proposed, we are using the latest available data to determine the CY 2022 home health market basket update and productivity adjustment for this final rule.

We recognize the unique challenges and market conditions as a result of the COVID–19 PHE, but based on the data available we continue to believe that the home health market basket adequately captures changes in prices associated with providing home health services. As described in the CY 2019 Home Health PPS final rule with comment period (83 FR 56427), the cost weights were calculated using the 2016 Medicare cost report data, which is provided directly by freestanding home health agencies. The price proxies used in the market basket reflect a projection of the expected price pressures for each category of expenses.

We contract with IHS Global Inc. (IGI) to purchase their quarterly forecasts of the price proxies that are used in the market baskets and multifactor productivity (MFP) that is used to determine the productivity adjustment, to ensure independence of the projections. Consistent with our proposal to use more recent data as they become available, for this final rule we have incorporated more current historical data and revised forecasts provided by IGI that factor in expected price and wage pressures. By incorporating the most recent estimates available of the market basket update and productivity adjustment, we believe these data reflect the best available projection of input price inflation faced by HHAs for CY 2022, adjusted for economy-wide productivity, which is required by statute.

We understand the commenters' concerns that the COVID–19 PHE had unexpected effects on operating costs for healthcare providers, including additional expenses related to PPE costs and services furnished remotely, for which HHAs are not paid directly. Section 1895(e)(1)(A) of the Act prohibits payment for home health services furnished via a telecommunications system, if such services substitute for in-person home health services ordered as part of a plan of care. These remote services also cannot be considered a home health visit for purposes of eligibility or payment; however, we do acknowledge the importance of these services during a PHE and beyond. In the CY 2021 final rule (85 FR 70323), we modified the language at § 409.46(e) allowing a broader use of telecommunications technology to be reported as allowable administrative costs on the home health cost report, recognizing that these services have the potential to improve efficiencies, expand the reach of healthcare providers, allow more specialized care in the home, and allow HHAs to see more patients or to communicate with patients more often.

We disagree that the market basket methodology should be modified from the current methodology to account for the incorporation of costs during this or future PHEs. The market baskets account for changes in provider input expenses in two ways: (1) Through the base year cost weights; and (2) through the projected price pressures for each cost category as measured by each of the price proxies.

As previously explained, the CMS market baskets are Laspeyres-type price indexes where relative cost weights are established for a base year. The major cost weights for the home health market basket are currently based on the reported expenses for the universe of home health agencies for 2016 on the Medicare Cost Report, and we periodically rebase the cost weights for each of the CMS market baskets to update the relative cost shares. Generally, these base year weights are updated within a five-year timeframe during a rebasing and revising of the market basket; this allows for the market baskets to reflect changes in the spending patterns of providers across the various cost categories. We have found that these cost weights typically do not change substantially from year to year. The Medicare Cost Report data are available with a time lag (for example, the most recent complete data available for home health agencies would reflect 2019 experience). We did not propose to rebase or revise the HHA market basket for CY 2022; however, as stated previously, we plan to review the 2020 Medicare cost report data when they become available to determine whether the distribution of costs faced by HHAs is different when compare to prior years. Any future rebasing or revising of the HHA market basket will be proposed and subject to public comments in future rulemaking.

Consistent with our proposal to use more recent data, the HHA CY 2022 market basket increase factor is 2.6 percent (3.1 percent market basket update reduced by 0.5 percentage point productivity adjustment) reflecting IGI's 2021 third quarter forecast. The proposed HHA CY 2022 market basket increase factor based on IGI's 2021 first quarter forecast was 1.8 percent.

Comment: MedPAC recognized that CMS must provide the statutorily mandated payment update, but they stated that this increase is not warranted based on their analysis of payment adequacy. In their March 2021 report to the Congress, the Commission found positive access, quality, and financial indicators for the sector, with margins of 15.8 percent for freestanding HHAs in 2019. Though consistent with statute, they believe that a payment update of 1.8 percent will keep payments higher than necessary for adequate access to quality care. They noted that the Commission recommended that the Congress reduce the 2021 Medicare base payment rate for HHAs by 5 percent for the 2021 payment year.

Response: We appreciate MedPAC's concern regarding the payment increase for HHAs; however, we do not have the statutory authority to implement its recommendation.

Final Decision: As proposed, we are finalizing our policy to use more recent data to determine the home health payment update percentage for CY 2022 in this final rule. Based on IHS Global Inc.'s third-quarter 2021 forecast with historical data through second-quarter 2021, the home health market basket update is 3.1 percent. The CY 2022 home health market basket update of 3.1 percent is then reduced by a productivity adjustment of 0.5 percentage point for CY 2022. For HHAs that submit the required quality data for CY 2022, the home health payment update is a 2.6 percent increase. For HHAs that do not submit the required quality data for CY 2022, the home health payment update is 0.6 percent (2.6 percent minus 2 percentage points).

b. CY 2022 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 home health services. Since the inception of the HH PPS, we have used inpatient hospital wage data in developing a wage index to be applied to home payments. We proposed to continue this practice for CY 2022, as we continue to believe that, in the absence of home health-specific wage data that accounts for area

differences, using inpatient hospital wage data is appropriate and reasonable for the HH PPS.

In the CY 2021 HH PPS final rule (85 FR 70298), we finalized the proposal to adopt the revised Office of Management and Budget (OMB) delineations with a 5 percent cap on wage index decreases, where the estimated reduction in a geographic area's wage index would be capped at 5 percent in CY 2021 only and no cap would be applied to wage index decreases for the second year (CY 2022). Therefore, we proposed to use the FY 2022 pre-floor, pre–reclassified hospital wage index with no 5 percent cap on decreases as the CY 2022 wage adjustment to the labor portion of the HH PPS rates. For CY 2022, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2017, and before October 1, 2018 (FY 2018 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 2022 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. The most recent wage index previously available for rural Puerto Rico is 0.4047. 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 2022, the only urban area without inpatient hospital wage data is Hinesville, GA (CBSA 25980). The CY 2022 wage index value for Hinesville, GA is 0.8539.

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 66085,66087), we adopted OMB's 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 2022 HH PPS wage index value for CBSA 46300, Twin Falls, Idaho, will be 0.8738. Bulletin No. 17–01 is available at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf.*

On April 10, 2018 OMB issued OMB Bulletin No. 18–03 which superseded the August 15, 2017 OMB Bulletin No. 17–01. On September 14, 2018, OMB issued OMB Bulletin No. 18–04 which superseded the April 10, 2018 OMB Bulletin No. 18–03. These bulletins established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. A copy of OMB Bulletin No. 18–04 may be obtained at: *https://www.bls.gov/bls/omb-bulletin-18-04-revised-delineations-of-metropolitan-statistical-areas.pdf.*

On March 6, 2020, OMB issued Bulletin No. 20–01, which provided updates to and superseded OMB Bulletin No. 18–04 that was issued on September 14, 2018. The attachments to OMB Bulletin No. 20–01 provided detailed information on the update to statistical areas since September 14, 2018, and were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2017 and July 1, 2018. (For a copy of this bulletin, we refer readers to *https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf.*) In OMB Bulletin No. 20–01, OMB announced one new Micropolitan Statistical Area, one new component of an existing Combined Statistical Are and changes to New England City and Town Area (NECTA) delineations. In the CY 2021 HH PPS final rule (85 FR 70298) we stated that if appropriate, we would propose any updates from OMB Bulletin No. 20–01 in future rulemaking. After reviewing OMB Bulletin No. 20–01, we have determined that the changes in Bulletin 20–01 encompassed delineation changes that would not affect the Medicare wage index for CY 2022. Specifically, the updates consisted of changes to NECTA delineations and the redesignation of a single rural county into a newly created Micropolitan Statistical Area. The Medicare wage index does not utilize NECTA definitions, and, as most recently discussed in the CY 2021 HH PPS final rule (85 FR 70298) we include hospitals located in Micropolitan Statistical areas in each State's rural wage index. Therefore, while we proposed to adopt the updates set forth in OMB Bulletin No. 20–01 consistent with our longstanding policy of adopting OMB delineation updates, we note that specific wage index updates would not be necessary for CY 2022 as a result of adopting these OMB updates. In other words, these OMB updates would not affect any geographic areas for purposes of the wage index calculation for CY 2022.

We received several comments on the CY 2022 home health wage index proposals. A summary of these comments and our responses are as follows:

Comment: A few commenters recommended overarching changes to the home health wage index including the creation of a home health specific wage index, allowing home health agencies to appeal their wage index values or utilize geographic reclassification, and establishing a home health floor of 0.80 similar to the hospice floor.

Response: While we thank the commenters for their recommendations, these comments are outside the scope of the proposed rule. Any changes to the way we adjust home health payments to account for geographic wage differences, beyond the wage index proposals discussed in the CY 2022 HH PPS proposed rule (86 FR 35874), would have to go through notice and comment rulemaking. While CMS and other stakeholders have explored potential alternatives to using OMB's statistical area definitions, CMS continues to explore potential alternatives to explore alternatives to using OMB's delineations but we continue to believe that in the absence of home health specific wage data, using the pre-floor, pre-reclassified hospital wage data is appropriate and reasonable for home health payments. The reclassification provision at section 1886(d)(10)(C)(i) of the Act states that the Board shall consider the application of any subsection (d) hospital requesting the Secretary change the hospital's

geographic classification. The reclassification provision found in section 1886(d)(10) of the Act is specific to hospital inpatient prospective payment system (IPPS) hospitals only.

Additionally, the application of the hospice floor is specific to hospices and does not apply to HHAs. The hospice floor was developed through a negotiated rulemaking advisory committee, under the process established by the Negotiated Rulemaking Act of 1990 (Pub. L. 101–648). Committee members included representatives of national hospice associations; rural, urban, large, and small hospices; multi-site hospices; consumer groups; and a government representative. The Committee reached consensus on a methodology that resulted in the hospice wage index. Because the reclassification provision applies only to hospitals, and the hospice floor applies only to hospices, we continue to believe the use of the pre-floor and pre-reclassified hospital wage index results in the most appropriate adjustment to the labor portion of the home health payment rates. This position is longstanding and consistent with other Medicare payment systems (for example, SNF PPS, IRF PPS, and Hospice).

Comment: A commenter stated that the pre-floor, pre-reclassified hospital wage index is 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''.

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: A few commenters recommended that CMS reconsider its decision to apply the new OMB geographic designations for CBSAs in the annual wage index update. Specifically, commenters had concerns with wages index decreases for counties in New Jersey that moved from the New York City Metropolitan CBSA and now make up the newly created New Brunswick-Lakewood, NJ, CBSA as well as Franklin County, Massachusetts, that moved from rural to urban status.

Response: We remind commenters that the revised OMB delineations were finalized in the CY 2021 HH PPS final rule (85 FR 70306). Additionally, we continue to believe it is important for the home health wage index to use the latest OMB delineations available in order to maintain an accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. We note that the wage-index value is applied to home health payments are based on where the individual is receiving home health services and not the location of the home health agency. For example, if a home health agency in New Jersey is servicing a patient in the New York City Metropolitan CBSA, the wage index for New York City would apply to the payment.

Comment: A few commenters stated that providers should be protected against substantial payment reductions due to dramatic reductions in wage index values from 1 year to the next and recommended that CMS maintain the 5 percent cap that was put in place for CY 2021. A commenter recommended that CMS should implement a 2 percent cap on wage index decreases for CY 2022. Other commenters recommended that CMS adopt a transition policy for home health providers that mirrors the 5–percent cap on annual wage index reductions included in the FY 2022 IPPS/LTCH PPS final rule.

Response: We appreciate the suggestions for improving the HH PPS wage index. We did not propose changes to the HH PPS wage index methodology for CY 2022, and therefore we are not finalizing any changes to that methodology in this final rule. However, we will take these comments into consideration to potentially inform future rulemaking.

Comment: A commenter stated that rural areas are disproportionately affected by what the commenter artificially reduced rural hospital wage indices. This commenter believes that in areas with lower population densities, travel costs are increased because of the time and mileage involved in traveling from patient to patient to provide services, and the current method of adjusting labor costs using the hospital wage index does not accurately account for increased travel costs and lost productivity in serving rural areas.

Response: As discussed in the CY 2017 HH PPS final rule (81 FR 76721), we do not believe that a population density adjustment is appropriate at this time. Rural HHAs continually cite the added cost of traveling from one patient to the next. However, urban HHAs cite the added costs associated with needed security measures and traffic congestion. The home health wage index values in rural areas are not necessarily lower than the home health wage index values in urban areas. The home health wage index reflects the wages that inpatient hospitals pay in their local geographic areas.

Final Decision: After considering the comments received in response to the CY 2022 HH PPS proposed rule, we are finalizing our proposal to continue to use the pre-floor, pre-reclassified hospital inpatient wage index with no 5 percent cap on wage index decreases as the wage adjustment to the labor portion of the HH PPS rates. For CY 2022, the updated wage data are for the hospital cost reporting periods beginning on or after October 1, 2017 and before October 1, 2018 (FY 2018 cost report data).

The final CY 2022 HH PPS wage index is available on the CMS website at: *https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center*.

c. CY 2022 Annual Payment Update

(1) Background

The 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 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 the CY 2020 HH PPS final rule with comment period (84 FR 60478), the unit of home health payment changed from a 60-day episode to a 30-day period effective for those 30-day periods beginning on or after January 1, 2020.

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 rebasing the home health market basket to reflect 2016 Medicare cost report data. We also finalized a revision to the labor share to reflect the 2016-based home health market basket compensation (Wages and Salaries plus Benefits) cost weight. We finalized our policy that for CY 2019 and subsequent years, the labor share would be 76.1 percent and the non-labor share would be 23.9 percent. The following are the steps we take to compute the case-mix and wage-adjusted 30-day period payment amount for CY 2022:

- Multiply the national, standardized 30-day period rate by the patient's applicable case-mix weight.

- Divide the case-mix adjusted amount into a labor (76.1 percent) and a non–labor portion (23.9 percent).
- Multiply the labor portion by the applicable wage index based on the site of service of the beneficiary.
- Add the wage-adjusted portion to the non-labor portion, yielding the case-mix and wage adjusted 30-day period payment amount, 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 home health quality data, as specified by the Secretary, the unadjusted national prospective 30-day period rate is equal to the rate for the previous calendar year increased by the applicable home health 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.

The final claim that the HHA submits for payment determines the total payment amount for the period and whether we make an applicable adjustment to the 30-day case-mix and wage-adjusted payment amount. The end date of the 30-day period, as reported on the claim, determines which calendar year rates Medicare will use to pay the claim.

We may adjust a 30-day case-mix and wage-adjusted payment based on the information submitted on the claim to reflect the following:

- A LUPA is provided on a per-visit basis as set forth in §§ 484.205(d)(1) and 484.230.
- A 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.

(2) CY 2022 National, Standardized 30-Day Period Payment Amount

In the CY 2022 HH PPS proposed rule (86 FR 35880), CMS provided preliminary monitoring data for the first year of the PDGM and presented a repricing method to determine the differences between assumed and actual behavior changes and the impact of such on estimated aggregate expenditures. For CY 2022, we did not propose to make any additional permanent or temporary adjustments to the national, standardized 30-day period payment in accordance with section 1895(b)(3)(D) of the Act.

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 2022 national, standardized 30-day period payment rate, we apply a case-mix weights recalibration budget neutrality factor, a wage index budget neutrality factor and the home health payment update percentage discussed in section III.C.2. of this final rule. As discussed previously, to ensure the changes to the PDGM case-mix weights are implemented in a budget neutral manner, we apply a case-mix weights budget neutrality factor to the CY 2021 national, standardized 30-day period payment rate. The final case-mix weights budget neutrality factor for CY 2022 is 1.0396.

Additionally, we also apply a wage index budget neutrality to ensure that wage index updates and revisions are implemented in a budget neutral manner. Typically, the wage index budget neutrality factor is calculated using the most recent, complete home health claims data available. However, due to the COVID–19 PHE, we looked at using the previous calendar year's home health claims data (CY 2019) to determine if there were significant differences between utilizing 2019 and 2020 claims data. Our analysis showed that there is only a small difference between the wage index budget neutrality factors calculated using CY 2019 and CY 2020 home health claims data. Therefore, we decided to continue our practice of using the most recent and complete home health claims data available; that is why we used CY 2020 claims data for the CY 2022 payment rate updates.

To calculate the wage index budget neutrality factor, we first determine the payment rate needed for non-LUPA 30-day periods using the CY 2022 wage index so those total payments are equivalent to the total payments for non-LUPA 30-day periods using the CY 2021 wage index and the CY 2021 national standardized 30-day period payment rate adjusted by the case-mix weights recalibration neutrality factor. Then, by dividing the payment rate for non-LUPA 30-day periods using the CY 2022 wage index by the payment rate for non-LUPA 30-day periods using the CY 2021 wage index, we obtain a wage index budget neutrality factor of 1.0019. We then apply the wage index budget neutrality factor of 1.0019 to the 30-day period payment rate.

Next, we update the 30-day period payment rate by the CY 2022 home health payment update percentage of 2.6 percent. The CY 2022 national, standardized 30-day period payment rate is calculated in Table 16.

TABLE 16: CY 2022 NATIONAL, STANDARDIZED 30-DAY PERIOD PAYMENT AMOUNT

CY 2021 National Standardized 30-Day Period Payment	Case-Mix Weights Recalibration Neutrality Factor	Wage Index Budget Neutrality Factor	CY2022 HH Payment Update	CY 2022 National, Standardized 30-Day Period Payment
$1,901.12	1.0396	1.0019	1.026	$2,031.64

The CY 2022 national, standardized 30-day period payment rate for an HHA that does not submit the required quality data is updated by the CY 2022 home health payment update of 2.6 percent minus 2 percentage points and is shown in Table 17.

TABLE 17: CY 2022 NATIONAL, STANDARDIZED 30-DAY PERIOD PAYMENT AMOUNT FOR HHAS THAT DO NOT SUBMIT THE QUALITY DATA

CY 2021 National Standardized 30-Day Period Payment	Case-Mix Weights Recalibration Neutrality Factor	Wage Index Budget Neutrality Factor	CY 2022 HH Payment Update Minus 2 Percentage Points	CY 2022 National, Standardized 30-Day Period Payment
$1,901.12	1.0396	1.0019	1.006	$1,992.04

(3) CY 2022 National Per-Visit Rates for 30-day Periods of Care

The national per-visit rates are used to pay LUPAs and to compute imputed costs in outlier calculations. The per-visit rates are paid by type of visit or home health 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 2022 national per-visit rates, we started with the CY 2021 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 30-day periods of care using the CY 2022 wage index and comparing it to simulated total payments for LUPA 30-day periods of care using the CY 2021 wage index. By dividing the payment rates for LUPA 30-day periods of care using the CY 2022 wage index by the payment rates for LUPA 30-day periods of care using the CY 2021 wage index, we obtained a wage index budget neutrality factor of 1.0019. We apply the wage index budget neutrality factor in order to calculate the CY 2022 national per–visit rates.

The LUPA per-visit rates are not calculated using case-mix weights therefore, no case–mix weights budget neutrality factor is needed to ensure budget neutrality for LUPA payments. Lastly, the per-visit rates for each discipline are updated by the CY 2022 home health payment update percentage of 2.6 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 2022 national per–visit rates for HHAs that submit the required quality data are updated by the CY 2022 home health payment update percentage of 2.6 percent and are shown in Table 18.

TABLE 18: CY 2022 NATIONAL PER-VISIT PAYMENT AMOUNTS

HH Discipline	CY 2021 Per-Visit Payment Amount	Wage Index Budget Neutrality Factor	CY 2022 HH Payment Update	CY 2022 Per-Visit Amount
Home Health Aide	$69.11	X 1.0019	X 1.026	$71.04
Medical Social Services	$244.64	X 1.0019	X 1.026	$251.48
Occupational Therapy	$167.98	X 1.0019	X 1.026	$172.67
Physical Therapy	$166.83	X 1.0019	X 1.026	$171.49
Skilled Nursing	$152.63	X 1.0019	X 1.026	$156.90
Speech-Language Pathology	$181.34	X 1.0019	X 1.026	$186.41

The CY 2022 per-visit payment rates for HHAs that do not submit the required quality data are updated by the CY 2020 home health payment update percentage of 2.6 percent minus 2 percentage points and are shown in Table 19.

TABLE 19: CY 2022 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

HH Discipline	CY 2021 Per-Visit Amount	Wage Index Budget Neutrality Factor	CY 2022 HH Payment Update Minus 2 Percentage Points	CY 2022 Per-Visit Amount
Home Health Aide	$69.11	X 1.0019	X 1.006	$69.66
Medical Social Services	$244.64	X 1.0019	X 1.006	$246.58
Occupational Therapy	$167.98	X 1.0019	X 1.006	$169.31
Physical Therapy	$166.83	X 1.0019	X 1.006	$168.15
Skilled Nursing	$152.63	X 1.0019	X 1.006	$153.84
Speech-Language Pathology	$181.34	X 1.0019	X 1.006	$182.77

The following is a summary of the public comments received about the CY 2022 payment update and our response.

Comment: Several commenters stated their support for the CY 2022 home health payment update. However, many stated that with the increasing demand of the home health industry because of the COVID–19 PHE, CMS should consider increasing Medicare payments to ensure that HHAs are able to provide quality care. MedPAC mentioned that though CMS was updating payment rates according to statute, they believe that payments were higher than necessary and should be reduced. Additionally, several commenters recommended that CMS establish a process and methodology to modify HHA payment systems and rates when an extreme and uncontrollable circumstance (for example, PHE) occurs to accurately account for new costs triggered by the emergency, such as personal protective equipment (PPE).

Response: We thank commenters for expressing their concerns. CMS is statutorily required to update the payment rates under the prospective payment system by the home health percentage in accordance with section 1895(b)(3)(B) of the Act. We understand commenters' request to establish a process to modify payments during an unforeseen circumstance, such as a PHE. However, we do not have the statutory authority to modify the HH PPS methodology, in the event of an extreme and uncontrollable circumstance.

Final Decision: For CY 2022, we are finalizing the national, standardized 30-day payment rates, the per-visit payment rates, and the home health payment update percentage of 2.6 percent for providers submitting quality data and 0.6 percent for those not submitting quality data.

We are reminding stakeholders of the policies finalized in the CY 2020 HH PPS final rule with comment period (84 FR 60544) and the implementation of a new one-time Notice of Admission (NOA) process starting in CY 2022. In that final rule, we finalized the lowering of the up-front payment made in response to Requests for Anticipated Payment (RAPs) to zero percent for all 30-day periods of care beginning on or after January 1, 2021 (84 FR 60544). For CY 2021, all HHAs (both existing and newly-enrolled HHAs) were required to submit a RAP at the beginning of each 30-day period in order to establish the home health period of care in the common working file and also to trigger the consolidated billing edits. With the removal of the upfront RAP payment for CY 2021, we relaxed the required information for submitting the RAP for CY 2021 and also stated that the information required for submitting an NOA for CYs 2022 and subsequent years would mirror that of the RAP in CY 2021. Starting in CY 2022, HHAs will submit a one-time NOA that establishes the home health period of care and covers all contiguous 30-day periods of care until the individual is discharged from Medicare home health services. Also, for the one-time NOA for CYs 2022 and subsequent years, we finalized a payment reduction if the HHA does not submit the NOA within 5 calendar days from the start of care. That is, if an HHA fails to submit a timely NOA for CYs 2022 and subsequent years, the reduction in payment amount would be equal to a 1/30 reduction to the wage and case-mix 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. In other words, the 1/30 reduction would be to the 30-day period adjusted payment amount, including any outlier payment, that the HHA otherwise would have received absent any reduction. For LUPA 30-day 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.

We remind stakeholders that for purposes of determining if an NOA is timely-filed, the NOA must be submitted within 5 calendar days after the start of care for the first 30-day period of care. For example, if the start of care for the first 30-day period is January 1, 2022, the NOA would be considered timely-filed if it is submitted on or before January 6, 2022.

Example

1/1/2022 = Day 0 (start of the first 30-day period of care).

1/6/2022 = Day 5 (An NOA submitted on or before this date would be considered ''timely–filed''.)

1/7/2022 and after = Day 6 and subsequent days (An NOA submitted on and after this date would trigger the penalty.) In the event that the NOA is not timely-filed, the penalty is calculated from the first day of that 30-day period (in the example, the penalty calculation would begin with the start of care date of January 1, 2022, counting as the first day of the penalty) until the date of the submission of the NOA.

Also, in the CY 2020 HH PPS final rule with comment period (84 FR 60478), we finalized exceptions to the timely filing consequences of the NOA requirements at § 484.205(j)(4). Specifically, we finalized our policy that CMS may waive the consequences

of failure to submit a timely-filed NOA if it is determined that a circumstance encountered by a home health agency is exceptional and qualifies for waiver of the consequence. As finalized in the CY 2020 HH PPS final rule with comment period and as set forth in regulation at § 484.205(j)(4), an exceptional circumstance may be due to, but is not limited to the following:

- Fires, floods, earthquakes, or similar unusual events that inflict extensive damage to the home health agency's ability to operate.
- A CMS or Medicare contractor systems issue that is beyond the control of the home health agency.
- A newly Medicare-certified home health agency that is notified of that certification after the Medicare certification date, or which is awaiting its user ID from its Medicare contractor.
- Other situations determined by CMS to be beyond the control of the home health agency.

If an HHA believes that there is a circumstance that may qualify for an exception, the HHA must fully document and furnish any requested documentation to their MAC for a determination of exception.

Though we did not solicit comments on the previously finalized NOA process for CY 2022, we did receive several comments on various components of the finalized policy. However, these comments were out of scope of the proposed rule because we did not propose to make any changes to the finalized policy. For more in-depth information regarding the finalized policies associated with the new one-time NOA process, we refer readers to the CY 2020 HH PPS final rule with comment period (84 FR 60544) as well as the regulations at § 484.205(j).

(4) LUPA Add-On Factors

Prior to the implementation of the 30-day unit of payment, LUPA episodes were eligible for a LUPA add-on payment if the episode of care was the first or only episode in a sequence of adjacent episodes. As stated in the CY 2008 HH PPS final rule, 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 period (83 FR 56440), in addition to finalizing a 30-day unit of payment, 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 final CY 2022 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 would be $289.50 (1.8451 multiplied by $156.90), subject to area wage adjustment.

(5) Occupational Therapy LUPA Add-On Factor

In order to implement Division CC, section 115, of CAA 2021, we proposed conforming changes to regulations at § 484.55(a)(2) and (b)(3) that were revised to allow OTs to conduct initial and comprehensive assessments for all Medicare beneficiaries under the home health benefit when the plan of care does not initially include skilled nursing care, but includes either PT or SLP. Because of this change, we proposed to establish a LUPA add-on factor for calculating the LUPA add-on payment amount for the first skilled occupational therapy visit in LUPA periods that occurs as the only period of care or the initial 30-day period of care in a sequence of adjacent 30-day periods of care. Currently, there is no sufficient data regarding the average excess of minutes for the first visit in LUPA periods when the initial and comprehensive assessments are conducted by occupational therapists. Therefore, we proposed to utilize the PT LUPA add-on factor of 1.6700 as a proxy until we have CY 2022 data to establish a more accurate OT add-on factor for the LUPA add-on payment amounts. We believe the similarity in the per-visit payment rates for both PT and OT make the PT LUPA add-on factor the most appropriate proxy. We solicited comments on this proposal.

Comment: Commenters were in support of CMS creating an OT add-on factor for the OT LUPA add-on payments. Additionally, there was support utilizing the PT LUPA add-on factor as a proxy until there is enough CY 2022 data to create an OT add-on factor for the OT LUPA add-on payments.

Response: We thank commenters for their support of the OT add-on factor.

Final Decision: We are finalizing our proposal to use the PT add-on factor as a proxy for the OT add-on factor, until we have sufficient CY 2022 data to create an OT add-on factor.

d. Rural Add-On Payments for CY 2022

(1) Background

Section 421(a) of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108–173) required, for home health 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 home health 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 home health 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 home health 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 home health services provided in a rural area (as defined in section 1886(d)(2)(D) of the Act), for episodes and visits ending before January 1, 2019.

(2) Rural Add-on Payments for CYs 2019 through CY 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 is available in the Downloads section associated with the publication of this rule at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices.html*. In addition, an Excel file containing the rural county or equivalent area name, their Federal Information Processing Standards (FIPS) State and county codes, and their designation into one of the three rural add-on categories is available for download.

The HH PRICER module, located within CMS' claims processing system, would increase the CY 2022 30-day base payment rates, described in section III.C.3. of this final rule, by the appropriate rural add-on percentage prior to applying any case-mix and wage index adjustments. The CY 2019 through CY 2022 rural add-on percentages outlined in law are shown in Table 20.

TABLE 20: HOME HEALTH PPS RURAL ADD-ON PERCENTAGES, CYs 2019-2022

Category	CY 2019	CY 2020	CY 2021	CY 2022
High utilization	1.5%	0.5%	None	None
Low population density	4.0%	3.0%	2.0%	1.0%
All other	3.0%	2.0%	1.0%	None

Though we did not make any proposals regarding the rural add-on percentages in the CY 2022 HH PPS proposed rule, we did receive some comments as summarized in this section of this final rule.

Comment: While commenters understood the rural add-on payments decrease has been mandated by the BBA of 2018, many expressed continued concern and frustration of the reduction in support for access to rural beneficiaries. Commenters stated that providers in rural areas face higher overhead expenses due to increased travel time between patients as well as demands for extra staff in areas where workforce challenges already exist. A few commenters suggested that CMS should work with Congress to provide immediate relief to rural home health providers that face increased costs responding to patient's during the COVID–19 PHE and to maintain the rural add-on payment at 3 percent in order to protect Medicare beneficiaries' access to home health in rural communities.

Response: We thank commenters for their recommendations. We understand commenter concerns about the 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 modify or extend it. CMS will continue to monitor patient access to home health services and the costs associated with providing home health care in rural versus urban areas.

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*. 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.

e. Payments for High-Cost Outliers Under the HH PPS

(1) Background

Section 1895(b)(5) of the Act allows for the provision of an addition or adjustment to the home health payment amount otherwise made in the case of outliers because of unusual variations in the type or amount of medically necessary care. Under the HH PPS and the previous unit of payment (that is, 60-day episodes), outlier payments were made for 60-day 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 PEP adjustment 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 home health 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, 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 redesignating the existing language as section 1895(b)(5)(A) of the Act and revised 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, 43742 and 81 FR 76702), we described our concerns regarding patterns observed in home health outlier episodes. Specifically, we noted 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 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.

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, the per unit rates used to estimate an episode's cost were 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 will continue to monitor the visit length by discipline as more recent data becomes available, and 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 calculated payment for high-cost outliers based upon 30-day period of care. Upon implementation of the PDGM and 30-day unit of payment, we finalized the FDL ratio of 0.56 for 30-day periods of care in CY 2020. Given that CY 2020 was the first year of the PDGM and the change to a 30-day unit of payment, we finalized to maintain the same FDL ratio of 0.56 in CY 2021 as we did not have sufficient CY 2020 data at the time of CY 2021 rulemaking to propose a change to the FDL ratio for CY 2021.

(2) Fixed Dollar Loss (FDL) Ratio for CY 2022

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 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 periods. Alternatively, a lower FDL ratio means that more periods can qualify for outlier payments, but outlier payments per period must be lower.

The FDL ratio and the loss-sharing ratio are 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. For the proposed rule, with CY 2020 claims data (as of March 30, 2021), we proposed an FDL ratio of 0.41. Using CY 2020 claims data (as of July 12, 2021) showed that for CY 2022 the final FDL ratio would need to be 0.40 to pay up to, but no more than, 2.5 percent of the total payment as outlier payments in CY 2022.

For this final rule, simulating payments using preliminary CY 2020 claims data (as of July 12, 2021) and the CY 2021 HH PPS payment rates (85 FR 70316), we estimate that outlier payments in CY 2021 would comprise 2.1 percent of total payments. Based on simulations using CY 2020 claims data (as of July 12, 2021) and the proposed CY 2022 payment rates presented in Section III.C.2 of this final rule, we estimate that outlier payments would constitute approximately 1.8 percent of

total HH PPS payments in CY 2022. Our simulations showed that the FDL ratio would need to be changed from 0.56 to 0.40 to pay up to, but no more than, 2.5 percent of total payments as outlier payments in CY 2022.

Comment: A commenter recommended ending the outlier provision and restore the 5 percent to fund the outlier payments into regular Medicare payments.

Response: The HH PPS allows for outlier payments to be made to providers for episodes that have unusually large amounts of cost because of a patient's home health care needs. Nevertheless, we believe that section 1895(b)(5)(A) of the Act allows the Secretary the discretion as to whether or not to have an outlier policy under the HH PPS. CMS believes the outlier provision is beneficial since it addresses any additional or unpredictable cost that is medically necessary for a patient. In addition, we believe outlier payments are beneficial in helping to mitigate the incentive for HHAs to avoid patients that need higher levels of medical care.

Final Decision: We are finalizing the fixed-dollar loss ratio of 0.40 for CY 2022 so the estimated total outlier payments are up to, but not more than, 2.5 percent of the payments estimated to be made under the HH PPS.

6. Conforming Regulations Text Changes Regarding Allowed Practitioners

As stated in the May 2020 COVID–19 interim final rule with comment period (85 FR 27550), we amended the regulations at parts 409, 424, and 484 to implement section 3708 of the CARES Act. This included defining a nurse practitioner (NP), a clinical nurse specialist (CNS), and a physician's assistant (PA) (as such qualifications are defined at §§ 410.74 through 410.76) as ''allowed practitioners'' (85 FR 27572). This means that in addition to a physician, as defined at section 1861(r) of the Act, an allowed practitioner may certify, establish and periodically review the plan of care, as well as supervise the provision of items and services for beneficiaries under the Medicare home health benefit. Additionally, we amended the regulations to reflect that we would expect the allowed practitioner to also perform the face-to-face encounter for the patient for whom they are certifying eligibility; however, if a face-to-face encounter is performed by a physician or an allowed non-physician practitioner (NPP), as set forth in § 424.22(a)(1)(v)(A), in an acute or post-acute facility, from which the patient was directly admitted to home health, the certifying allowed practitioner may be different from the physician or allowed practitioner that performed the face-to-face encounter. These regulations text changes are not time limited to the period of the COVID–19 PHE.

When implementing plan of care changes in the CY 2021 HH PPS final rule (85 FR 70298), the term ''allowed practitioner'' was inadvertently deleted from the regulation text at § 409.43. Therefore, in the CY 2022 HH PPS proposed rule (86 FR 35915), we proposed conforming regulations text changes at § 409.43 to reflect that allowed practitioners, in addition to physicians, may establish and periodically review the plan of care.

Comment: Commenters were supportive of the proposed conforming regulations text changes at § 409.43 and noted that they are appreciative of CMS' attention to updating the regulations to prevent confusion regarding who is authorized to establish and review the home health plan of care. Additional commenters requested changes to the regulations at 42 CFR 424.22.

Response: We thank commenters for their review of the rule and support of the changes at § 409.43, and note that the suggested changes at 42 CFR 424.22 are out of scope of this final rule and would require a notice of proposed rulemaking.

Final Decision: We are finalizing the conforming regulations at § 409.43, consistent with section 3708 of the CARES Act to allow ''allowed practitioners'' to establish and periodically review the home health plan of care.

III. Home Health Value–Based Purchasing (HHVBP) Model

A. Expansion of the HHVBP Model Nationwide

1. Background

As authorized by section 1115A of the Act and finalized in the CY 2016 HH PPS final rule (80 FR 68624), the CMS Center for Medicare and Medicaid Innovation (Innovation Center) implemented the Home Health Value-Based Purchasing Model (original Model) in nine States on January 1, 2016. The last year of data collection for the original Model ended on December 31, 2020. The original Model design leveraged the successes of and lessons learned from other value-based purchasing programs and demonstrations to shift from volume-based payments to a Model designed to promote the delivery of higher quality care to Medicare beneficiaries. The specific goals of the original Model were 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 original 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 were required to compete in the original Model. We stated that requiring all Medicare-certified HHAs in the selected States to participate in the Model ensures that there is no selection bias, participants are representative of HHAs nationally, and there would be sufficient participation to generate meaningful results.

The original Model uses the waiver authority under section 1115A(d)(1) of the Act to adjust the Medicare payment amounts under section 1895(b) of the Act based on the competing HHAs' performance on applicable quality measures. Under the original Model, CMS adjusts fee-for-service payments to Medicare-certified HHAs based on each HHA's performance on a set of quality measures in a given performance year measured against a baseline year and relative to peers in its State. The maximum payment adjustment percentage increased incrementally, upward or downward, over the course of the original 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, which is comprised of performance on: (1) A set of measures already reported via the Outcome and Assessment Information Set (OASIS),[8] completed Home Health Consumer Assessment of Healthcare Providers and Systems (HHCAHPS) surveys, and claims-based measures; and (2) three New Measures for which points were achieved for reporting data. Payment adjustments for a given year are based on the TPS calculated for performance 2 years' prior; for example, the CY 2018 payment adjustments were based on CY 2016 performance.

[8] OASIS is the instrument/data collection tool used to collect and report performance data by HHAs.

In the CY 2017 HH PPS final rule (81 FR 76741 through 76752), CY 2018 HH PPS final rule (83 FR 51701 through 51706), and CY 2019 HH PPS final rule (83 FR 56527 through 56547), we finalized changes to the original 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.

On January 8, 2021, we announced that the HHVBP Model had been certified for expansion nationwide,[9] as well as our intent to expand the Model through notice and comment rulemaking beginning no sooner than CY 2022. The original Model has resulted in an average 4.6 percent improvement in home health agencies' quality scores as well as average annual savings of $141 million to Medicare.[10]

As described in this final rule, we proposed to expand the HHVBP Model (expanded Model/Model expansion) to all 50 States, the District of Columbia and the territories starting in CY 2022. We proposed to codify HHVBP Model expansion policies at §§ 484.340; 484.345; 484.350; 484.355; 484.360; 484.365; 484.370; and 484.375, as discussed in more detail in the sections that follow.

2. Requirements for Expansion

Section 1115A(c) of the Act provides the Secretary with the authority to expand (including implementation on a nationwide basis), through notice and comment rulemaking, the duration and scope of a model that is being tested under section 1115A(b) of the Act if the following findings are made, taking into account the evaluation of the model under section 1115A(b)(4) of the Act: (1) The Secretary determines that the expansion is expected to either reduce spending without reducing quality of care or improve the quality of patient care without increasing spending; (2) the CMS Chief Actuary certifies that the expansion would reduce (or would not result in any increase in) net program spending; and (3) the Secretary determines that the expansion would not deny or limit the coverage or provision of benefits.

- *Improved Quality of Care without Increased Spending:* As observed in the Third Annual Evaluation Report,[11] the HHVBP Model resulted in improved quality of care (for example, consistently increasing TPS scores) and a reduction in Medicare expenditures through three performance years of the HHVBP Model (CYs 2016 to 2018). The HHVBP Model's intervention has led to savings without evidence of adverse risks. The evaluation also found reductions in unplanned acute care hospitalizations and skilled nursing facility (SNF) visits, resulting in reductions in inpatient and SNF spending. Based on these findings, the Secretary determined that expansion of the HHVBP Model would reduce spending and improve the quality of care.
- *Impact on Medicare Spending:* The CMS Chief Actuary has certified that expansion of the HHVBP Model would produce Medicare savings if expanded to all States.[12]
- *No Alteration in Coverage or Provision of Benefits:* The HHVBP Model did not make any changes to coverage or provision of benefits for Medicare beneficiaries. Therefore, the Secretary has determined that expansion of the HHVBP Model would not deny or limit the coverage or provision of Medicare benefits for Medicare beneficiaries.

Consistent with our statutory authority, we stated in the proposed rule that we would continue to test and evaluate the expanded HHVBP Model. In the future, we would assess whether the expanded implementation of HHVBP is continuing to reduce Medicare spending without reducing quality of care or to improve the quality of patient care without increasing spending, and could modify the expanded HHVBP Model as appropriate through rulemaking.

We summarize in this section of this rule comments received regarding the requirements for expansion and our responses.

Comment: Commenters disagreed that CMS has met the statutory requirement that expansion of the HHVBP Model would not deny or limit the coverage or provision of Medicare benefits for Medicare beneficiaries and stated that while incremental improvements in quality performance and cost-savings are encouraging, they questioned whether those numbers are sufficient to justify ending the original model early during a pandemic and expanding it nationwide. Commenters asserted that access under the original Model was negatively impacted and expansion of HHVBP will exponentially worsen access to care.

Response: We disagree that expansion of the HHVBP Model should be suspended or the Model not expanded, or that the Model denies coverage to people who are not expected to improve. As stated previously, the original HHVBP Model did not make any changes to coverage or provision of benefits for Medicare beneficiaries. We further note that evaluation findings to date show that the implementation of the original HHVBP Model did not adversely impact home health utilization or market entries and exits differentially in HHVBP states relative to non-HHVBP states. We refer readers to Section 3, pages 25–36 in the *Evaluation of the Home Health Value-Based Purchasing (HHVBP) Model Third Annual Report* [13] for our full analysis on beneficiary access to home health care covering the post-implementation period 2016–2018 and to Section 3, pages 25–50 in the *Evaluation of the Home Health Value-Based Purchasing (HHVBP) Model Fourth Annual Report* [14] for an updated analysis covering the post-implementation period 2016–2019. As previously summarized, the CMS Chief Actuary's certification and the Secretary's determination were based on evaluation findings.

3. Overview

We stated in the proposed rule that the proposed HHVBP Model expansion presents an opportunity to improve the quality of care furnished to Medicare beneficiaries nationwide through payment incentives to HHAs. We stated that if finalized, all Medicare-certified HHAs in the 50 States, District of Columbia and the territories would be required to participate in the expanded HHVBP Model beginning January 1, 2022. These HHAs would compete on value based on an array of quality measures related to the care that HHAs furnish.

We stated in the proposed rule that the proposed Model expansion would be tested under section 1115A of the Act. Under section 1115A(d)(1) of the Act, the Secretary may waive such requirements of Titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), and 1903(m)(2)(A)(iii) of the Act as may be

[9] *https://www.cms.gov/files/document/certification-home-health-value-based-purchasing-hhvbp-model.pdf.*

[10] *https://innovation.cms.gov/data-and-reports/2020/hhvbp-thirdann-rpt.*

[11] The HHVBP Third Annual Evaluation Report is available at *https://innovation.cms.gov/data-and-reports/2020/hhvbp-thirdann-rpt.*

[12] The full CMS Actuary Report is available at *https://www.cms.gov/files/document/certification-home-health-value-based-purchasing-hhvbp-model.pdf.*

[13] The HHVBP Third Annual Evaluation Report is available at *https://innovation.cms.gov/data-and-reports/2020/hhvbp-thirdann-rpt.*

[14] *https://innovation.cms.gov/data-and-reports/2021/hhvbp-fourthann-rpt.*

necessary solely for purposes of carrying out section 1115A of the Act with respect to testing models described in section 1115A(b) of the Act. The Secretary is not issuing any waivers of the fraud and abuse provisions in sections 1128A, 1128B, and 1877 of the Act or any other Medicare or Medicaid fraud and abuse laws for this Model expansion at this time. In addition, CMS has determined that the anti-kickback statute safe harbor for CMS-sponsored model arrangements and CMS-sponsored model patient incentives (42 CFR 1001.952(hh)(9)(ii)) will not be available to protect remuneration exchanged pursuant to any financial arrangements or patient incentives permitted under the Model. Thus, notwithstanding any other provisions of this final rule, all Medicare-certified HHAs in the 50 States, District of Columbia and the territories must comply with all applicable fraud and abuse laws and regulations.

We proposed to use the section 1115A(d)(1) of the Act waiver authority to apply a reduction or increase of up to 5 percent to Medicare payments to Medicare-certified HHAs delivering care to beneficiaries in the 50 States, District of Columbia and the territories, depending on the HHA's performance on specified quality measures relative to its peers. Specifically, the expanded HHVBP Model proposes to utilize the section 1115A(d)(1) of the Act waiver authority to adjust the Medicare payment amounts under section 1895(b) of the Act. We stated in the proposed rule that in accordance with the authority granted to the Secretary in section 1115A(d)(1) of the Act, we would waive section 1895(b)(4) of the Act only to the extent necessary to adjust payment amounts to reflect the value-based payment adjustments under this proposed expanded Model for Medicare-certified HHAs in the 50 States, District of Columbia and the territories. We further stated that we may make changes to the payment adjustment percentage through rulemaking in future years of the expansion, as additional evaluation data from the HHVBP expanded Model become available, and we learn about performance within the Model under the expansion. The evaluation of the expanded Model would use a time series type approach to examine the outcomes of interest (cost or utilization) over time prior to the start of the intervention and follow that outcome after the start of the expansion.

a. Overview of Timing and Scope

As noted, we proposed to begin the expanded HHVBP Model on January 1, 2022. Under this proposal, CY 2022 would be the first performance year and CY 2024 would be the first payment year, with payment adjustments in CY 2024 based on an HHA's performance in CY 2022. Performance year means the calendar year during which data are collected for the purpose of calculating a competing HHA's performance on applicable quality measures. Payment year means the calendar year in which the applicable percent, a maximum upward or downward adjustment, applies.

We proposed that the expanded Model would apply to all Medicare-certified HHAs in the 50 States, District of Columbia and the territories, which means that all Medicare-certified HHAs that provide services in the 50 States, District of Columbia and the territories would be required to compete in the expanded Model. We proposed to codify this requirement at § 484.350. We proposed to define a 'competing HHA' within the scope of the proposed expanded HHVBP Model as an HHA that has a current Medicare certification and is being paid by CMS for home health care services. We proposed that all HHAs certified for participation in Medicare before January 1, 2021 would have their CY 2022 performance assessed and would be eligible for a CY 2024 payment adjustment. We proposed to base participation in the expanded Model on CMS Certification Numbers (CCNs), meaning that the Total Performance Score as discussed further in section III.A.7.a. of this final rule and payment adjustment would be calculated based on an HHA's CCN.[15]

We summarize in this section of this rule comments received on the proposed timing and scope of the expanded model and our responses.

Comment: The majority of commenters supported a home health value-based purchasing payment model, but were opposed to expansion beginning in CY 2022 as the first performance year. Commenters expressed concern that HHAs continue to contend with challenges of the PHE and that expansion should be postponed until CY 2023 or the calendar year that is 1 year post the public health emergency which they stated would be a more stable time in the trajectory of health care delivery. Commenters expressed that HHAs need more time to prepare, institute operational reforms, and learn about the Model and encouraged CMS to provide technical assistance and training to support HHAs in preparing for the Model. Commenters stated that CMS should allow for more study time/data gathering and extend the original HHVBP Model for another year to collect data that is more reflective of the current state of care before expanding nationwide. A commenter recommended CMS carefully evaluate the impact of the HHVBP Model on hospital-operated HHAs as part of its overall evaluation of the Model before scaling it on a national level and seek broad stakeholder input on the design of the HHVBP expanded model in future rulemaking. Commenters requested that CMS develop a comprehensive plan for implementing the HHVBP model nationwide in CY 2023 after the conclusion of the original model. A commenter recommends that CMS make the first year of expansion voluntary and move to mandatory in CY 2023. We received a few comments that supported a CY 2022 start date for expansion.

Response: We thank the commenters for their support for a value-based purchasing payment model in the home health setting. However, we disagree that additional study time or an extension of the original Model to collect additional data is needed prior to expansion. The original Model was tested for four years, CYs 2016–2019. The original Model has met statutory requirements based on the CMS Chief Actuary's certification and evaluation findings in the Third Annual Evaluation Report covering the implementation period 2016–2018 that showed the Model improved quality of care without increased spending. Updated analysis of the original Model in the Fourth Annual Evaluation Report, covering the implementation period 2016–2019, continues to indicate improved quality of care without increased spending or adverse impacts on home health utilization, or market entries and exits. We note that the Fourth Annual Evaluation Report includes evaluation of the impacts to hospital-operated HHAs, and found that hospital based HHAs (in both HHVBP and non-HHVBP states) do care for higher risk patients. The model payment and the primary evaluation impact estimation use risk adjustment to account for such differences. The evaluation did not specifically analyze the outcomes by free-standing vs hospital-based entities in HHVBP and non-HHVBP states. However, we examined whether there is a pattern of the Model limiting admissions for more medically complex patients and do not find that to be the

[15] HHAs are required to report OASIS data and any other quality measures by its own unique CMS Certification Number (CCN) as defined under title 42, chapter IV, subchapter G, § 484.20 Available at URL *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-484?toc=1.*

case. We continued to observe a pattern of increasing clinical severity over time among all home health patients based on multiple measures of medical complexity or severity, and the trends were generally similar in HHVBP and non-HHVBP states. In addition, the CMS Chief Actuary concluded in its certification that since the selection of the states was random and participation by HHAs in the selected states was mandatory, it is unlikely that these evaluation results were biased.

We understand the PHE, declared in January 2020, has had an impact on HHAs. We also believe that technical assistance and training may help those HHAs not part of the original Model to prepare for successful participation in the expanded HHVBP Model.

After consideration of the comments received, we are therefore finalizing that CY 2022 will be a pre-implementation year, with CY 2023 as the first performance year and CY 2025 as the first payment year, as we discuss further in this section and later in this rule.

Comment: A commenter stated that expansion should be delayed until a payment framework is built to adequately account for the differences in healthcare systems, such as Medicaid safety-net hospitals, that by definition provide a disproportionate share of charity and other forms of uncompensated care to individuals who have a high level of social need, beyond their medical treatment. The commenter also stated that nationwide implementation of the HHVBP model should be delayed until the evaluation of appropriate risk adjustment for types of Social Determinants of Health (SDoH) and payment mechanisms appropriately account for the interaction of biological, behavioral, and social care needs when it comes to providing patient-tailored, comprehensive value-based care.

Response: As shown in Table 21, simulating the expanded HHVBP Model's national volume-based cohorts with CY 2019 data indicates a higher average payment adjustment for HHAs with a high percentage of dually eligible beneficiaries. Consequently, we do not have evidence to suggest that HHAs that care for beneficiaries with more significant social risk factors would receive decreased FFS payments under the expanded Model. We thank the commenter for their recommendations to evaluate types of Social Determinants of Health (SDoH) to account for the interaction of biological, behavioral, and social care needs when it comes to providing patient-tailored, comprehensive value-based care for potential modifications to risk adjustment and we will take this under consideration. As noted in section III.A.6.e.2 of this final rule, we are working collaboratively with HH QRP to determine how data collected on SDoHs under HH QRP could be part of the HHVBP Model expansion.

Comment: Commenters stated that CMS should include a ''shared savings'' component to the expanded HHVBP Model to enhance the incentives that led HHAs to achieve significant savings to Medicare.

Response: We appreciate this comment, but it is outside the scope of our proposals on the expansion of the HHVBP Model.

Final Decision: After consideration of comments received, we are finalizing our proposal with modification. We are finalizing a one-year delay in assessing HHA performance and the calculation of a payment adjustment. To allow HHAs time to prepare and learn about the expanded Model, CY 2023 will be the first performance year and CY 2025 will be the first payment year, based on CY 2023 performance. CY 2022 will be a pre- implementation year, as discussed in more detail later in this rule. We will provide learning support about the Model to HHAs during CY 2022. We believe that by delaying payment adjustments by one year and providing HHAs with learning support in the pre-implementation phase, all HHAs will be better prepared to participate in the Model for the CY 2023 performance year. HHAs will incur a 0 percent payment adjustment risk for the CY 2022 pre-implementation year.

We are finalizing as proposed that the expanded Model will apply to all Medicare-certified HHAs in the 50 States, District of Columbia, and the territories, which means that all Medicare-certified HHAs that provide services in the 50 States, District of Columbia, and the territories will be required to compete in the expanded Model. We are also finalizing to codify this requirement at § 484.350. We are finalizing as proposed to define a 'competing HHA' within the scope of the expanded HHVBP Model as an HHA that has a current Medicare certification and is being paid by CMS for home health care services. We are finalizing to base participation in the expanded Model on CMS Certification Numbers (CCNs), meaning that the Total Performance Score as discussed further in section III.A.7.a. of this final rule and payment adjustment will be calculated based on an HHA's CCN. Under our finalized policy to delay application of payment adjustments under the expanded Model, all HHAs certified for participation in Medicare before January 1, 2022, will have their CY 2023 performance assessed and would be eligible for a CY 2025 payment adjustment.

b. Overview of the Payment Adjustment

We proposed that the distribution of payment adjustments would be based on quality performance, as measured by both achievement and improvement, across a proposed set of quality measures constructed to minimize burden as much as possible and improve care. Competing HHAs that demonstrate they can deliver higher quality of care in a given performance year measured against a baseline year relative to peers nationwide (as defined by larger- versus smaller-volume cohorts based upon their unique beneficiary count in the prior calendar year), could have their HH PPS claims final payment amount adjusted higher than the amount that otherwise would be paid. Competing HHAs that do not perform as well as other competing HHAs in the same volume-based cohort might have their HH PPS claims final payment amount reduced and those competing HHAs that perform similarly to others in the same volume-based cohort might have no payment adjustment. This operational concept is similar in practice to what is used in the Hospital Value-Based Purchasing (HVBP) Program (76 FR 26531).

We stated in the proposed rule that we expect that the risk of having payments adjusted in this manner would provide an incentive among all competing HHAs to provide significantly better quality through improved planning, coordination, and management of care. We stated that under the expanded duration and scope of this Model, we would continue to examine whether the proposed adjustments to the Medicare payment amounts that would otherwise be made to competing HHAs would result in statistically significant improvements in the quality of care being delivered to Medicare beneficiaries, as well as reductions in Medicare spending. The degree of the payment adjustment would be dependent on the level of quality achieved or improved from the baseline year, with the highest upward performance adjustments going to competing HHAs with the highest overall level of performance based on either achievement or improvement in quality. The size of a competing HHA's payment adjustment for each year under the expanded Model would be dependent upon that HHA's performance with respect to the applicable performance year relative to other competing HHAs in the same volume-based cohort and relative to its

own performance during the baseline year. These proposals, as well as our finalized policies, are discussed in sections III.A.4, III.A.5, and III.A.7.a of this final rule.

In addition, at § 484.345 we proposed to add the following definitions:

- Achievement threshold
- Applicable measure
- Applicable percent
- Baseline year
- Benchmark
- Competing home health agency
- Home health prospective payment system
- Improvement threshold
- Larger-volume cohort
- Linear exchange function
- Nationwide
- Payment adjustment
- Payment year
- Performance year
- Smaller-volume cohort
- Total Performance Score

We note that we are generally finalizing the definitions at § 484.345 as proposed, with the addition of the term, *pre-implementation year,* to reflect that under our final policy to delay the application of payment adjustments under the expanded Model, CY 2022 will be a pre-implementation year. We summarize and respond to any comments received on particular proposed definitions in the applicable sections of this rule.

4. Defining Cohorts for Benchmarking and Competition

Under the original HHVBP Model, we grouped HHAs into cohorts by State for setting benchmarks and achievement thresholds and by both State and smaller- versus larger-volume HHAs when determining the cohorts used for competing for payment adjustments, in accordance with § 484.330. For the nationwide expansion of the HHVBP Model, we proposed to redefine the cohort structure to account for States, territories, and the District of Columbia with smaller numbers of HHAs, while also allowing for the use of volume-based cohorts in determining benchmarks, achievement thresholds, and payment adjustments.

a. Smaller- and Larger-Volume Cohorts

As discussed further in this section, we believe that separating smaller- and larger-volume HHAs into cohorts under the expanded Model would facilitate like comparisons by allowing for the majority of HHAs to receive benchmarks and compete for payment against other HHAs of similar size and based on the same set of measures. As under the original HHVBP Model, we proposed to align the larger-volume cohort with the group of competing HHAs that administers the Home Health Care Consumer Assessment of Healthcare Providers and Systems (HHCAHPS) survey, in accordance with the HH QRP regulations concerning the HHCAHPS survey in § 484.245(b), and we proposed to align the Model's smaller-volume HHA cohort with the group of HHAs that are exempt from submitting the HHCAHPS survey under HH QRP under § 484.245(b)(1)(iii)(A). We clarify in this final rule that, unlike under the HH QRP, and consistent with the original Model, HHAs would not need to submit an exemption request for HHCAHPS in accordance with the regulations at 42 CFR 484.245(b)(1)(iii)(A) for the purposes of qualifying for the smaller-volume HHA cohort. We stated that under the expanded HHVBP Model, we would not alter the HHCAHPS survey current scoring methodology or the participation requirements in any way. Details on HHCAHPS survey scoring methodology are available at: *https://homehealthcahps.org/Survey-and-Protocols/Survey-Materials.*[16]

The HH QRP requires, in part, that an HHA submit HHCAHPS survey data to CMS. An HHA that has fewer than 60 unique HHCAHPS survey-eligible patients must annually submit their total HHCAHPS survey patient count to CMS to be exempt from the HHCAHPS survey reporting requirements for a calendar year under the HH QRP. As under the original HHVBP Model, we proposed to align with this HHCAHPS survey reporting requirement by defining the larger-volume cohort as those HHAs that are required to submit an HHCAHPS survey in the performance year. We note that under the original Model, the HHA is not required to secure an exemption in order to qualify for the smaller-volume cohort; rather, CMS assesses whether an HHA qualifies for the smaller-volume cohort based on the volume of unique patients eligible to submit the HHCAHPS survey in a calendar year. As under the original Model, we also proposed to set an HHCAHPS survey measure minimum of at least 40 completed HHCAHPS surveys in the performance year for those HHAs to receive a score on the HHCAHPS survey measure, as reflected in proposed §§ 484.345 and 484.360. Accordingly, because smaller-volume HHAs are less likely to be assessed on the HHCAHPS survey measure, which would account for 30 percent of the overall performance score in the expanded Model, we stated that we believe that separating smaller- and larger-volume HHAs into distinct cohorts would allow for the majority of HHAs to compete against other HHAs of similar size and based on the same set of measures.

b. Cohorts for the Model Expansion

As discussed, we believe that applying separate larger- and smaller-volume cohorts within the expanded HHVBP Model would group HHAs that are of similar size and are more likely to receive scores on the same set of measures for purposes of setting benchmarks and achievement thresholds and determining payment adjustments. However, a valid cohort must have a sufficient number of HHAs to—(1) create a robust distribution of Total Performance Scores, which allows meaningful and reasonable translation into payment adjustments using the linear exchange function (LEF);[17] and (2) set stable, reliable benchmarks and achievement thresholds that are not heavily skewed by outliers. The LEF is designed so that the majority of the payment adjustment values fall closer to the median and a smaller percentage of HHAs receive adjustments at the higher and lower ends of the distribution. However, when only a small number of HHAs fall within a cohort, one HHA's outlier TPS could skew the payment adjustments and deviate from the intended design of the LEF payment methodology. As a result, a key consideration in defining the cohorts is ensuring sufficient HHA counts within each cohort.

Under the original Model, CMS applied a minimum of eight HHAs for any size cohort, such that a smaller-volume cohort must have a minimum of eight HHAs in order for the HHAs in that cohort to be compared only against each other, and not against the HHAs in the larger–volume cohort (81 FR 76742). This policy was based on an analysis of the minimum number of HHAs needed in a smaller-volume cohort in order to insulate that cohort from the effect of outliers. We stated in the proposed rule that expanding the HHVBP Model beyond the nine mid- to large-sized States included in the original Model requires us to re-examine these cohort definitions because, certain territories and the District of Columbia would fall short of the original Model's minimum

[16] Detailed scoring information is contained in the Protocols and Guidelines manual posted on the HHCAHPS web site and available at *https://homehealthcahps.org/Survey-and-Protocols/Survey-Materials.*

[17] The Linear Exchange Function (LEF) is used to translate an HHA's TPS into a percentage of the value-based payment adjustment earned by each HHA. For a more detailed description, please see section III.A.8. of this final rule.

of 8 HHAs to compose their own cohort even where the volume-based cohorts are combined. This was not an issue in the original Model because the nine selected States are relatively populous as compared to the smaller States, territories, and the District of Columbia that would be included in the expanded Model. Based on CY 2019 Home Health Compare Star Ratings, we evaluated the viability of smaller- and larger-volume cohorts, as defined previously, for each of the 55 States, territories, and the District of Columbia. Based on our analysis, of the 110 potential cohorts based on both State and HHA volume for the expanded HHVBP Model, 46 of the 110 potential cohorts had too few HHAs to reliably meet the original Model minimum of 8 HHAs, after accounting for the risk of attrition from the expanded Model. Under this approach, for 42 of these 46 cohorts, the smaller-volume cohorts would need to be combined with the larger-volume cohorts in their respective States and territories, while 3 territories and the District of Columbia would need to be combined with other States or territories since they do not meet the 8 HHA minimum after consolidating the volume-based cohorts. See Table 21 for the counts of HHAs in each of the potential cohorts, if we were to apply separate State- and volume-based cohorts for each State, territory, and the District of Columbia under the expanded Model.

TABLE 21: HHA COUNTS IN STATE/TERRITORY/DISTRICT OF COLUMBIA- AND VOLUME-BASED COHORTS BASED ON CY 2019 HOME HEALTH CARE COMPARE DATA

State	Large HHAs	Small HHAs	All HHAs	State	Large HHAs	Small HHAs	All HHAs
AK	12	1	13	MT	22	2	24
AL	114	1	115	NC	152	4	156
AR	90	2	92	ND	12	-	12
AZ	106	2	108	NE	40	8	48
CA	993	76	1,069	NH	20	1	21
CO	105	4	109	NJ	42	-	42
CT	74	-	74	NM	58	4	62
DC*	7	-	7	NV	97	8	105
DE	12	-	12	NY	105	-	105
FL	677	54	731	OH	287	10	297
GA	99	-	99	OK	183	10	193
GU*	4	-	4	OR	43	1	44
HI	14	-	14	PA	229	12	241
IA	94	7	101	PR	33	-	33
ID	42	1	43	RI	18	-	18
IL	399	64	463	SC	63	-	63
IN	138	11	149	SD	19	4	23
KS	84	5	89	TN	112	1	113
KY	90	-	90	TX	982	97	1,079
LA	167	-	167	UT	68	6	74
MA	127	5	132	VA	187	6	193
MD	49	2	51	VI*	1	-	1
ME	19	1	20	VT	10	-	10
MI	322	54	376	WA	57	-	57
MN	97	9	106	WI	73	-	73
MO	123	9	132	WV	50	1	51
MP*	2	-	2	WY	16	2	18
MS	45	-	45	**All**	**7,084**	**485**	**7,569**

*These territories and the District of Columbia fall short of the original HHVBP Model's minimum of 8 HHAs to compose their own cohort even where the volume-based cohorts are combined.

As noted, under the original HHVBP Model, a minimum of eight HHAs is required for each size cohort. For the expanded HHVBP Model, we proposed to establish cohorts prospectively and with sufficient HHA counts to prevent the need to combine multiple cohorts retrospectively. We proposed to provide HHAs with their applicable benchmarks and achievement thresholds prior to the start of or during the performance year so that they can be used to set performance targets to guide HHAs' quality improvement projects. To reliably define cohorts prospectively and to avoid regrouping multiple States, territories, or the District of Columbia into a single cohort retrospectively based solely on their lower HHA counts, we estimated that a minimum of 20 HHAs in each cohort would be necessary to ensure that attrition and variation in episode counts do not lead to insufficient HHA counts at the end of the performance year. Based on the data set forth in Table 21, 61 out of the 110 potential cohorts would have fewer than 20 HHAs in a size–based cohort, and 11 out of those potential cohorts would not meet the 20 HHA minimum after combining the size-based cohorts.

To allow for a sufficient number of HHAs in each volume-based cohort, for purposes of setting benchmarks and achievement thresholds and determining payment adjustments, we proposed to use cohorts based on all HHAs nationwide, rather than by State as under the original Model. Referencing the CY 2019 data in Table 21, under this approach, 7,084 HHAs would fall within the larger-volume cohort and 485 HHAs fall within the smaller-volume cohort. These HHA counts would provide a sufficiently large number of values in each cohort to allow ranking of HHA performance scores and payment adjustment percentages across the range of –5 percent to +5 percent. Further, our analysis found that many of the smaller-volume HHAs would not receive a score on the HHCAHPS survey measures, which were proposed to account for 30 percent of the overall TPS, while most of the larger-volume cohort HHAs would be scored on the full set of applicable measures. Accordingly, and as previously discussed, we stated that we believe the volume-based cohorts would allow for competition among HHAs across similar measures. Using nationwide rather than State/territory-based cohorts in performance comparisons would also be consistent with the Skilled Nursing Facility and Hospital VBP Programs, in addition to the Home Health Compare Star Ratings. Finally, this option would be the least operationally complex to implement.

For the reasons discussed, we stated in the proposed rule that we believe the use of nationwide smaller- and larger-volume–based cohorts would allow for appropriate groupings of HHAs under the expanded Model while also providing sufficient numbers of HHAs in each cohort for purposes of setting stable and reliable benchmarks and achievement thresholds and allowing for a robust distribution of payment adjustments. However, we also considered an alternative approach of using State/territory-based cohorts, without volume-based groupings. Applying the State, territory, and District of Columbia–level cohorts, we found that 11 of the 55 potential cohorts would have fewer than 20 HHAs based on the CY 2019 Home Health Star Ratings data. As noted, we stated that we do not believe this would allow for a sufficient number of HHAs to develop prospective benchmarks and achievement thresholds. While one approach would be to exclude any States, territories, or the District of Columbia from the expanded Model for years in which there are fewer than 20 HHAs in the cohort, we stated that we believe such a policy would be inconsistent with the goal of including all eligible HHAs nationwide in the Model. Another option would be to consolidate those States, territories, and the District of Columbia with less than 20 HHAs in the cohort, and to calculate benchmarks, achievement thresholds, and payment adjustments based on that consolidated grouping of HHAs. We noted that while slight differences do exist between quality measure scores based on geographic location, we do not believe that codifying these small differences into long-term performance standards is necessary to appropriately determine payment adjustments under the expanded Model.

We proposed to establish nationwide volume-based cohorts for the expanded HHVBP Model, such that HHAs nationwide would compete within either the larger-volume cohort or the smaller-volume cohort. We proposed to codify this policy at § 484.370, and to codify the proposed definitions of smaller-volume cohort and larger-volume cohort at § 484.345. Under this proposal, HHAs currently participating in the original HHVBP Model would no longer compete within just their State. We also requested comment on the alternative approach of applying State/territory-based cohorts only, without volume-based cohorts.

We sought public comment on these proposals. We summarize in this section of this rule the comments received and provide our responses.

Comment: Most commenters supported the use of State-based rather than national cohorts in order to preserve the geographical differences in quality benchmarks, which they contend result from variation in home health utilization and other differences across regions. They expressed concern that not using State-based cohorts will significantly shift home health payments across State lines, leading to shortages of necessary home health services in certain areas.

Response: We thank commenters for their comments on selection of the appropriate cohorts to compare HHAs. We do not have evidence that suggests that moving to national small- and large-volume cohorts would significantly redistribute resources between states. We refer readers to Table 43 of this final rule for an analysis of expected shifts in FFS expenditures, as represented by the average FFS payment adjustments for small- and large-volume HHAs in each of the States, territories, and the District of Columbia, simulated with the proposed national size-based cohorts using CY 2019 data and a maximum adjustment of ±5 percent. We note that when the small- and large-volume HHAs in each of the States, territories, and the District of Columbia are combined, the average payment adjustment for the majority of States, territories, and the District of Columbia is within ±1 percent, with none exceeding ±2 percent. Furthermore, as discussed in the proposed rule, using the State-based cohorts could potentially lead to an insufficient count of HHAs in 11 States, territories, and the District of Columbia. It is not apparent that clear similarities exist between those States, territories, or the District of Columbia with less than 20 HHAs in a cohort to support grouping them for competition based solely on their lower HHA counts, nor do we believe excluding these States, territories, or the District of Columbia would be consistent with the goal of including all eligible HHAs nationwide in the expanded Model.

Comment: Several commenters expressed concern that using national rather than State-based cohorts would result in a shifting of resources away from geographic areas with a higher burden of social risk factors and toward areas with less social risk factors.

Response: We thank the commenters for sharing this concern. The commenters' concern appears to assume that quality measure scores and payments would be lower in areas with a higher burden of social risk factors.

Table 41 in the proposed rule (86 FR 35996) demonstrates, however, that simulating the proposed national cohorts with CY 2019 data, a high percentage of dually eligible beneficiaries is associated with a higher average payment adjustment under the expanded Model. This association supports that use of national, volume-based cohorts would not disadvantage those HHAs that care for beneficiaries with more significant social risk factors. As noted previously, we also refer readers to Table 43 of this final rule for an analysis of the shifts of expenditures, as represented by the average payment adjustments for small- and large-volume HHAs in each of the States, territories, and the District of Columbia, simulated with the proposed national size-based cohorts using 2019 data and a maximum adjustment of ±5 percent. When the small- and large-volume HHAs in each of the States, territories, and the District of Columbia are combined, the average payment adjustment for the majority of States, territories, and the District of Columbia is within ±1 percent, with none exceeding ±2 percent. We welcome further feedback or analysis on this issue from the public.

Comment: A commenter, on the other hand, strongly supported using national cohorts, as proposed, stating that Medicare is a national program and beneficiaries should have the same expectations for high-quality care, regardless of which state they live in.

Response: We thank the commenter for this feedback. We agree that since Medicare is a national program, all beneficiaries should have the same expectations for high-quality care. As discussed previously, we believe the use of national cohorts for purposes of the expanded Model would allow for competition among HHAs across similar measures while also providing sufficient numbers of HHAs in each cohort. This is also consistent with value-based purchasing programs and the Home Health Compare star ratings.

Comment: Other commenters requested that HHAs in States that did not compete on quality in the original Model not be compared to the same standard as HHAs in the original nine States, because they have only been subject to publicly reporting of the measures, without payment adjustments, over the past 5 years.

Response: We agree that HHAs in the 9 original Model States may have more knowledge about the expanded Model, given many of these HHAs have participated in the original HHVBP Model since 2016. However, as discussed in section III.A.3.a of this final rule, after consideration of the comments received, we are delaying implementation of payment adjustments for 1 year, with CY 2023 serving as the first performance year and CY 2025 serving as the first payment year, in order to provide all HHAs with additional time to become familiar with and gain experience with the expanded Model. We further note, as stated in section XI.8.F.2 of the proposed rule and this final rule, based on our analysis of the State-level impacts and using CY 2019 data to simulate payment adjustments, we did not see any obvious correlation of the impacts within States that are currently in the original Model versus those that will be new to the expanded Model of using the national, volume-based cohorts.

Final Decision: After considering the public comments received on the cohorts for model expansion, we are finalizing the use of national, volume-based cohorts in setting payment adjustments under the expanded Model, as proposed, and are also finalizing to codify this policy at § 484.370. We are also finalizing the proposed definitions of smaller-volume cohort and larger-volume cohort at § 484.345. Consistent with the original HHVBP Model, CMS will assess whether an HHA qualifies for the smaller-volume cohort based on the volume of unique patients eligible to submit the HHCAHPS survey in the prior calendar year.

5. Payment Adjustment Percentage and Performance Assessment and Payment Adjustment Periods

a. Payment Adjustment

Under the original Model, the payment adjustment ranges from a minimum of 3 percent in 2018 to maximum of 8 percent in 2022. For the expanded Model, we proposed that the maximum payment adjustment, upward or downward, would be 5 percent. We stated that we believe that beginning the expansion with a 5 percent maximum payment adjustment would strike a balance between the 3 percent maximum adjustment that applied for CY 2018, the first payment year of the original HHVBP Model, and the 7 percent maximum adjustment currently in place for CY 2021. We proposed that the first payment year of the expanded HHVBP Model would be CY 2024 (January 1, 2024 through December 31, 2024), with payment adjustments based on performance in CY 2022 (January 1, 2022 through December 31, 2022). We stated in the proposed rule that we may consider changes to the proposed 5 percent maximum payment adjustment percentage through rulemaking in future years of the expansion, as additional evaluation data from the original Model and expansion become available. We note that the CMS Actuary certification was based on evaluation of the Model when the maximum payment adjustment was 3 percent. However, in their certification memo, they indicated they believe the Model would result in savings at higher payment adjustment amounts as well.

We solicited public comment on the proposed payment adjustment percentage. We summarize in this section of this rule the comments received on the proposed payment adjustment percentage and provide our responses.

Comment: Some commenters expressed concern that the proposed 5 percent maximum payment adjustment was too high for the first year of the expanded model. A few commenters suggested a 3 percent maximum payment adjustment to match the first payment adjustment year of the original model, other commenters suggested a 2 percent maximum payment adjustment to match Hospital Value Based Purchasing, and others suggested a 1 percent maximum payment adjustment. A few commenters suggested starting the expanded model at a lower percentage and slowly increasing the maximum payment adjustment over time.

Response: We appreciate commenters sharing their concerns about the potential for a 5 percent payment adjustment. Under the payment adjustment methodology described in III.A.8 of this rule, we anticipate that most HHAs will receive a positive or negative payment adjustment smaller than the proposed 5 percent maximum adjustment. We reviewed the payment distribution under the original HHVBP Model for CY 2019, the second payment adjustment year, when the maximum payment adjustment was 5 percent. During that year, 93.2 percent of the HHAs participating in the original HHVBP Model received a payment adjustment ranging from −3 percent to +3 percent and 98.8 percent of the HHAs received a payment adjustment ranging from −4 percent to +4 percent. Using simulated data with national cohorts, we found 72 percent of HHAs would have received a payment adjustment ranging from −3 percent to +3 percent and 85 percent of HHAs would have received a payment adjustment ranging from −4 percent to +4 percent. In the original HHVBP model, we increased the maximum payment adjustment each year to allow HHAs the opportunity to become familiar with the operation of the model before applying higher percentage

payment adjustments in later years, including a maximum payment adjustment of 5 percent for the second payment year. In this final rule, we are delaying the first payment adjustment year to provide HHAs with learning support in advance of the application of payment adjustments under the expanded Model. As discussed in the proposed rule, we will continue to evaluate the 5 percent payment adjustment and consider any changes for future rule making.

Final Decision: After consideration of the public comments, we are finalizing the payment adjustment as proposed. As discussed previously, we are also finalizing a delay in the start of payment adjustments under the expanded Model, such that CY 2025 would be the first payment year, with payment adjustments based on performance in CY 2023.

b. Baseline Year

(1) General

For the expanded HHVBP Model, due to the potentially de-stabilizing effects of the COVID–19 public health emergency (PHE) on quality measure data in CY 2020, we proposed that the baseline year would be CY 2019 (January 1, 2019 through December 31, 2019) for the CY 2022 performance year/CY 2024 payment year and subsequent years. The data from this baseline year would provide a basis from which each respective HHA's performance would be measured for purposes of calculating achievement and improvement points under the expanded Model. We stated in the proposed rule that we may propose to update the baseline year for subsequent years of the expanded Model through future rulemaking. We stated that we would also propose the applicable baseline year for any additional quality measures that may be added to the measure set for the expanded HHVBP Model through future rulemaking.

We solicited public comment on the proposed baseline year for the expanded Model. We summarize in this section of this rule the comments received on the proposed baseline year and provide our responses.

Comment: A few commenters supported using CY 2019 as the baseline year. Other commenters cautioned against using 2019 as a baseline year because they asserted it inherently means comparing pre-COVID–19, pre-Patient Driven Grouping Model (PDGM) performance to performance in a very different environment. A commenter recommended CMS provide clarification on subsequent baseline periods in future years of the Model in a timely fashion so that HHAs have as much advance notice as possible. The commenter also encouraged CMS to eventually automatically advance the baseline period of the model by one year as each performance year is advanced, like other value-based programs.

Response: We proposed using CY 2019 as the baseline year, as opposed to CY 2020, due to the potentially de-stabilizing effects of the PHE on the CY 2020 data and because it was the most recent full year of data available prior to CY 2020 to provide HHAs with achievement thresholds and benchmarks as soon as administratively feasible and prior to the start or soon after the start of the applicable performance year. As noted later in this final rule, the PDGM is a case-mix adjustment model intended to pay for services more accurately and we believe the HHVBP Model can continue unchanged when HHA periods of care are paid according to the case-mix adjustments of the PDGM. We further believe that the payment change should not affect measure scoring between the baseline year and the performance years. However, CMS may consider conducting analyses of the impact of using various baseline periods, and would address any changes to the baseline period in future rulemaking. We appreciate the commenter's suggestion to eventually automatically advance the baseline period by one year as each performance year is advanced in an effort to align with other value-based programs and will take it under consideration.

Final Decision: After consideration of comments received, we are finalizing our proposal to use CY 2019 (January 1, 2019 through December 31, 2019) as the baseline year. As discussed previously, we are also finalizing to delay the first performance and payment year under the expanded Model. Accordingly, the baseline year would be CY 2019 for the CY 2023 performance year/CY 2025 payment year and subsequent years; however, we may conduct analyses of the impact of using various baseline periods and consider any changes for future rulemaking.

(2) New HHAs

As noted previously, we generally proposed that for the expanded Model, the baseline year would be CY 2019 (January 1, 2019 through December 31, 2019) for the CY 2022 performance year/CY 2024 payment year and subsequent years. For new HHAs, specifically those HHAs that are certified by Medicare on or after January 1, 2019, we proposed that the baseline year under the expanded Model would be the HHA's first full CY of services beginning after the date of Medicare certification, with the exception of HHAs certified on January 1, 2019 through December 31, 2019, for which the baseline year would be CY 2021. Furthermore, we proposed that new HHAs would begin competing under the expanded HHVBP Model in the first full calendar year following the full calendar year baseline year. For example, and as previously discussed, we proposed that all HHAs certified for participation in Medicare before January 1, 2021, would have their CY 2022 performance assessed and would be eligible for a CY 2024 payment adjustment. For HHAs certified on January 1, 2020 through December 31, 2020, the baseline year would be CY 2021, the first full CY of services beginning after the date of Medicare certification. For those HHAs certified on January 1, 2019 through December 31, 2019, the baseline year would also be CY 2021, rather than CY 2020 (the first full CY of services beginning after the date of Medicare certification), due to the potentially destabilizing effects of the PHE on quality measure data in CY 2020. For an HHA certified by Medicare on January 1, 2021 through December 31, 2021, for example, the first full calendar year of services that would establish the HHA's baseline year would be CY 2022. The HHA's first performance year would be CY 2023 and the HHA's first payment year, based on CY 2023 performance, would be CY 2025. Table 22 shows the proposed HHA baseline, performance and payment years based on the HHA's Medicare-certification date through December 31, 2021.

TABLE 22: PROPOSED HHA BASELINE, PERFORMANCE AND PAYMENT YEAR BASED ON MEDICARE-CERTIFICATION DATE THROUGH DECEMBER 31, 2021

Medicare-certification Date	Baseline Year	Performance Year	Payment Year
Prior to January 1, 2019	2019	2022	2024
On January 1, 2019 - December 31, 2019	2021	2022	2024
On January 1, 2020 – December 31, 2020	2021	2022	2024
On January 1, 2021 – December 31, 2021	2022	2023	2025

We also proposed to codify our proposal on new HHAs at § 484.350. We solicited public comment on these proposals.

Final Decision: We did not receive any comments on our proposals regarding new HHAs and are finalizing our proposal that for new HHAs, specifically those HHAs that are certified by Medicare on or after January 1, 2019, the baseline year under the expanded Model would be the HHA's first full CY of services beginning after the date of Medicare certification, with the exception of HHAs certified on January 1, 2019 through December 31, 2019, for which the baseline year would be CY 2021. Furthermore, we are finalizing that new HHAs would begin competing under the expanded HHVBP Model in the first full calendar year (beginning with CY 2023) following the full calendar year baseline year. For example, under this final policy, all HHAs certified for participation in Medicare before January 1, 2022, would have their CY 2023 performance assessed and would be eligible for a CY 2025 payment adjustment. For HHAs certified on January 1, 2020 through December 31, 2020, the baseline year would be CY 2021, the first full CY of services beginning after the date of Medicare certification. For those HHAs certified on January 1, 2019 through December 31, 2019, the baseline year would also be CY 2021, rather than CY 2020 (the first full CY of services beginning after the date of Medicare certification), due to the potentially destabilizing effects of the PHE on quality measure data in CY 2020. For an HHA certified by Medicare on January 1, 2021 through December 31, 2021, for example, the first full calendar year of services that would establish the HHA's baseline year would be CY 2022. The HHA's first performance year would be CY 2023 and the HHA's first payment year, based on CY 2023 performance, would be CY 2025. Table 23 shows the finalized HHA baseline, performance and payment years based on the HHA's Medicare-certification date through December 31, 2021.

TABLE 23 : FINAL HHA BASELINE, PERFORMANCE AND PAYMENT YEAR BASED ON MEDICARE-CERTIFICATION DATE THROUGH DECEMBER 31, 2021

Medicare-certification Date	Baseline Year	Performance Year	Payment Year
Prior to January 1, 2019	2019	2023	2025
On January 1, 2019 - December 31, 2019	2021	2023	2025
On January 1, 2020 – December 31, 2020	2021	2023	2025
On January 1, 2021 – December 31, 2021	2022	2023	2025

We are also finalizing our proposed codification of this policy at § 484.350 with modification to reflect the one-year delay in the first performance year from CY 2022 to CY 2023. Specifically, we are adding ''(beginning with CY 2023)'' to reflect that for new HHAs certified by Medicare on or after January 1, 2019, the first performance year is the first full calendar year (beginning with CY 2023) following the baseline year.

6. Quality Measures

a. General Considerations Used for the Selection of Quality Measures for the Expanded HHVBP Model

We stated in the proposed rule that we plan to apply, to the extent possible, principles from CMS' Meaningful Measures Initiative [18] in selecting the applicable measures as defined at § 484.345 to be included in the Model expansion. A central driver of the proposed applicable measure set is to have a broad, high impact on care delivery and support priorities to improve health outcomes, quality, safety, efficiency, and experience of care for patients. To frame the selection process, we also considered the domains of the CMS Quality Strategy [19] that maps to the six National Quality Strategy (NQS) [20] priority areas: Clinical

[18] *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.*

[19] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy.*

[20] For NQF endorsed measures see The NQF Quality Positioning System available at *http://www.qualityforum.org/QPS.* For non–NQF measures using OASIS see links for data tables related to OASIS measures at *https://www.cms.gov/*

Continued

quality of care; Care coordination; Population/community health; efficiency and cost reduction; safety; and, Patient and caregiver-centered experience.

We stated that we believe that Medicare-certified HHAs should be evaluated using measures designed to encompass multiple NQS domains, and provide future flexibility to incorporate and study newly developed measures over time. Additionally, so that measures for the expanded HHVBP Model take a more holistic view of the patient beyond a particular disease, functional status, State or care setting, we would prioritize outcome measures that have the potential to follow patients across multiple settings, reflect a multi-faceted approach, and foster the intersection of health care delivery and population health.

The proposed expanded Model measures mostly align with those under the HH QRP. However, we stated in the proposed rule that we intend to consider new measures for inclusion in subsequent years of the expanded HHVBP Model through future rulemaking. We stated that we may consider adding new measures to the expanded HHVBP Model measure set that address gaps within the NQS domains or the home health service line and are good indicators of home health quality of care. When available, NQF endorsed measures would be used. The expanded Model's authority under section 1115A of the Act also affords the opportunity to study other measures, such as, measures developed in other care settings or new to the home health industry, should CMS identify such measures. A key consideration behind this approach is to use measures that are readily available, and, in subsequent Model years, augment the applicable measure set with innovative measures that have the potential to be impactful and fill critical measure gap areas. This approach to quality measure selection aims to balance the burden of collecting data with the inclusion of new and important measures. We stated that we would carefully consider the potential burden on HHAs to report the measure data that is not already collected through existing quality measure data reporting systems and reiterated that we would propose any new measures through future rulemaking.

b. Initial Measure Set for the Expanded Model

We proposed that the initial applicable measure set for the expanded HHVBP Model for the CY 2022 performance year focus on patient outcome and functional status, utilization, and patient experience. (As discussed in the preceding section, we are finalizing CY 2023 as the first performance year, and CY 2025 as the first payment year, under the expanded Model.) The proposed measures were also used under the original Model (83 FR 56533). However, we noted that no ''New Measures'' as defined in the original Model (80 FR 68674) were being proposed for data collection under the expanded Model beginning with the CY 2022 performance year given there was sufficient data collected on the ''New Measures'' under the original Model for analysis of the appropriateness for use in the home health setting. We noted that any future additional measures proposed for the expanded HHVBP Model would not be considered ''New Measures'' as used in the original Model.

We proposed the measures as detailed in Tables 26 and 27 of the proposed rule (86 FR 35923 through 35926) for inclusion in the expanded Model. The measure set also includes outcome measures, which illustrate the end result of care delivered to HHA patients and address an important quality aim for HHA patients. We stated in the proposed rule that we believe the proposed measure set under the expanded HHVBP Model, where most measures currently align with HH QRP measures, supports enhancing quality because of the value-based incentives provided under the expanded Model. Further, we stated that we believe that the expanded Model measure set, as proposed, includes an array of measures that would capture the care that HHAs furnish and incentivize quality improvement. The measures in the proposed measure set are divided into measure categories based on their data source as indicated in Table 26 of the proposed rule (86 FR 35923 through 35926): Claims-based, OASIS-based, and the HHCAHPS survey-based. We note that the HHCAHPS survey-based measure has five individual components. The term ''applicable measure'' applies to each of the five components for which a competing HHA has submitted a minimum of 40 completed HHCAHPS surveys (This is discussed in more detail in sections III.A.4.a., III.A.7.c., and III.A.7.d. of this final rule). That is, each component counts as one applicable measure towards the five measure minimum that is required for an HHA to receive a Total Performance Score (TPS) (this is discussed in more detail in section III.A.7.d of this final rule).

(1) Additional Background on the Total Normalized Composite Measures

The proposed measure set includes two composite measures: Total Normalized Composite (TNC) Self-Care and TNC Mobility, which were included in the original HHVBP Model measure set in CY 2019, as finalized in the CY 2019 HH PPS final rule (83 FR 56529 through 56535). The methodology for these measures takes into account patients who may not have goals for improvement.

The proposed TNC Self-Care measure computes the magnitude of change, either positive or negative, based on a normalized amount of possible change on each of six OASIS M items. These six M items and their short name are as follows:

- Grooming (M1800)
- Upper Body Dressing (M1810)
- Lower Body Dressing (M1820)
- Bathing (M1830)
- Toileting Hygiene (M1845)
- Eating (M1870)

The TNC Mobility measure computes the magnitude of change, either positive or negative, based on the normalized amount of possible change on each of three OASIS M items and their short name are as follows:

- Toilet Transferring (M1840)
- Bed Transferring (M1850)
- Ambulation/Locomotion (M1860)

For each TNC measure, we calculate at the episode level and then aggregate to the home health agency level using a five-step process: Steps 1 to 3 calculate the normalized change values for each applicable OASIS item at the episode level. Steps 4 and 5 aggregate these values to the agency level. As composite measures, the TNC Self-Care and TNC Mobility measures reflect multiple OASIS items, so there are no numerators or denominators for these two measures. A detailed description of the five steps can be found at: *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/hhvbp%20computing%20the%20hhvbp%20composite%20measures.pdf.*

We stated in our discussion of the proposed TNC measures in the proposed rule that we expect that HHAs already focus on improvement in such areas not just because such items are included in the OASIS, but because self-care and mobility are areas of great importance to patients and families. In this final rule, we acknowledge that use of the term ''improvement'' to describe the TNC measures does not take into account the risk adjustment

Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits.

methodology used to calculate these measures or that the structure of the measures also addresses how effectively a HHA can limit any decline of the patient because it implies that the TNC measures would only measure an increase in a patient's functional status, and we have revised our discussion of these proposed measures in this final rule accordingly. The risk adjustment methodology for these two measures is designed to take into account instances where the goal of home health care is to maintain the patient's current condition or to prevent or slow further deterioration of the patient's condition by including risk factors for a wide variety of beneficiary-level characteristics, including age, risk for hospitalization, living arrangements and caregivers available, pain, cognitive function, baseline functional status, and others. For instance, a beneficiary with impaired cognition would not be expected to improve in self-care as much as a beneficiary without cognitive impairment. In effect, the self-care change score would shift up slightly for a beneficiary with impaired cognition relative to a beneficiary without cognitive impairment to account for the difference in expectations. Both TNC measures' computations can be found at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/hhvbp%20computing%20the%20hhvbp%20composite%20measures.pdf* and the technical specifications can be found at: *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/hhvbp%20technical%20specification%20resource%20for%20composite%20outcome%20measures_4.pdf.* As discussed in our response to comments in this section of this rule, the technical specifications for the composite measures have been updated and the updated specifications can be found in the downloads section on the CMS website.[21] Additional information on the predictive modeling and methodology for the composite measures can be found in the CY 2019 HH PPS final rule (83 FR 56529 through 56535).

We noted in the proposed rule that we had considered the inclusion of stabilization measures which are measures that identify all patients whose function has not declined, including both those who have improved or stayed the same in the original HHVBP Model's measure set and refer readers to the CY 2016 HH PPS final rule (80 FR 68669 through 68670) and the CY 2019 HH PPS final rule (83 FR 56529 through 56535). In the CY 2016 HH PPS final rule, we explained that we considered using some of the stabilization measures for the original Model and found that the average HHA stabilization measure scores ranged from 94 to 96 percent and, with average rates of nearly 100 percent, we do not believe these high measure scores would allow for meaningful comparisons between competing-HHAs on the quality of care delivered. We acknowledge that skilled care may be necessary to improve a patient's current condition, to maintain the patient's current condition, or to prevent or slow further deterioration of the patient's condition. However, we stated in the proposed rule that we believe that the two proposed TNC measures represent a new direction in how quality of patient care is measured in home health as patients who receive care from an HHA may have functional limitations and may be at risk for further decline in function because of limited mobility and ambulation.

(2) Additional Background on the Home Health Care Consumer Assessment of Healthcare Providers and Systems Survey Measure

The Home Health Care Consumer Assessment of Healthcare Providers and Systems Survey (HHCAHPS) survey is part of a family of CAHPS® surveys that asks patients to report on and rate their experiences with health care. The HHCAHPS survey specifically presents home health patients with a set of standardized questions about their home health care providers and about the quality of their home health care. The survey is designed to measure the experiences of people receiving home health care from Medicare-certified home health care agencies and meet the following three broad goals to: (1) Produce comparable data on the patient's perspective that allows objective and meaningful comparisons between HHAs on domains that are important to consumers; (2) create incentives through public reporting of survey results for agencies to improve their quality of care; and (3) enhance public accountability in health care by increasing the transparency of the quality of care provided in return for public investment through public reporting.[22]

We note that the HHCAHPS survey is also part of the HH QRP requirements, which are codified for that program at 42 CFR 484.245(b). As proposed, expanded HHVBP Model participants would not need to submit separate HHCAHPS survey measure data already submitted as a requirement under HH QRP, because the requirements as proposed for the expanded Model are aligned with those currently under HH QRP. For more details about the HHCAHPS Survey, please see *https://homehealthcahps.org/.*

We invited public comment on our proposed measure set. We summarize in this section of this rule the comments and provide our responses.

Comments on the Measure Set Generally

Comment: A commenter encouraged CMS to include more measures in a future nationwide HHVBP, including (but not limited to) measures of outcomes, safety, and caregiver engagement. Another commenter supported the proposed measure set saying the quality measures reflect functional independence and agreed with CMS that using measures that are outcome focused and risk adjusted is the most useful to stakeholders to demonstrate value. The commenter stated that process-based measures are of little value and that measures should be a balance of health outcomes, utilization, and patient satisfaction.

Response: We thank the commenters for their recommendations and feedback on the proposed measure set. We agree that outcome, utilization and patient satisfaction measures are good indicators of value-based care and therefore have proposed to include these measure types in the expanded HHVBP Model. We believe the proposed measure set encourages HHAs to provide care that supports patients who wish to remain in their home whether the patient's goal is functional independence, stabilization or to prevent further decline. CMS will continue to monitor measure performance and to seek stakeholder input and may propose measure modification in future rulemaking.

Comment: Commenters supported the removal of the three ''New Measures'' from the measure set under HHVBP Model expansion.

Response: We thank the commenters for their support.

Comment: Commenters stated that CMS should establish a Technical Expert Panel (TEP) to evaluate the proposed HHVBP measures to ensure that the measures appropriately consider the full scope of the patient population served with the home health benefit, particularly patients not likely to experience condition improvement. Another commenter asserted that there

[21] *https://innovation.cms.gov/innovation-models/home-health-value-based-purchasing-model.*

[22] *https://homehealthcahps.org/General-Information/About-Home-Health-Care-CAHPS-Survey.*

is no evidence that CMS has sought out experts who can determine how to devise meaningful and inclusive measurements, and that there must be measurement experts CMS can engage who can determine how to measure everyone. The commenter further asserted that CMS should have located or developed appropriate quality measurements during the implementation period of the original HHVBP Model or for the Quality Reporting Program.

Response: As described in the CY 2019 final rule (83 FR 56528–56529), CMS received input from a TEP on measure set modifications for the measures under the original Model. As under the original Model, and noted in section III.A.6.5 of this final rule, we plan to continue to seek input on the measure set, including from stakeholders in relevant fields such as clinicians, statisticians, quality improvement, and methodologists, and to monitor quality measure performance to inform potential measure set changes under the expanded Model. We further note that the majority of the measures in the proposed expanded Model measure set were used since the implementation of the original Model in CY 2016 and that the majority of the measures overlap with the HH QRP, except for the TNC change measures.

Comment: A commenter stated that home health payment reform must be implemented in a way that maintains beneficiary access to care and ensures beneficiaries receive necessary and appropriate care. A commenter stated that excessively stringent model payment design may increase Medicare savings but simultaneously cause HHAs to leave the market, particularly in rural and other underserved areas. The commenter stated that HHAs may also respond to payment pressure by avoiding beneficiaries whose care is perceived as potentially jeopardizing HHAs' performance scores, when those beneficiaries may be the ones having the greatest clinical needs for home health services.

Response: We agree that home health payment reform, specifically for HHVBP, should be implemented so that beneficiaries maintain access to care and receive necessary and appropriate care. We disagree with the comments that the HHVBP model payment design may cause HHAs to leave the market. As previously noted, evaluation findings showed that implementation of the original HHVBP Model did not adversely impact home health utilization, market entry and exit.

Comment: A commenter raised concerns that the measure set should score a small set of outcomes, patient experience, and value (for example, resource use) measures that are not unduly burdensome for providers to report. The commenter suggested that scores could be based on three claims-based measures of quality and resource use: All-condition hospitalizations with the HH stay, successful discharge to the community, and Medicare spending per beneficiary.

Response: The proposed measure set for the expanded HHVBP Model includes measures that are currently already reported by HHAs and therefore we do not believe these measures would be unduly burdensome for HHAs to report. As discussed in the proposed rule, in evaluating whether to augment the initial measure set, we would consider the potential burden on HHAs to report measure data that is not already collected through existing quality measure data reporting systems. We thank the commenter for their suggestion to score HHAs on three claims-based measures. We note that the HHVBP expanded Model measure set was developed to encourage HHAs to focus on quality, patient-centered care and quality improvement across various focus areas, including those which are not directly measured through claims-based measures, such as patient experience. We further note that we did not propose the claims measures described but we may consider the use of additional claims-based measures in the expanded HHVBP Model for future rulemaking.

Comment: Some commenters stated that quality measures are not always under the control of the HHA. One example they provided is the OASIS quality measure, Self-Management of Oral Medications, where medication management could be done by an assisted living facility rather than the HHA. Commenters requested that CMS take these types of discrepancies into account so that the HHA is not penalized.

Response: We disagree with the commenters that HHAs serving patients in an assisted living facility are at a disadvantage to achieve a higher quality score in this area of measurement. We believe that all HHAs must aim to provide high quality care and therefore assess for and put into place care planning and coordination of services, including the coordination on the management of oral medications, to mitigate poor quality outcomes regardless of care setting.

Comments Regarding Claims-Based Measures

Comment: A commenter stated CMS should consider how recent changes to the payment system affect scoring some of the measures. The two claims-based measures, Acute Care Hospitalizations (ACH) and Emergency Department (ED) Use without Hospitalization, are measured during the first 60 days of home health. They encourage CMS to consider how the changes to the home health payment system from the 60-day unit under the previous case-mix system (in CY 2019) to the 30-day unit under Patient Driven Grouping Model (PDGM) (in CY 2020 and later) could affect HHAs' scores on the ACH and ED use measures between the baseline and performance years.

Response: The PDGM is a case-mix adjustment model intended to pay for services more accurately We believe the HHVBP Model can continue unchanged when HHA periods of care are paid according to the case-mix adjustments of the PDGM. We may consider conducting analysis of the effects on HHAs' scores for ACH and ED Use measures between the baseline year and a performance year.

Comment: A commenter suggested using functional status as a risk adjuster for the hospitalization measures in the HHVBP model.

Response: Currently, there is no risk adjuster on our proposed claims measures. The proposed initial measure set for the expanded HHVBP Model includes the ACH measure which does not have any functional mobility elements. We thank the commenter for their suggestion and may take into consideration as we move forward in the implementation of the expanded HHVBP Model. We further note that we may make adjustments to the risk adjustment methodology based upon the removal of measures, changes to the assessment instrument, and diagnosis code changes.

Comments Regarding the OASIS-Based Measures

Comment: A commenter recommends that CMS replace the OASIS-based Discharge to Community measure in the HHVBP proposed measure set with the new, claims-based Discharged to Community measure used under HH QRP. The commenter stated that maintaining both measures is confusing to HHAs as the measures have similar names but are calculated differently and that the new claims-based measure provides a more accurate score.

Response: We thank the commenter for their recommendation. Additional

analysis is needed to evaluate the use of the claims-based Discharge to Community Measure used under the HH QRP in place of the OASIS-based measure. We will continue to monitor quality measure performance under expansion and will consider any potential measure modifications for future rulemaking.

Comment: A commenter requested more detail on what changed in the updated risk adjustment methodology as it relates to the TNC measures.

Response: We have updated the risk adjustment methodology as it relates to the TNC measures, which is available on the HHVBP Model Expansion webpage.[23] CMS made optional OASIS items (M1030, M1242, M2030, and M2200) collected at the start or resumption of a care that were used in the risk adjustment and the update posted on the HH QRP website.[24] Since voluntary items may be missing for some home health quality episodes, these four voluntary items were removed from the risk adjustment model update effective for episodes of care beginning 1/1/2021 and posted on the HH QRP website, as noted above. We note that the updated methodology, posted on the HHVBP Model Expansion webpage noted above, is applicable to episodes of care for the CY 2022 pre-implementation year, however as noted previously in this rule, HHAs will not be assessed on their performance of the TNC measures in CY 2022 that are based on the updated risk adjustment methodology. We note that the next update of the risk adjustment models is planned for the release of OASIS E which would apply to episodes of care beginning 1/1/2023, the first performance year under the expanded HHVBP Model. That is, as CY 2023 is the first performance year under the expanded Model, HHAs would be assessed on their performance on the TNC measures based on the updated risk adjusted methodology for episodes of care that would begin 1/1/2023. We further note that, during that update of the methodology that would be effective with episodes of care beginning 1/1/2023 and for which HHA's performance will be assessed, the risk adjustment models will be based on refreshed data and all risk factors will be re-tested for inclusion.

Comment: A commenter strongly supported the use of outcomes measures on functional status, such as the two OASIS composite measures (TNC Change in Mobility and TNC Change in Self-Care), stating that a patient's functional status is inextricably related to their ability to remain in a community setting and avoid unnecessary utilization of health care services. The commenter stated that it appreciates that these measures are broadly risk-adjusted to recognize patients with inherently limited goals for improvement, which can help account for differences in patient type that may affect an HHA's performance on certain measures. The commenter, however, recommended CMS consider whether additional risk adjustment would better account for patient differences, specifically for those with more limited potential for functional improvement.

Response: We thank the commenter for their support of the use of outcome measures on functional status. We appreciate the commenter's suggestion regarding additional risk adjustment to better account for patients with more limited potential for functional improvement and refer readers to our detailed response, discussed later in this section, on the risk adjusted methodology for the TNC measures.

Comment: Commenters expressed concern that the OASIS measures have the potential to reward non-legitimate quality improvement, because HHAs record and report functional assessment data through the OASIS assessment, and this information affects payments for HHAs and the calculation of certain quality metrics. The commenters asserted that providers have an incentive to report the information in ways that raise payments and appear to improve performance, resulting in questionable value for payment, quality measurement, and care planning. A commenter agreed that improving a patient's functional ability is a goal of home health care, but urged CMS not to include these OASIS-based measures of function (for example, TNC Change in Self-Care and TNC Change in Mobility) in the expanded HHVBP Model until their accuracy is improved.

Response: With regard to concern that the OASIS measures may have the potential to reward non-legitimate quality improvement or that the measures may incentivize providers to report their OASIS assessments in ways that raise payments, we believe that the OASIS-based measures yield reliable information for assessing HHAs' quality performance and capture important information about beneficiaries' function based on reliability testing.[25] Most OASIS items achieve moderate to near perfect reliability based on reported Kappa values. With regard to the comment that CMS should not include the TNC measures in HHVBP until their accuracy is improved, we refer readers to our detailed response, that follows this response, on the TNC measures including their methodologies. We believe that our analysis of the TNC measures supports that these measures capture a change in a patient's status for the beneficiary population that may not have goals of improvement. We will continue, as with all measures in the measure set, to evaluate the benefit of the measure as the expanded Model progresses.

Comment: We received many comments about including stabilization/maintenance measures in the expanded Model and the proposed TNC measures. A commenter suggested that there be a modified risk adjustment that accounts for patients in palliative care population (for example, discharge to hospice care). Commenters suggest that a stronger risk adjustment model is needed for HHVBP to recognize that some home health agencies care for a much sicker and more complex population than others so agencies can be compared fairly and to ensure that incentives are aligned to care for patients with complex health and social determinant needs. Alternatively, commenters expressed that CMS could remove all patients with maintenance goals from HHVBP until all measures, incentives, and disincentives equally reflect their needs and qualifications for Medicare coverage as for those beneficiaries who can improve. The commenters suggest that improvement measures coupled with the higher weights assigned to the hospitalization and emergency department use claims-based measures may serve to disincentivize home health agencies from accepting into service Medicare beneficiaries that have chronic and/or unstable conditions or that the proposed measure set would negatively impact beneficiary access because HHAs may choose to care for patients who can show improvement in order to maximize their payment adjustment. Commenters stated that expansion should be temporarily halted in order to refine the methodology of how improvement is to be calculated to sufficiently account for patient populations whose appropriate goal may be to slow or temporarily halt

[23] *https://innovation.cms.gov/innovation-models/home-health-value-based-purchasing-model.*

[24] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Home-Health-Quality-Measures* in a file titled Risk Adjustment Technical Specifications.

[25] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/OASIS-Field-Test-Summary-Report_02-2018.pdf.*

functional decline, but who cannot reasonably be expected to make major improvements in activities of daily life (ADL) scores. Some commenters expressed concern that the proposed measures focus largely on improvement and should include stabilization and maintenance measures as well. Commenters asserted that the measure set's improvement standards are relied upon too heavily, which will negatively impact HHAs with chronic care, palliative care, and end of life patient populations, and that CMS's current risk adjuster does not account for these differences sufficiently. A commenter asserted that since the HHVBP Model was first proposed in 2015, quality measures discriminate against Medicare beneficiaries with longer-term, chronic conditions who require skilled care but are not expected to improve—patients covered by the *Jimmo* class action settlement and provided an example of a patient that it asserted would be harmed by expanding HHVBP. The commenter asserted that the proposed TNC Self-Care and TNC Mobility composite measures are not appropriate or adequate for beneficiaries who are not able to improve. The commenter believes that the methodology for the TNC measures does not allow agencies to benefit from providing care to beneficiaries who are not expected to improve regardless of how high the quality of care.

Response: We believe the goals of home health care are to provide restorative care when improvement is expected, maintain function and health status if improvement is not expected, slow the rate of functional decline to avoid institutionalization in an acute or post-acute care setting, and/or facilitate transition to end-of-life care, when appropriate. We remind commenters that the structure of the home health benefit requires a multidisciplinary approach of not only therapy services, but skilled nursing, home health aide, and medical social services. The TNC measures, as previously stated, are not improvement measures but rather, they measure the change in function in either direction, both positive and negative.

The TNC measures, in the proposed measure set, capture any risk-adjusted change (negative and positive). In general, a positive change between Start of Care (SOC)/Resumption of Care (ROC) and End of Care (EOC) assessment increases the measure values more than no change or a negative change. But the risk adjustment methodology for these measures is designed to level the ''playing field'' based on underlying risk factors. We also have exclusions in place for nonresponsive patients. Relative to the functional improvement measures in the initial HHVBP measure set, the TNC measures reward HHAs that help patients maintain or prevent excessive decline in their functional abilities overall. The TNC measure is a composite of changes, not improvement. We provide an example to help demonstrate how HHAs would not be dis-incentivized to care for beneficiaries who are not expected to improve, demonstrating how the risk-adjustment model recalibrates the scores for HHAs caring for beneficiaries with more complex medical needs relative to HHAs caring for less complex beneficiaries.

Risk Adjustment for Proposed TNC Measures

Risk adjustment is necessary to account for differences in patient case mix among different HHAs that affect performance on outcome measures. That is, age and pre-existing conditions impact how patients perform on outcome measures and risk adjustment accounts for the differing types of patients served by HHAs and enables comparison across HHAs. These same risk adjustment methods are employed in other quality measures, such as the hospital-based mortality measures, to prevent providers from avoiding the sickest patients and preferencing the healthiest.

The general formula for risk adjustment of OASIS outcomes measure is as follows:

$$Outcome_{RA} = (Observed_{HHA} - Predicted_{HHA}) + National$$

Where

$Outcome_{RA}$ is the HHA's risk adjusted outcome measure value,

$Observed_{HHA}$ is the HHA's average observed values for the outcome measure,

$Predicted_{HHA}$ is the HHA's average predicted values for the outcome. Predicted values are obtained from a regression model using a set of risk factors, and

National is the average predicted value across all episodes in the nation.

An HHA's risk adjusted measure value is calculated by averaging the HHA observed measure value across all its patients and subtracting the HHA's average predicted measure value across all its patients. To standardize the result, the national measure value is then added to obtain the risk adjusted outcome measure for the HHA.

The following example demonstrates how the formula, as previously discussed, would work for a hypothetical patient with the following risk factors, as referenced by a commenter:

- Age 56
- Diagnosis of multiple sclerosis
- Use of catheter

Table 24 shows the risk adjustment coefficients on the selected risk factors for OASIS-based measures in the proposed measure set for the HHVBP expansion for this hypothetical beneficiary. The presence of these risk factors is almost always associated with lower predicted measure values for the OASIS-based outcome measures used in the proposed measure set for HHVBP expansion, as evidenced by the negative signs on the coefficients shown in this table.

TABLE 24. RISK ADJUSTMENT COEFFICIENTS FOR SELECT BENEFICIARY RISK FACTORS ACROSS FIVE MEASURES

	TNC MOB	TNC Self	Imprv Dyspnea	Imprv Oral Meds	Disch to Comm
AGE_55_59	-0.0149	-0.0327	-0.0764	-0.0484	-0.1227
URINCONT_CATH	-0.1369	-0.2711	-0.2470	-0.2543	-0.6561
HC DX Nervous	-0.0477	-0.1133	-	-0.1669	0.0880
Sum	***-0.1995***	***-0.4171***	***-0.3234***	***-0.4696***	***-0.6908***

Source: Estimated coefficients on risk factors: https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/hhvbp%20technical%20specification%20resource%20for%20composite%20outcome%20measures_4.pdf; https://www.cms.gov/files/document/risk-adjustment-technicalspecifications508cfinal.pdf

Negative coefficients lower the predicted value for a beneficiary with these characteristics and positive coefficients increase the predicted value. For each of the measures, summing the coefficients on the three risk factors shows that the presence of all three risk factors contributes negatively to the predicted value for those beneficiaries with the risk factors for all five measures in Table 24. Using the risk adjustment formula as previously discussed, the lower predicted values for these episodes would contribute to boosting the risk adjusted measure value if all other risk adjustment variables are equal across HHAs.

For illustrative purposes, imagine that the national average TNC Mobility score is 0.73 and a particular HHA has an observed score of 0.60. If all the HHA's patients had the three, previously discussed, risk factors (and no others), the HHA's risk adjusted TNC Mobility score would be 0.60—0.45 [26] + 0.73 = 0.88. This score (0.88) is higher than the national score even though the observed value is lower than the national score. Note that this is purely hypothetical—actual episodes for an HHA would trigger multiple different risk factors (there are over a hundred) and the predicted value would be summed over the coefficients for all of these risk factors.

Based on the risk adjustment formula, the lower the average predicted measure value is for an HHA, the higher the HHA's risk adjusted outcome score. That is, patients with multiple risk factors associated with lower measure performance will have a lower predicted value than patients without those risk factors. The lower predicted value will increase the risk-adjusted measure score.

We believe that our analysis of the TNC measures supports that these measures capture a change in a patient's status for the beneficiary population that may not have goals of improvement. We will continue, as with all measures in the measure set, to evaluate the benefit of the measures as the Model progresses.

Comment: A commenter suggested that CMS consider including a falls prevention measure as key patient safety data necessary for a comprehensive HHVBP model. The commenter suggested, for example, that NQF 0101/CMIT 1247 Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls could be considered. The commenter stated that a falls prevention measure would help to ensure that HHAs are addressing risks and planning for interventions to minimize patient falls in the home, which can lead to greatly increased cost if a patient requires an emergency room visit, hospitalization, or other care to treat any injuries. Another commenter suggested that because family caregivers often play an important role in caring for the beneficiary, CMS consider adopting a measure for use in both the HHVBP model and HH QRP program that addresses HHAs documenting whether the beneficiary has a family caregiver and provided additional factors for the HHA to collect surrounding a beneficiary's family caregiver.

Response: We thank the commenters for their recommendations and we may consider these measures for inclusion in the expanded Model's measure set in a future year.

Comments Regarding the HHCAHPS Survey Measure

Comment: A commenter was not in favor of the overall quality rating proposed as a HHCAHPS measure as they believe it is not specific or necessarily actionable for improvement opportunities.

Response: We believe that patient experience is an important way to assess quality of care. The HHVBP expanded Model measure set was developed to encompass a home health episode of care from intake through to the patient experience survey encouraging HHAs to focus on quality, patient-centered care and quality improvement across various focus areas, including those which are not directly measured through the claims-based measures, such as patient experience.

Comment: A commenter supported HHCAHPS as part of the expanded Model's measure set. Another commenter stated that since patient experience is a key measure of a provider's quality, the HHVBP Model should continue to score HHCAHPS measures and that the measure set should be revised as other measures become available.

Response: We thank the commenters for their feedback. We agree that the HHCAHPS measure is a key measure of a provider's quality of care provided. We will continue to monitor quality measure performance as we consider any potential measure set changes for future rulemaking.

Final Decision: After consideration of comments received, we are finalizing the measure set as proposed effective with the CY 2022 pre-implementation year and subsequent years. We are also

[26] To calculate the 0.45, we sum the coefficients in the table above with the constant estimated from the updated risk adjustment model (*https://www.innovation.cms.gov/innovation-models/home-health-value-based-purchasing-model*) and apply the logistic formula (see Chapter 6 of *https://www.cms.gov/files/document/hh-qrp-qm-users-manual-v1-addendum.pdf*).

finalizing our proposed regulation text at § 484.355(a)(1) with modification to reflect that an HHA must submit data on the specified measures under the expanded HHVBP model for both the pre-implementation year and each performance year. As discussed in section III.A,3.a of this final rule, we are finalizing CY 2025 as the first payment year, instead of CY 2024. CY 2022 will be a pre-implementation year to allow all HHAs time to prepare and learn about the HHVBP expanded Model for successful implementation. Quality measure data collected during CY 2022 will not be assessed for purposes of a payment adjustment under the expanded HHVBP Model; that is, HHAs will incur zero percent (0%) payment risk based upon CY 2022 performance. CY 2023 will be the first performance year, beginning January 1, 2023; CY 2025 will be the first payment year. Table 25 sets forth the finalized measure set for the expanded HHVBP Model. We note that in Table 26 of the proposed rule, the Measure Steward and Identifier for the Discharged to Community measure was NA and NA, respectively. In Table 25, the finalized measure set for the expanded Model, the Measure Steward and the Identifier is updated to CMS and NQF 3477, respectively.

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TABLE 25: FINALIZED MEASURE SET FOR THE EXPANDED HHVBP MODEL

NQS Domains	Measure Full Title/Short Form Name (if applicable)	Measure Type	Measure Steward	Identifier	Data Source	Numerator	Denominator	Link to Measure Specifications/NQF Info
OASIS-based								
Clinical Quality of Care	Improvement in Dyspnea/Dyspnea	Outcome	NA	NA	OASIS (M1400)	Number of home health episodes of care where the discharge assessment indicates less dyspnea at discharge than at start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.	https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-Outcome-Measures-Table-OASIS-D-11-2018c.pdf
Communication & Care Coordination	Discharged to Community	Outcome	CMS	NQF 3477	OASIS (M2420)	Number of home health episodes where the assessment completed at the discharge indicates the patient remained in the community after discharge.	Number of home health episodes of care ending with discharge or transfer to inpatient facility during the reporting period, other than those covered by generic or measure-specific exclusions.	https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-Outcome-Measures-Table-OASIS-D-11-2018c.pdf NQF Measure Information
Patient Safety	Improvement in Management of Oral Medications/Oral Medication	Outcome	CMS	NQF 0176	OASIS (M2020)	Number of home health episodes of care where the value recorded on the discharge assessment indicates less impairment in taking oral medications correctly at discharge than at start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.	https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-Outcome-Measures-Table-OASIS-D-11-2018c.pdf NQF Measure Information
Patient and Family Engagement	Total Normalized Composite Change in Mobility*/TNC Mobility	Composite Outcome	NA	NA	OASIS (M1840) (M1850) (M1860)	The total normalized change in mobility functioning across three OASIS items (toilet transferring, bed transferring, and ambulation/locomotion)	A prediction model is computed at the episode level. The predicted value for the HHA and the national value of the predicted values are calculated and are used to calculate the risk-adjusted rate for the HHA, which is calculated using this formula: HHA Risk Adjusted = HHA Observed + National Predicted – HHA Predicted.	https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/hhvbp%20technical%20specification%20resource%20for%20composite%20outcome%20measures_4.pdf

NQS Domains	Measure Full Title/Short Form Name (if applicable)	Measure Type	Measure Steward	Identifier	Data Source	Numerator	Denominator	Link to Measure Specifications/NQF Info
Patient and Family Engagement	Total Normalized Composite Change in Self-Care**/TNC Self-Care	Composite Outcome	NA	NA	OASIS (M1800) (M1810) (M1820) (M1830) (M1845) (M1870)	The total normalized change in self-care functioning across six OASIS items (grooming, bathing, upper & lower body dressing, toilet hygiene, and eating)	A prediction model is computed at the episode level. The predicted value for the HHA and the national value of the predicted values are calculated and are used to calculate the risk-adjusted rate for the HHA, which is calculated using this formula: HHA Risk Adjusted = HHA Observed + National Predicted – HHA Predicted.	https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/hhvbp%20technical%20specification%20resource%20for%20composite%20outcome%20measures_4.pdf
Claims-based								
Efficiency & Cost Reduction	Acute Care Hospitalization During the First 60 Days of Home Health Use/ACH	Outcome	CMS	NQF 0171	CCW (Claims)	Number of home health stays for patients who have a Medicare claim for an unplanned admission to an acute care hospital in the 60 days following the start of the home health stay.	Number of home health stays that begin during the 12-month observation period. A home health stay is a sequence of home health payment episodes separated from other home health payment episodes by at least 60 days.	https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-Outcome-Measures-Table-OASIS-D-11-2018c.pdf NQF Measure Information
Efficiency & Cost Reduction	Emergency Department Use without Hospitalization During the First 60 Days of Home Health/ED Use	Outcome	CMS	NQF 0173	CCW (Claims)	Number of home health stays for patients who have a Medicare claim for outpatient emergency department use and no claims for acute care hospitalization in the 60 days following the start of the home health stay.	Number of home health stays that begin during the 12-month observation period. A home health stay is a sequence of home health payment episodes separated from other home health payment episodes by at least 60 days.	https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-Outcome-Measures-Table-OASIS-D-11-2018c.pdf NQF Measure Information
HHCAHPS Survey-based								
Patient & Caregiver-Centered Experience	Home Health Consumer Assessment Healthcare Providers and Systems (HHCAHPS) Survey	Outcome	CMS	NQF 0517	CAHPS	Survey-based. HHCAHPS has five component questions that together are used to represent one NQF-endorsed measure	Survey-based. HHCAHPS has five component questions that together are used to represent one NQF-endorsed measure	Links provided in Table XX NQF Measure Information

*Because the Total Normalized Composite Change in Mobility measure is a composite measure rather than simply an outcome measure, the terms "Numerator" and "Denominator" do not apply.

**Because the Total Normalized Composite Change in Self-Care measure is a composite measure rather than simply an outcome measure, the terms "Numerator" and "Denominator" do not apply.

Table 26 provides more granular detail on the elements of the Home Health Care Consumer Assessment of Healthcare Providers and Systems (HHCAHPS) Survey measure.

TABLE 26: HHCAHPS SURVEY MEASURE COMPONENTS AND COMPONENT QUESTIONS

HHCAHPS Survey-based Component Name/ Short Name and Component Questions*	Type	NQF ID	Data Source	Link to Measure Specs/Response Categories
Care of Patients/Professional Care	Outcome	0517	CAHPS	https://cmit.cms.gov/CMIT_public/ViewMeasure?MeasureId=2062
Q9. In the last 2 months of care, how often did home health providers from this agency seem informed and up-to-date about all the care or treatment you got at home?				Never, Sometimes, Usually, Always
Q16. In the last 2 months of care, how often did home health providers from this agency treat you as gently as possible?				Never, Sometimes, Usually, Always
Q19. In the last 2 months of care, how often did home health providers from this agency treat you with courtesy and respect?				Never, Sometimes, Usually, Always
Q24. In the last 2 months of care, did you have any problems with the care you got through this agency?				Yes, No
Communications between Providers and Patients/Communication	Outcome	0517	CAHPS	https://cmit.cms.gov/CMIT_public/ViewMeasure?MeasureId=2580
Q2. When you first started getting home health care from this agency, did someone from the agency tell you what care and services you would get?				Yes, No
Q15. In the past 2 months of care, how often did home health providers from this agency keep you informed about when they would arrive at your home?				Never, Sometimes, Usually, Always
Q17. In the past 2 months of care, how often did home health providers from this agency explain things in a way that was easy to understand?				Never, Sometimes, Usually, Always
Q18. In the past 2 months of care, how often did home health providers from this agency listen carefully to you?				Never, Sometimes, Usually, Always
Q22. In the past 2 months of care, when you contacted this agency's office did you get the help or advice you needed?				Yes, No
Q23. When you contacted this agency's office, how long did it take for you to get the help or advice you needed?				Same day; 1 to 5 days; 6 to 14 days; More than 14 days
Specific Care Issues/Team Discussion	Outcome	0517	CAHPS	https://cmit.cms.gov/CMIT_public/ViewMeasure?MeasureId=2582
Q3. When you first started getting home health care from this agency, did someone from the agency talk with you about how to set up your home so you can move around safely?				Yes, No
Q4. When you started getting home health care from this agency, did someone from the agency talk with you about all the prescription medicines you are taking?				Yes, No
Q5. When you started getting home health care from this agency, did someone from the agency ask to see all the prescription medicines you were taking?				Yes, No
Q10. In the past 2 months of care, did you and a home health provider from this agency talk about pain?				Yes, No
Q12. In the past 2 months of care, did home health providers from this agency talk with you about the **purpose** for taking your new or changed prescription medicines?				Yes, No
Q13. In the last 2 months of care, did home health providers from this agency talk with you about **when** to take these medicines?				Yes, No
Q14. In the last 2 months of care, did home health providers from this agency talk with you about the **important side effects** of these medicines?				Yes, No
Overall rating of home health care/Overall Rating	Outcome	0517	CAHPS	https://cmit.cms.gov/CMIT_public/ViewMeasure?MeasureId=2581
Q20. What number would you use to rate your care from this agency's home health providers?				Use a rating scale (0-10) (0 is worst, 10 is best)
Willingness to recommend the agency/Willing to Recommend	Outcome	0517	CAHPS	https://cmit.cms.gov/CMIT_public/ViewMeasure?MeasureId=2583
Q25. Would you recommend this agency to your family or friends if they needed home health care?				Definitely no; Probably no; Probably yes; Definitely yes

*The HHCAHPS survey measure component has five component questions that together are used to represent one NQF-endorsed measure. Detailed scoring information is contained in the Protocols and Guidelines manual posted on the HHCAHPS website and available at https://homehelathcahps.org/Survey-and-Protocols/Survey-Materials.

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c. Measure Modifications

During the expanded Model, we will monitor the quality measures for lessons learned and address any needed adjustments or modifications to the expanded Model measure set.

(1) Substantive vs. Non-Substantive Changes Policy

Updates to measures may result from various sources including, for example, measure stewards and owners, new clinical guidelines, a public health

emergency, CMS-identified, a technical expert panel (TEP), or NQF. We stated in the proposed rule that how we incorporate those updates would depend on whether the changes are substantive or non-substantive.

With respect to what constitutes a substantive versus a non-substantive change, we stated in the proposed rule that we expect to make this determination on a measure-by-measure basis. Examples of such non-substantive changes might include updated diagnosis or procedure codes, medication updates for categories of medications, broadening of age ranges, and changes to exclusions for a measure. We believe that non-substantive changes may include updates to measures based upon changes to guidelines upon which the measures are based. These types of maintenance changes are distinct from more substantive changes to measures that result in what can be considered new or different measures, and that they do not trigger the same agency obligations under the Administrative Procedure Act.

We proposed that, in the event that an update to a measure is necessary in a manner that we consider to not substantially change the nature of the measure, we will use a sub-regulatory process to incorporate those updates to the measure specifications. Specifically, we would revise the information that is posted on the CMS website so that it clearly identifies the updates and provides links to where additional information on the updates can be found. In addition, we would provide sufficient lead time for HHAs to implement the changes where changes to the data collection systems would be necessary.

We also proposed to use notice and comment rulemaking to adopt changes to measures that we consider to substantially change the nature of the measure. Examples of changes that we might consider to be substantive would be those in which the changes are so significant that the measure is no longer the same measure, or when a standard of performance assessed by a measure becomes more stringent, such as changes in acceptable timing of medication, procedure/process, test administration, or expansion of the measure to a new setting. We stated that we believe that our proposal adequately balances the need to incorporate changes to measures used in the expanded HHVBP Model in the most expeditious manner possible, while preserving the public's ability to comment on updates to measures that so fundamentally change a measure that it is no longer the same measure originally adopted. We note that CMS adopted a similar policy for the HH QRP in the CY 2015 HH PPS final rule (79 FR 66079 through 66081).

We invited public comment on our proposal. We summarize in this section of this rule the comments received and provide our responses.

Comment: A commenter suggested that ongoing modifications to the HHVBP expanded model (for example, scoring methodology, quality measure inclusion, risk adjustment methodology) are necessary to ensure the expanded model accurately and appropriately reflects the value of services delivered and the beneficiary populations cared for.

Response: CMS will continue to evaluate and monitor the expanded HHVBP Model for potential modifications to ensure the expanded model accurately and appropriately reflects the value of services delivered and the beneficiary populations cared for.

Final Decision: After consideration of comments received, we are finalizing our proposal as proposed.

d. Measure Removals

The measure set used for the expanded Model would be subject to change including the removal of measures during subsequent years. In the proposed rule, for greater transparency, we proposed factors we would consider in proposing to remove a measure as well as a policy for when immediate suspension is necessary.

(1) Removal Factors

We proposed to generally use the following removal factors when considering a quality measure for removal for use in the expanded HHVBP Model:

- Factor 1. Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made (that is, topped out). To determine ''topped-out'' criteria, we will calculate the top distribution of HHA performance on each measure, and if the 75th and 90th percentiles are statistically indistinguishable, we will consider the measure topped-out.
- Factor 2. Performance or improvement on a measure does not result in better patient outcomes.
- Factor 3. A measure does not align with current clinical guidelines or practice.
- Factor 4. A more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available.
- Factor 5. A measure that is more proximal in time to desired patient outcomes for the particular topic is available.
- Factor 6. A measure that is more strongly associated with desired patient outcomes for the particular topic is available.
- Factor 7. Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.
- Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program.

With respect to Factor 8, under our Meaningful Measures Initiative, we are engaging in efforts to ensure that the expanded HHVBP Model measure set continues to promote improved health outcomes for beneficiaries while minimizing the overall costs associated with the program. We believe that these costs are multifaceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the expanded HHVBP Model. We have identified several different types of costs, including, but not limited to the following:

- Provider and clinician information collection burden and burden associated with the submitting/reporting of quality measures to CMS.
- The provider and clinician cost associated with complying with other HH programmatic requirements.
- The provider and clinician cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs.
- The cost to CMS associated with the program oversight of the measure, including measure maintenance and public display.
- The provider and clinician cost associated with compliance with other Federal and State regulations (if applicable).

For example, it may be of limited benefit to retain or maintain a measure which our analyses show no longer meaningfully supports the expanded HHVBP Model goals (for example, no longer provides incentives for better quality care with greater efficiency). It may also be costly for HHAs to track confidential feedback and publicly reported information on a measure where we use the measure in more than one initiative, model, or program. We may also have to expend resources to maintain the specifications for the measure, including the tools needed to collect, validate, analyze, and publicly report the measure data.

When these costs outweigh the evidence supporting the continued use of a measure in the expanded HHVBP Model, we believe that it may be appropriate to remove the measure from the Model. Although we recognize that the expanded HHVBP Model is to encourage HHAs to improve beneficiary outcomes by incentivizing health care providers, we also recognize that this can have limited utility where, for example, the data is of limited use because it is not meaningful. In these cases, removing the measure from the expanded HHVBP Model may better accommodate the costs of expansion administration and compliance without sacrificing improved health outcomes.

We proposed that we would remove measures based on Factor 8 on a case-by-case basis. For example, we may decide to retain a measure that is burdensome for HHAs to report if we conclude that the benefit to beneficiaries is so high that it justifies the reporting burden. Our goal is to move the expanded HHVBP Model forward in the least burdensome manner possible, while maintaining a parsimonious set of meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients.

We believe that even if one or more of the measure removal factors applies, we might nonetheless choose to retain the measure for certain specified reasons. Examples of such instances could include when a particular measure addresses a gap in quality that is so significant that removing the measure could result in poor quality. We would apply these factors on a case-by-case basis.

In addition, as noted previously, the authority to expand the HHVBP Model affords the opportunity to study new measures that are not currently collected or submitted to CMS by HHAs. Because of this, there may be other unforeseen reasons that necessitate the removal of a measure that is not currently captured in one of the factors noted previously. In such cases, we would still use notice and comment rulemaking to remove the measure and provide the reasons for doing so.

We solicited public comment on our proposals.

Final Decision: We did not receive any comments on our proposal and are finalizing the measure removal factors as proposed.

(2) Measure Suspension Policy

We stated in the proposed rule that removal of an expanded HHVBP Model measure would take place through notice and comment rulemaking as proposed in the preceding section unless we determine that a measure is causing concern for patient safety or harm. We proposed that in the case of an expanded HHVBP Model measure for which there is a reason to believe that the continued collection raises possible patient safety concerns, we would promptly suspend the measure and immediately notify HHAs and the public through the usual communication channels, including listening sessions, memos, email notification, and Web postings. We would then propose to remove or modify the measure as appropriate during the next rulemaking cycle.

We solicited public comment on our proposal.

Final Decision: We did not receive any comments on our proposal and are finalizing the measure suspension policy as proposed.

e. Future Topics or Measure Considerations

(1) Consideration To Align or Remove Measures With the HH QRP

In section IV.C. of the proposed rule, CMS proposed to replace the Acute Care Hospitalization During the First 60 Days of Home Health (ACH) measure and Emergency Department Use Without Hospitalization During the First 60 days of Home Health (ED Use) measure with the Home Health Within Stay Potentially Preventable Hospitalization (PPH) measure beginning with the CY 2023 under the HH QRP. (As discussed in section IV.C of this final rule, CMS is finalizing its proposal to replace the ACH and ED Use measures with the PPH measure for the HH QRP measure set beginning with CY 2023.) We noted in the proposed rule that while both the ACH and ED Use measure were being proposed for removal under the HH QRP, these measures were being proposed for inclusion in the expanded HHVBP Model beginning with the CY 2022 performance year. We solicited public comment on whether we should instead align the expanded HHVBP Model with the proposed changes for HH QRP by proposing to remove the same two measures from the expanded Model in a future year. We noted that any measure removals would be proposed in future notice and comment rulemaking.

We requested public feedback on this future consideration. We summarize in this section of this rule the feedback received and provide our responses.

Comment: Commenters recommended that the HHVBP measure set align to measures of the HH QRP. Another commenter suggested that CMS move to align the included measures with the Star Ratings and other quality reporting activities. Another commenter stated that by bringing consistency to tracked outcomes across the HH QRP, Star Ratings, and HHVBP, CMS will minimize the difficulty of beneficiaries and payers to make comparative assessment of provider quality while also streamlining home health providers' data capture and reporting processes.

Response: We thank the commenters for their suggestions. We note that the proposed measure set for the expanded HHVBP Model generally aligns with the HH QRP. We will take into consideration opportunities for further alignment, including with respect to the claims-based measures. If we consider adding new measures that require data that is not already collected through existing quality measure data reporting systems, we would propose that in future rulemaking being mindful of provider burden.

Comment: Commenters expressed that they need at least one year to become familiar with the Home Health Within-Stay Potentially Preventable Hospitalization (PPH) measure, and to affect outcomes, if needed, before including it in the HHVBP expanded Model measure set.

Response: We thank the commenters for their feedback and will take into future consideration.

(2) Health Equity Considerations for the Expanded HHVBP Model

In section VIII.B. of the proposed rule, we included a Request for Information on ways to close the health equity gap in post-acute care quality reporting programs, including the HH QRP. In the proposed rule, we referred readers to that section for discussion of our current health equity efforts in quality measurement and reporting and potential modifications we have considered or may consider in the future. However, in recognition of persistent health disparities and the importance of closing the health equity gap, we requested public comment on ways in which we could incorporate health equity goals and principles into the expanded HHVBP Model. Specifically, we sought comment on the challenges unique to value-based purchasing frameworks in terms of promoting health equity, and ways in which we could incorporate health equity goals into the expanded HHVBP Model.

In this section of this rule, we summarize comments received and provide our responses.

Comment: A commenter stated that in an effort to prevent bias in patient selection, it encouraged CMS to consider potential stabilization measures, rather than sole reliance on improvement measures. The commenter stated that this will continue to promote access to care for individuals with chronic illness or limited ability to improve, and is consistent with the renewed focus on health equity. Another commenter generally supported health equity goals and principles incorporated in the expanded HHVBP Model. The commenter recommended CMS collect patient-level demographic information based on segmented demographics (race, ethnicity, gender, etc.) on existing measures, instead of creating new or more complex measures. The commenter stated that should CMS move forward with adopting new health equity measures, it recommended CMS include these measures in the HH QRP prior to inclusion in the HHVBP Model.

Response: We thank the commenters for their feedback. As discussed in section III.A.6.b of this final rule, we are finalizing the measure set as proposed, which includes improvement, total normalized composite change measures, utilization and patient experience measures. We refer readers to our earlier detailed response in this section of the rule on the TNC change measures, including the measure methodology, and why we believe the measure set would not dis-incentivize HHAs from caring for beneficiaries with chronic illness or limited ability to improve. Health equity including access to care for all beneficiaries is a priority. CMS will continue to monitor beneficiary access under the HHVBP Model expansion.

Comment: A commenter recommended that outcomes measured in the HH QRP and HHVBP Model be stratified by various patient populations to determine how they are affected by Social Determinants of Health (SDOH).

Response: We note that in section VIII.B of this final rule, we are finalizing our proposal to revise compliance dates for HHAs under the HH QRP. This policy includes the submission of certain standardized patient assessment data, some of which address social determinants of health (SDoH). These standardized patient assessment data, in part, support efforts to evaluate health equity in a manner we believe is consistent with the policy set out in Executive Order 13985 of January 20, 2021, entitled ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government'' (86 FR 7009). We are working collaboratively with HH QRP to determine how data collected on SDoHs under HH QRP could be part of the HHVBP Model expansion in the future.

f. Measure Submissions—Form, Manner, and Timing

We proposed at § 484.355 that home health agencies will be evaluated using a set of quality measures, and data submitted under the expanded Model must be submitted in the form and manner, and at a time, specified by CMS. Additional details regarding specific types of measures are discussed later in this section.

As noted in the proposed rule and previously in this final rule, the measures that we proposed and are finalizing for the expanded HHVBP Model measure set would use data currently already reported by HHAs. The measure set includes OASIS [27] measures, submitted through the OASIS assessment, which is required to be submitted as part of the Medicare Conditions of Participation (CoPs), the HHCAHPS survey measure, which is required under the HH QRP, and claims-based measures, which are calculated by CMS based on claims data HHAs already submit for purposes of payment. As we stated in the proposed rule, in many cases, measures from the expanded HHVBP Model overlap with those in the HH QRP, and HHAs would only need to submit data once to fulfill requirements of both. However, as described in section III.6.a. of the proposed rule and this final rule, in the future we may propose new measures that may not otherwise already be collected or submitted by HHAs.

We solicited comment on our proposal.

As previously noted, we are finalizing our proposed regulation text at § 484.355 with modification to reflect that an HHA must submit data on the specified measures under the expanded HHVBP model for both the pre-implementation year and each performance year.

(1) Form, Manner, and Timing of OASIS Measure Data

CMS home health regulations, codified at § 484.250(a), require HHAs to submit to CMS OASIS data as is necessary for CMS to administer payment rate methodologies. All HHAs must electronically report all Outcome and Assessment Information Set (OASIS) [28] data collected in accordance with § 484.55(b), (c) and (d) in order to meet the Medicare CoPs, and as a condition for payment at § 484.205(c). The OASIS assessment contains data items developed to measure patient outcomes and improve home health care. HHAs submit the OASIS assessment in the Internet Quality Improvement Evaluation System (iQIES) (*https://iqies.cms.gov/*). We note that the CoPs require OASIS accuracy and that monitoring and reviewing is done by CMS surveyors (§ 488.68(c)). It is important to note that to calculate quality measures from OASIS data, there must be a complete quality episode, which requires both a Start of Care (SOC) (initial assessment) or Resumption of Care (ROC) OASIS assessment and a Transfer or Discharge OASIS assessment. Failure to submit sufficient OASIS assessments to allow calculation of quality measures, including transfer and discharge assessments, is a failure to comply with the CoPs § 484.225(i). HHAs do not need to submit OASIS data for patients who are excluded from the OASIS submission requirements Reporting Outcome and Assessment Information Set Data as Part of the Conditions of Participation for Home Health Agencies final rule (70 FR 76202) where we excluded patients—

- Receiving only non-skilled services;
- For whom neither Medicare nor Medicaid is paying for HH care (patients receiving care under a Medicare or Medicaid Managed Care Plan are not excluded from the OASIS reporting requirement);
- Receiving pre- or post-partum services; or
- Under the age of 18 years.

We proposed that HHAs participating in the expanded HHVBP Model would also be required to submit OASIS data according to the requirements of the CMS home health regulations codified at § 484.250(a) and OASIS data described in § 484.55(b), (c) and (d). We stated in the proposed rule that if finalized, this would mean that HHAs would not be required to submit additional data through OASIS specifically for the expanded Model compared to what is already required for COPs, and there would be no additional burden. We note that this proposed requirement also aligns with requirements under the Home Health QRP (82 FR 4578).

For the expanded Model, we proposed that the underlying source

[27] For detailed information on OASIS see the official CMS web resource available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits.*

[28] For detailed information on OASIS see the official CMS web resource available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits.*

data used to calculate an OASIS quality measure score beginning with the CY 2022 performance year comes from 12 months of OASIS assessment data from the applicable performance period via iQIES. The data extracted from iQIES for all OASIS measures, besides the two TNC measures, are aggregated to the monthly level for each HHA, separated by observed and predicted values used to calculate risk adjusted values. For the two TNC measures, we proposed to use raw OASIS assessments to calculate applicable measure scores consistent with how we developed these measures.

We solicited comment on our proposals. We summarize in this section of this rule comments received and provide our responses.

Comment: Several commenters were interested in knowing, if the HHA discharges the patient to either inpatient hospice care, or home hospice care, will declines in outcomes scored on the Home Health Discharge OASIS be counted against the HHA or would those declines be considered an outlier due to the patient transfer or discharge to a Hospice Provider. Another commenter questioned whether the agency data proposed to be collected from OASIS for completed episodes of care is SOC or ROC to discharge. Commenters expressed concern that if a patient opts for hospice, there is no ability to exclude these patients from the payment calculation at this point.

Response: For some of the HHVBP OASIS measures, such as the TNC measures, OASIS items used in calculating the measure are only collected at discharge [29] and therefore episodes that end in transfer are excluded from the measure calculation.[30]

If the home health episode ends with a transfer to an institutional provider (M0100 = 06 or 07) or death (08), then the patient would be excluded from the Dyspnea, Oral Medications, TNC Mobility, and TNC Self-Care measures because the OASIS items that these measures use are not collected at the time of transfer for these patients. Patients who are transferred to an inpatient hospice facility count as a ''transfer to an inpatient facility'' (07) and are not included in the OASIS-based measures, while patients discharged to in-home hospice count as regular discharges (09) and are included in the OASIS-based measures. The two claims-based measures use the 60 days after the start of home health, and there are no exclusions for patients who go to a hospice. It is correct that an OASIS quality episode of care does go from SOC/ROC to transfer/discharge.

Comment: Commenters discouraged CMS from including future VBP measures that are not collected in the OASIS data set (or through HHCAHPS or claims). Commenters stated that this would help prevent duplicative data collection and reduce administrative burden for agencies and assist HHAs to achieve better outcomes.

Response: We note that we may, through future rulemaking, add new measures to the expanded Model where data is not already collected in order to study them for their appropriateness in the home health setting. As discussed in the proposed rule, if we consider adding new measures that require data that is not already collected through existing quality measure data reporting systems, we would propose that in future rulemaking being mindful of provider burden. We note that the proposed measure set for the expanded Model uses data already collected through OASIS, claims, and HHCAHPS.

Final Decision: After consideration of the comments received, we are finalizing our proposals on the form, manner and timing of OASIS measure data as proposed. We reiterate that CY 2022 quality data will not be used to impact payments to eligible HHAs in CY 2024. CY 2023 will be the first year in which the data collected on the OASIS, claims, and HHCAHPS measures in the expanded HHVBP Model's set will be assessed to determine payment adjustments for eligible HHAs in the expanded HHVBP Model in CY 2025, the first payment year under the expanded Model.

(2) Form, Manner, and Timing of HHCAHPS Survey Measure Data

Under the HH QRP, HHAs are required to contract with an approved, independent HHCAHPS survey vendor to administer the HHCAHPS on its behalf (42 CFR 484.245(b)(1)(iii)(B)) among other requirements.

For purposes of the expanded HHVBP Model, we proposed similar requirements that align with the HH QRP HHCAHPS survey measure data reporting requirement at § 484.245(b)(1)(iii). Specifically, under the expanded Model we proposed that—

- HHAs must contract with an approved, independent HHCAHPS survey vendor to administer the HHCAHPS survey on its behalf;
- 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;
- 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;
- 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;
- Approved HHCAHPS survey vendors must fully comply with all HHCAHPS survey oversight activities, including allowing CMS and its HHCAHPS survey team to perform site visits at the vendors' company locations; and
- Patient count exemption: HHAs that have fewer than 60 eligible unique HHCAHPS survey patients must annually submit to CMS their total HHCAHPS survey patient count to CMS to be exempt from the HHCAHPS survey reporting requirements for a calendar year.

A CMS contractor provides the agency with the HHCAHPS survey measure score aggregated to the 12-months of data for the applicable performance period.

The list of approved HHCAHPS survey vendors is available at *https://homehealthcahps.org* or contact the HHCAHPS help desk *hhcahps@rti.org.* Again, we reiterate that these proposed requirements would align with those under the HH QRP and would not add additional burden to HHAs.

We also proposed to codify these proposals at § 484.355(a)(1)(ii).

We requested public comment on these proposals.

Final Decision: We did not receive comments on these proposals and are finalizing our proposals, including our proposed regulation text at § 484.355(a)(1)(ii), as proposed.

(3) Form, Manner, and Timing of Claims-Based Measures

Claims-based measures are derived from claims data submitted to CMS for payment purposes. Claims-based utilization measures provide information related to the use of health care services (for example, hospitals, emergency departments, etc.) resulting from a change in patient health status. We calculate claims-based measures

[29] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/draft-OASIS-D-Guidance-Manual-7-2-2018.pdf.*

[30] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-QRP-QM-Users-Manual-V10-August-2019.pdf.*

based on claims data submitted to CMS for payment purposes. Therefore, HHAs do not need to submit additional information for purposes of calculating claims-based measures.

We proposed that the underlying source data for claims-based measures is 12 months of claims data during the applicable performance period for purposes of payment under the expanded Model.

We requested comment on our proposal.

Final Decision: We did not receive comments on this proposal and are finalizing our proposal as proposed.

(4) Data Reporting for Monitoring and Evaluation of the Expanded HHVBP Model

Consistent with requirements under the original HHVBP Model at § 484.315(c), we proposed that competing HHAs under the expanded HHVBP Model would be required to collect and report information to CMS necessary for the purposes of monitoring and evaluating this model as required by statute.[31] We also proposed to codify this at § 484.355(b).

We sought public comment on these proposals.

Comment: A commenter strongly recommended that CMS have a clear, ongoing plan to monitor beneficiary access in place from the inception of the expanded model, including distribution of HHAs in historically underserved areas. The commenter stated that the monitoring plan should be as close to real-time as is operationally feasible and include steps for corrective action for those HHAs found to be avoiding complex patients. The commenter stated that monitoring also should incorporate beneficiary input, such as surveys and focus groups, as well as frequent assessments of the numbers and types of beneficiary complaints and appeals.

Response: We thank the commenter for their recommendations. We will continue to evaluate and monitor the expanded HHVBP Model and will take the commenter's recommendations under consideration.

Final Decision: After consideration of comments received, we are finalizing our proposals as proposed, including our proposed regulation text at § 484.355(b).

(5) Use Authority Under Section 1115A(d)(1) of the Act To Waive Provisions Outlined in 1890A(a)(1) and (3) Through (6) of the Act

As discussed in section III.A.11. of the proposed rule and this final rule, we proposed a public reporting framework for the expanded HHVBP Model that would include annual public reporting of quality performance data. This data includes national benchmarks and achievement thresholds, HHA-level performance results for HHAs that qualify for an annual payment adjustment that includes applicable quality measure scores, Total Performance Scores and percentile rankings, improvement thresholds, and payment adjustment percentages. Section 1890A(a)(1) through (6) of the Act set forth requirements regarding the pre-rulemaking process for the selection of quality and efficiency measures described in section 1890(b)(7)(B) of the Act, including quality and efficiency measures used in reporting performance information to the public. We proposed to utilize the Center for Medicare and Medicaid Innovation's waiver authority under section 1115A(d)(1) of the Act to waive the steps outlined in section 1890A(a)(1) and (3) through (6) of the Act that pertain to the pre-rulemaking process for publicly reporting performance information to the extent necessary to test the proposed expanded Model.

Section 1115A(d)(1) of the Act allows the Secretary to waive certain statutory requirements ''as may be necessary solely for purposes of carrying out this section with respect to testing models described in subsection (b).'' Specifically, we proposed to waive section1890A(a)(1) and (3) through (6) of the Act which pertains to: Convening multi-stakeholder groups to provide input to the Secretary on the use of quality and efficiency measures; transmitting the input from the multi-stakeholder groups to the Secretary; consideration of the input by the Secretary from the multi-stakeholder groups; publication in the **Federal Register** of the rationale on the quality and efficiency measures not endorsed for use; and, conduct an impact assessment every three years on the use of such measures.

We note that we did not propose to waive step 2 of the 6 steps in the pre-rulemaking process. Step 2 pertains to the public availability of measures considered for selection. Section 1890A(a)(2) of the Act specifically applies to quality and efficiency measures under Title XVIII, whereas the expanded model would be implemented under section 1115A of the Act, which is in Title XI.

We proposed to waive the steps outlined in sections 1890A(a)(1) and (3) through (6) of the Act to the extent necessary in order to allow maximum flexibility to continue to test the expanded HHVBP Model under authority of section 1115A of the Act. We stated in the proposed rule that the timeline associated with completing the steps described by these provisions would impede our ability to support testing new measures in a timely fashion, as well as testing new ways to incentivize quality performance in the home health setting and a new way to pay for home health care services. We stated that we plan to continue to seek input from a Technical Expert Panel (TEP) and to monitor quality measure performance to inform potential measure set changes under the expanded Model. We stated that waiving the five steps noted previously for the expanded HHVBP Model would allow for a more flexible timeline with more timely evaluation and monitoring of quality performance and results.

We stated in the proposed rule that flexibility in timing to adjust the quality measure set and/or methodology to respond to unexpected events and trends in home health care, as well as to respond timely to any stakeholder concerns, is critical to the success of the HHVBP Model expansion. The ongoing uncertainty levied by the COVID–19 pandemic, and similar events that may come in the future, requires us to maintain responsiveness to anomalies in the quality measure data. These challenges may require the flexibility to timely implement changes to ensure that measure sets continue to appropriately assess performance in light of external factors. In addition, trends in market consolidation and small business policies in the home health care industry could require certain adjustments to measure methodology, that is, minimum volume requirements, or require adjustment to the applicability of measures. The home health care sector is also becoming a more important source of care for beneficiaries who prefer to age in the community, rather than in an institution. This trend, in addition to the national shift in beneficiary demographics, could require flexibility in the quality measure set. This flexibility would be a key lever to adapt the Model to the unpredictable changes led by beneficiary preference, industry trends, and unforeseen nationwide events that HHAs are particularly sensitive to. We sought comment on our proposal to waive the steps outlined in section 1890A(a)(1) and (3) through (6) of the Act as applicable and to the extent necessary to test the proposed expanded Model.

We summarize in this section of this rule comments received and provide our responses.

[31] See 1115A(b)(4) of the Act (42 U.S.C. 1315a).

Comment: A couple of commenters encouraged CMS to maintain current processes when developing, considering, and implementing new quality measures in any Medicare quality program, particularly for those measures that are not NQF endorsed and suggested CMS consider establishing a streamlined but standardized pathway applicable to the expanded HHVBP model that would allow for stakeholder input without unnecessarily delaying adoption of high-value measures.

Response: We agree that stakeholder input is valuable to future measure set modifications for the HHVBP expanded model. As stated previously, in section III.A.6.5 of this final rule, we plan to continue to seek input on the measure set, including from stakeholders of various fields of expertise and to monitor quality measure performance to inform potential measure set changes under the expanded Model.

Final Decision: After consideration of the public comments we received, we are finalizing our proposal as proposed.

7. Performance Scoring Methodology

a. Considerations for Developing the Total Performance Score Methodology

We considered several factors when we initially developed and subsequently refined the performance scoring methodology over the course of the original Model, and we proposed to apply a similar methodology for the expanded HHVBP Model. We explain later in this section how we proposed to calculate a ''performance score'' for each applicable measure for each competing HHA, which is defined as the achievement or improvement score (whichever is greater). The ''Total Performance Score,'' or ''TPS,'' is the numeric score, ranging from 0 to 100, awarded to each qualifying HHA based on the weighted sum of the performance scores for each applicable quality measure under the HHVBP Model expansion. The following principles guided the original Model's design, as well as these proposals for the expanded Model.

First, we believe the performance scoring methodology should be straightforward and transparent to HHAs, beneficiaries, and other stakeholders. HHAs should be able to clearly understand performance scoring methods and performance expectations to optimize quality improvement efforts. The public should also understand performance score methods to utilize publicly-reported information when choosing HHAs.

Second, we believe the performance scoring methodology for the proposed HHVBP Model expansion should be aligned appropriately with the quality measurements adopted for other Medicare value-based purchasing programs, including those introduced in the hospital and skilled nursing home settings. This alignment would facilitate the public's understanding of quality measurement information disseminated in these programs and foster more informed consumer decision-making about their health care choices.

Third, we believe that differences in performance scores must reflect true differences in performance. To make sure that this point is addressed in the performance scoring methodology for the proposed HHVBP Model expansion, we assessed quantitative characteristics of the measures, including the current state of measure development, number of measures, and the number and grouping of measure categories.

Fourth, we believe that both quality achievement and improvement must be measured appropriately in the performance scoring methodology for the expanded HHVBP Model. The proposed methodology specifies that performance scores under the expanded HHVBP Model would be calculated utilizing the higher of achievement or improvement scores for each measure, with achievement out of 10 points and improvement out of 9. We considered the impact of performance scores utilizing achievement and improvement on HHAs' behavior and the resulting payment implications. We stated in the proposed rule that as under the original Model, using the higher of achievement or improvement scores would allow the Model expansion to recognize HHAs that have made improvements, though their measured performance score may still be relatively lower in comparison to other HHAs. We stated that by limiting the improvement score to a scale across 0 to 9, we prioritize achievement relative to improvement.

Fifth, we stated that we intend that the expanded Model would utilize the most currently available data to assess HHA performance, to the extent appropriate and feasible within the current technology landscape. We recognize that not all HHAs have the ability to submit data electronically or digitally and that the proposed quality measure data would not be available instantaneously due to the time required to collect, submit, and process quality measurement information accurately; however, we intend to process data as efficiently as possible.

b. Performance Score Methodology

(1) Overview

We stated in the proposed rule that the goal of the performance scoring methodology would be to produce a TPS for each qualifying HHA based on its raw scores on each applicable quality measure included in the expanded HHVBP Model. We would then use the HHA's TPS to determine the HHA's payment adjustment percentage. At a high level, the following summarizes the proposed steps for determining an HHA's TPS under the expanded Model, which is similar to the approach used under the original Model: (1) Each HHA would receive a raw quality measure score for each applicable measure during the performance year; (2) the HHA would receive an ''achievement score'' for each applicable measure, which is defined as a numeric value between 0 and 10 that quantifies an HHA's performance on a given quality measure compared to other HHAs in the same cohort in the baseline year (calculated using the achievement threshold and benchmark, as defined in section III.A.7.b.2. of this final rule); (3) each HHA would also receive an ''improvement score'' for each applicable measure, which is defined as a numeric value between 0 and 9, that quantifies an HHA's performance on a given quality measure compared to its own individual performance in the baseline year (the improvement threshold, as defined in section III.A.7.b.2. of this final rule); (4) each HHA would be assigned a ''performance score'' on each applicable measure that is the higher of the achievement score or the improvement score, as described in section III.A.7.b.2 of this final rule; and (5) each performance score would then be weighted, using each measure's assigned weight, and summed to generate the HHA's TPS, as described in section III.A.7.e. of this final rule. The result of this process would be a TPS for each competing HHA that can be translated into a payment adjustment percentage using the LEF applicable to each cohort, as described in section III.A.8. of this final rule.

Our proposal for the performance scoring methodology under the expanded HHVBP Model follows closely to that of the original Model. As discussed in more depth in the sections that follow, under the expanded HHVBP Model, we proposed that we would assess each HHA's TPS based upon all applicable quality measures (defined later in this section) in the expanded Model measure set in the applicable performance year. Each competing HHA would receive an interim assessment on

a quarterly basis, as described in detail in section III.A.9.a. of this final rule. The performance scoring methodology would be used to determine an annual distribution of value-based payment adjustments among HHAs in a cohort so that HHAs achieving the highest performance scores would receive the largest upward payment adjustment. The proposed methodology includes three primary features, each of which is discussed in more detail in the sections that follow:

- The HHA's TPS would reflect all of the claims- and OASIS-based measures for which the HHA meets the minimum of 20 home health episodes of care per year and all of the individual components that compose an HHCAHPS survey measure for which the HHA meets the minimum of 40 HHCAHPS surveys received in the performance year, defined as ''applicable measures''.
- An HHA's TPS would be determined by weighting and summing the higher of that HHA's achievement or improvement score for each applicable measure as described in section III.A.7.b. of this final rule.
- The claims-based, OASIS assessment-based, and the HHCAHPS survey-based measure categories would be weighted 35 percent, 35 percent, and 30 percent, respectively, and would account for 100 percent of the TPS. If an HHA is missing a measure category or a measure within the OASIS-based measure category, the measures would be reweighted, as described further in section III.A.7.e. of this final rule.

As noted, we proposed that many of the key elements from the original Model's performance scoring methodology would also apply for the expanded HHVBP Model, as we discuss in more detail in the sections that follow. We stated in the proposed rule that the primary changes between the original Model and the expanded Model would be that first, because we were not proposing to require submission of the New Measures data, we would not consider New Measures in calculating the TPS under the expanded Model. The New Measures reporting currently accounts for 10 percent of the TPS under the original HHVBP Model. In addition, we proposed small changes to the achievement and improvement score formulas to simplify their calculation and interpretation, without materially changing the output. We also proposed to calculate benchmarks and achievement thresholds based on national volume-based cohorts, as opposed to the State-based cohorts under the original Model, to align with the proposal for volume-based cohorts as described in section III.A.4. of this final rule. Finally, we proposed to change the potential score range for the TNC Mobility and TNC Self-Care measures from 0 to 15 points for achievement and 0 to 13.5 points for improvement as under the original Model, to 0 to 10 points for achievement and 0 to 9 points for improvement in the expanded Model. We stated that this change simplifies and aligns the calculation of the composite measure scores. The proposed weighting in the expanded Model, which follows the original Model, accounts for the intended increase in relative contribution from these composite measures to the TPS.

(2) Calculation of the Benchmark and Achievement Threshold

For scoring HHAs' performance on measures in the claims-based, OASIS-based, and the HHCAHPS survey-based categories, we proposed similar elements of the scoring methodology as set forth in the original Model (as described in § 484.320), including allocating points based on achievement or improvement and calculating those points based on benchmarks and thresholds. As finalized in section III.A.5.b.1. of this final rule, with the exception of new HHAs, the baseline year would be CY 2019 (January 1, 2019 through December 31, 2019) for the CY 2023 performance year/CY 2025 payment year and subsequent years. All benchmarks and achievement thresholds would be set based on HHA performance in the designated baseline year.

We proposed that to determine achievement points for each measure, HHAs would receive points along an achievement range, which is a scale between the achievement threshold and a benchmark. We proposed to define the ''achievement threshold'' as the median (50th percentile) of all HHAs' performance scores on the specified quality measure during the baseline year, calculated separately for the larger- and smaller-volume cohorts. We proposed to calculate the benchmark as the mean of the top decile of all HHAs' performance scores on the specified quality measure during the baseline year, calculated separately for the larger- and smaller-volume cohorts. Unlike the original Model, for the expanded HHVBP Model, we proposed to use a national sample separated into larger-volume and smaller-volume HHA cohorts to calculate both the achievement threshold and the benchmark, rather than calculating individual values for each selected State as in the original Model, as described in section III.A.4.b. of this final rule. We also proposed that to determine improvement points for each measure, HHAs would receive points along an improvement range, which is a scale between an HHA's performance during the baseline year and the benchmark. The HHA's baseline year score is termed the ''improvement threshold.'' The benchmark is the same benchmark used in the achievement calculation. The achievement threshold and benchmarks for each cohort, and the improvement threshold for each HHA, calculated using baseline year performance scores, would be provided to the HHAs as soon as feasible. In addition, benchmarks, achievement thresholds, and improvement thresholds for each measure would be restated on each HHA's interim performance report (IPR). We also proposed to codify the proposed definitions of achievement threshold, benchmark, and improvement threshold at § 484.345. We sought public comment on these proposals.

Final Decision: We did not receive comments on these proposals and are finalizing these proposals as proposed, including the proposed definitions of achievement threshold, benchmark, and improvement threshold at § 484.345.

(i) Calculation of Achievement Score

In the original Model, we calculated the achievement score by dividing the difference between the HHA's performance score and the achievement threshold by the difference between the benchmark and the achievement threshold, multiplying the quotient by 9, and then taking the product and adding 0.5 (80 FR 68681).

Under the expanded HHVBP Model, we proposed a similar approach, but with minor modifications intended to improve and simplify the calculation and the interpretation of the achievement score. Under the expanded Model, as under the original Model, we proposed that an HHA could earn between 0 to 10 achievement points for each applicable measure based on its performance during the performance year relative to other HHAs in its cohort in the baseline years, quantified by the achievement threshold and the benchmark, as proposed in section III.A.7.b.2. of this final rule. We proposed to calculate the achievement score using the following formula:

$$\text{Achievement Score} = 10 \times \left(\frac{HHA\ Performance\ Score - Achievement\ Threshold}{Benchmark - Achievement\ Threshold} \right)$$

Relative to the original Model, this proposed equation is simplified, for ease of calculation and interpretation, by multiplying it by 10, as opposed to 9, and by no longer adding 0.5. The performance rankings would not be materially affected by this change. Should the calculated achievement points exceed 10 in the equation, we proposed that the maximum achievement points would be capped at 10 achievement points. As under the original Model, we proposed to round each measure's achievement points up or down to the third decimal point under the expanded HHVBP Model. For example, an achievement score of 4.5555 would be rounded to 4.556. This ensures precision in scoring and ranking HHAs within each cohort. In determining an achievement score based on the HHA's raw quality measure score, we proposed to apply the following rules to the achievement score calculation to ensure the achievement score falls within the range of 0 to 10 points to align with the simplified equation:

- An HHA with a raw quality measure score greater than or equal to the benchmark receives the maximum of 10 points for achievement.
- An HHA with a raw quality measure score greater than the achievement threshold (but below the benchmark) receives greater than 0 but less than 10 points for achievement (prior to rounding), by applying the achievement score formula.
- An HHA with a raw quality measure score that is less than or equal to the achievement threshold receives 0 points for achievement.

We proposed to no longer calculate the achievement scoring for the TNC Self-Care and TNC Mobility measures out of 15 possible points, as under the original Model, and to instead simplify and align the calculation with other measures by calculating achievement scoring for the composite measures out of 10 possible points. The proposed weighting, consistent with the original Model, would already assign a larger contribution from these composite measures to the overall OASIS category score, as described in section III.A.7.e.(2).(iii). of this final rule. We also proposed to codify these proposals at § 484.360. We sought public comment on these proposals.

Final Decision: We did not receive comments on these proposals and are finalizing our proposals as proposed, including our proposed regulation text at § 484.360.

(ii) Calculation of the Improvement Score

In the original Model, beginning with performance year 4, we calculated improvement scores by dividing the difference between the HHA's performance year score and the HHA's baseline year score by the difference between the benchmark and the HHA's baseline year score, multiplying the quotient by 9, and then taking the product and subtracting 0.5 to calculate the improvement score (83 FR 56543).

Similarly, under the expanded HHVBP Model, we proposed to allocate 0 to 9 improvement points to an HHA for each applicable measure based upon how much an HHA's performance score in the performance year improved relative to its performance score during the baseline year. We stated in the proposed rule that the expanded HHVBP Model aims to ensure that all HHAs provide high quality care and awarding more points for achievement than for improvement supports this goal. This continues to also align with the HVBP Program, where hospitals can earn a maximum of 9 improvement points if their measure score falls between the improvement threshold and the benchmark (76 FR 26515).

We proposed to establish a unique improvement range for each measure and for each HHA that defines the difference between the HHA's baseline year score (referred to as the ''improvement threshold'') and the benchmark for the applicable measure, calculated for the applicable volume-based HHA cohort, which is the same benchmark used in the achievement scoring calculation. The following proposed improvement score formula quantifies the HHA's performance on each applicable measure in the performance year relative to its own performance in the baseline year by calculating the improvement score:

$$\text{Improvement Score} = 9 \times \left(\frac{HHA\ Performance\ Score - HHA\ Improvement\ Threshold}{Benchmark - HHA\ Improvement\ Threshold} \right)$$

Relative to the original Model, this proposed equation is simplified, for ease of calculation and interpretation, by no longer subtracting 0.5. Should the calculated points exceed 9, we proposed that the maximum improvement points would be capped at 9 improvement points. Like the achievement points, we proposed to round each measure's improvement points up or down to the third decimal point under the expanded HHVBP Model.

In calculating the improvement score based on the HHA's raw quality measure score, we proposed to apply the following rules to the improvement score calculation to ensure the improvement score falls within the range of 0 to 9 points to align with the simplified equation:

- If the HHA's raw quality measure score is greater than or equal to the benchmark, the HHA would receive an improvement score of 9 points—an HHA with a raw quality measure score greater than or equal to the benchmark could still receive the maximum of 10 points for achievement.
- If the HHA's raw quality measure score is greater than its improvement threshold but below the benchmark (within the improvement range), the HHA would receive an improvement score that is greater than 0 and less than 9 (before rounding) based on the improvement score formula and as illustrated in the examples in the next section.
- If the HHA's raw quality measure score is less than or equal to or its improvement threshold for the measure, the HHA would receive 0 points for improvement.

We proposed to no longer calculate the improvement scoring for the TNC Self-Care and TNC Mobility measures out of 13.5 possible points, as under the original Model, and to instead simplify and align the calculation with other measures by calculating improvement scoring for the composite measures out of 9 possible points, as previously stated. (We note that the discussion in the proposed rule referred to 10 rather than 9 possible points in error.) The proposed weighting, consistent with the original Model, would already assign a larger contribution from these composite measures to the overall OASIS category, as described in section

III.A.7.e.(2).(iii). of this final rule. We also proposed to codify these proposals at § 484.360. We sought public comment on these proposals. We summarize in this section of this rule comments received and provide our responses.

Comment: A commenter requested that we no longer score improvement in quality measures relative to the baseline and only use the achievement score for calculating the TPS. The commenter stated that having one continuous performance scale results in every HHA having an incentive to improve, leaving no need for an improvement score, in addition to creating uniform beneficiary expectations.

Response: We thank the commenter for their feedback on the proposed improvement score. While we agree with the commenter that the achievement score maintains the incentive to improve in the long-term, we believe that continuing to include the improvement score methodology is important in the initial years of the expanded model. This will allow HHAs with lower measure performance historically to be rewarded for improving upon those scores, even if the improvement does not move them into the highest performing tier of HHAs. By setting the highest possible improvement score out of 9 points, compared to the achievement score out of 10 points, we place a stronger emphasis on achievement relative to improvement. Furthermore, we note that this would be consistent with existing value-based purchasing programs.

Comment: Several commenters expressed concern with using the improvement score methodology to assess HHAs on each of the quality measures, asserting that it may lead HHAs to exclude beneficiaries who are unlikely to improve.

Response: We believe that these comments may be in reference to certain quality measures, rather than the improvement score methodology, and refer readers to our earlier responses regarding why we do not believe the measure set would disincentivize HHAs from serving beneficiaries who are less likely to improve. The improvement score methodology assesses improvement of HHAs across each of the applicable measures and does not measure improvement of beneficiaries over time.

Final Decision: After consideration of the public comments we received, we are finalizing our proposals as proposed, including our proposed regulation text at § 484.360.

(iii) Examples of Calculating Achievement and Improvement Scores

For illustrative purposes, the following examples demonstrate how the performance scoring methodology would be applied in the context of the measures in the claims-based, OASIS-based, and the HHCAHPS survey-based categories. As previously discussed, we are finalizing CY 2023 as the first performance year and have updated the following examples from the proposed rule to reflect CY 2023 as the performance year. Other than the updating the hypothetical performance year from CY 2022 to CY 2023, all other detail in the following examples from the proposed rule remain the same. These HHA examples are based on illustrative data from CY 2019 (for the baseline year) and hypothetical data for CY 2023 (for the performance year). The benchmark calculated for the Dyspnea measure is 97.676 for HHA A (calculated as the mean of the top decile of HHA performance from the CY 2019 baseline year for the volume-based cohort). The achievement threshold is 75.358 (calculated as the median or the 50th percentile of HHA performance from the CY 2019 baseline year for the same volume-based cohort).

Figure 4 shows the scoring for HHA 'A' as an example. HHA A's CY 2023 performance year score for the Dyspnea measure was 98.348, exceeding both the CY 2019 achievement threshold and benchmark, which means that HHA A earned the maximum 10 points based on its achievement score. Its improvement score is irrelevant in the calculation because the HHA's performance score for this measure exceeded the benchmark, and the maximum number of improvement points possible is 9.

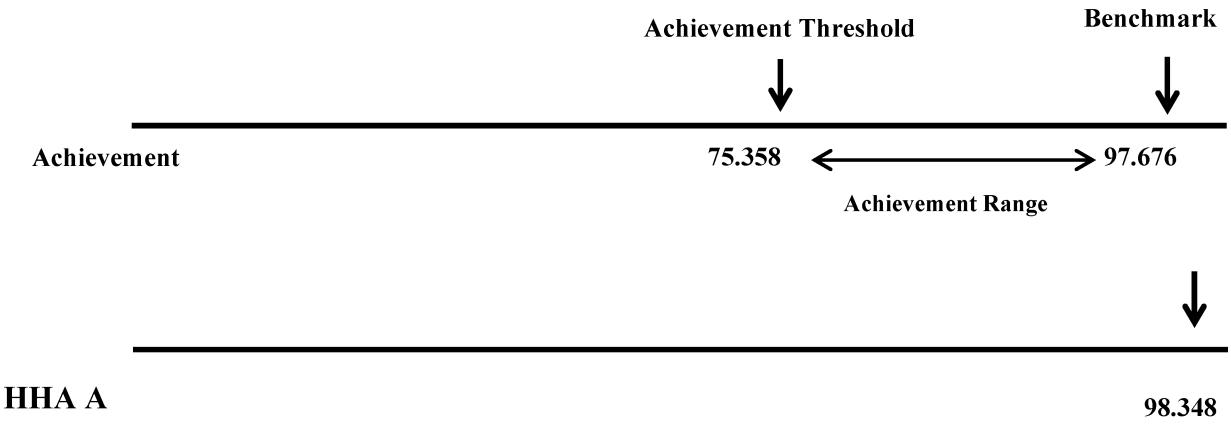
Figure 4 also shows the scoring for HHA 'B.' HHA B's performance on the Dyspnea measure was 52.168 for the CY 2019 baseline year (HHA B's improvement threshold) and increased to 76.765 (which is above the achievement threshold of 75.358) for the CY 2023 performance year. To calculate the achievement score, HHA B would earn 0.630 achievement points, calculated as follows: 10 * (76.765 − 75.358)/(97.676 − 75.358) = 0.630.[32] Calculating HHA B's improvement score yields the following result: Based on HHA B's period–to-period improvement, from 52.168 in the baseline year to 76.765 in the performance year, HHA B would earn 4.864 improvement points, calculated as follows: 9 * (76.765 − 52.168)/(97.676 − 52.168) = 4.864.[33] Because the higher of the achievement and improvement scores is used, HHA B would receive 4.864 improvement points for this measure.

In Figure 5, HHA 'C' yielded a decline in performance on the TNC Self-Care measure, falling from 70.266 to 58.487. HHA C's performance during the performance year was lower than the achievement threshold of 75.358 and, as a result, HHA C would receive zero points based on achievement. It would also receive zero points for improvement because its performance during the performance year was lower than its improvement threshold.

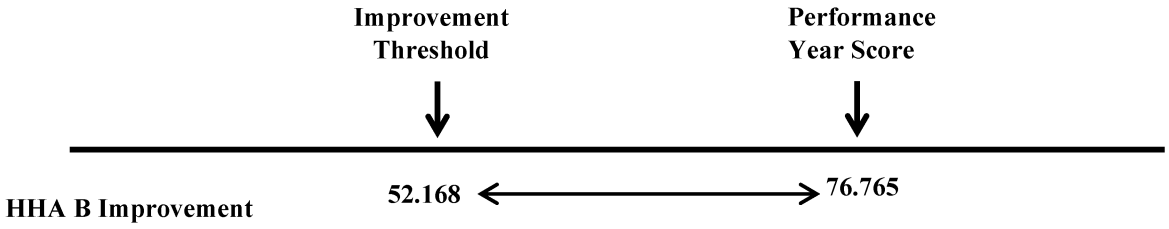
[32] The finalized formula for calculating achievement points is 10 * (HHA Performance Year Score − Achievement Threshold)/(Benchmark − Achievement Threshold).

[33] The finalized formula for calculating improvement points is 9 * (HHA Performance Year Score − HHA Improvement Threshold)/(HHA Benchmark − HHA Improvement Threshold).

FIGURE 4: EXAMPLE OF AN HHA EARNING POINTS BY ACHIEVEMENT OR IMPROVEMENT SCORING

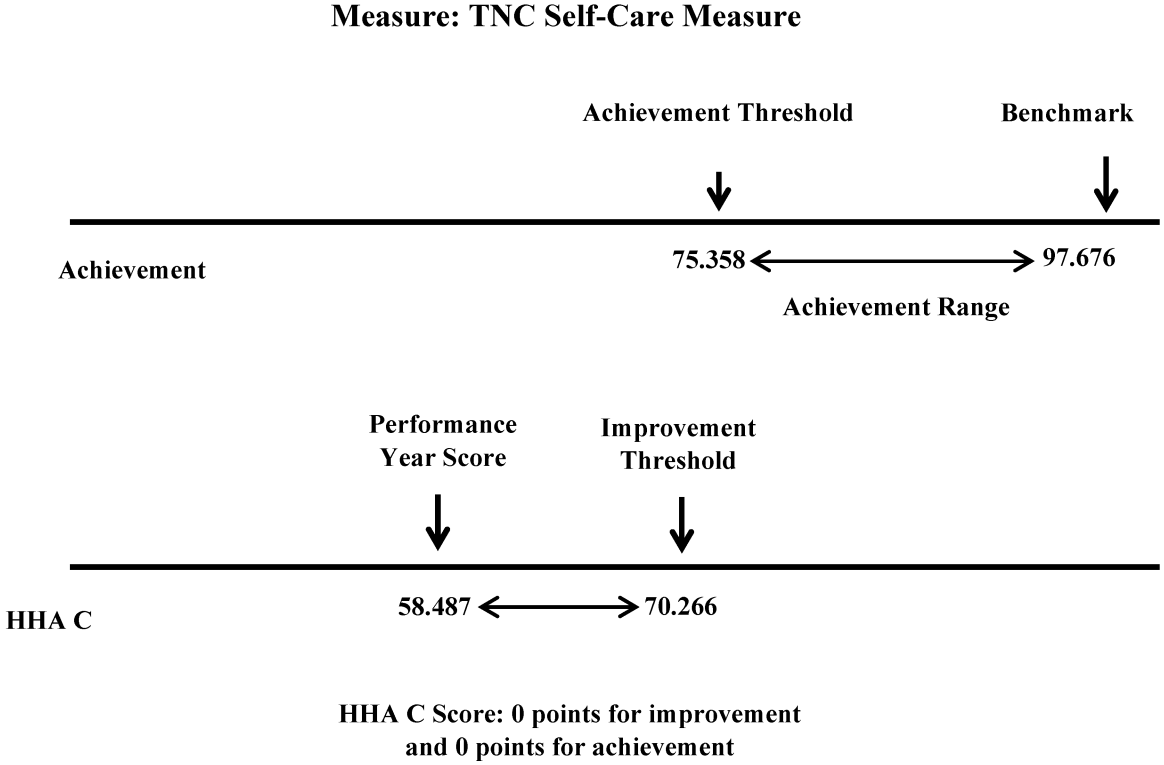


HHA A Score: 10 maximum points for achievement



HHA B Score: The greater of 0.630 points for achievement and 4.864 points for improvement.

FIGURE 5: EXAMPLE OF AN HHA NOT EARNING POINTS BY ACHIEVEMENT OR IMPROVEMENT SCORING



c. Minimum Threshold Number of Cases for Claims-Based, OASIS-Based, and HHCAHPS Survey-Based Measures To Receive a Measure Score

For the expanded Model, we proposed to apply the same policies around minimum case counts for each measure as implemented under the original Model, as described in proposed § 484.345. We proposed to continue to award an HHA the higher-of achievement or improvement points, as discussed previously, for ''applicable measures'' only. Under this proposal, for the measures included in the claims-based and OASIS-based measure categories, an ''applicable measure'' is one for which the HHA has provided a minimum of 20 home health episodes of care per year and, therefore, has at least 20 cases in the denominator. We proposed this minimum to align with the original HHVBP Model and the measure specifications used for the Patient Quality of Care Star Ratings.[34] For the individual components that compose the HHCAHPS survey measure, we proposed that an ''applicable measure'' means a component for which a competing HHA has submitted a minimum of 40 completed HHCAHPS surveys. We stated that a minimum of 40 completed HHCAHPS surveys for each applicable measure for the expanded Model represents a balance between providing meaningful data for payment adjustments and having more HHAs with sufficient numbers of measures with performance scores. Moreover, using a minimum of 40 completed HHCAHPS surveys for each applicable measure would align with the Patient Survey Star Ratings on Home Health Compare.[35]

We also proposed to codify this proposed definition of an ''applicable measure'' at § 484.345. We solicited public comment on these proposals.

Final Decision: We did not receive comments on these proposals and are finalizing our proposals as proposed, including the proposed definition of an ''applicable measure'' at § 484.345.

d. Minimum Number of Applicable Measures for an HHA To Receive a Total Performance Score

For the expanded Model, we proposed to apply the same policies around the minimum number of applicable measures to receive a TPS, as implemented under the original Model. We proposed that, beginning with the CY 2022 performance year, which we are delaying until CY 2023 as the first performance year as described in section III.A.3 of this final rule, and for subsequent years, an HHA that does not meet the minimum threshold of cases or completed HHCAHPS surveys, as applicable, on five or more measures under the expanded Model would not receive a TPS or a payment adjustment based on that performance year. Under the expanded Model, this means 5 of the 12 possible applicable measures in the measure set, which includes two claims-based measures, 5 OASIS-based measures, and the 5 components from the HHCAHPS survey measure. HHAs without five applicable measures for a performance year would be paid for HHA services in an amount equivalent to the amount that would have been paid under section 1895 of the Act. We stated that we believe that a minimum of five applicable measures allows for a

[34] Centers for Medicare & Medicaid Services. (2020, April). Quality of Patient Care Star Ratings Methodology. Home Health Quality of Patient Care Star Ratings. *https://www.cms.gov/files/document/quality-patient-care-star-ratings-methodologyapril-2020.pdf.*

[35] Centers for Medicare & Medicaid Services. (2016, March). Technical Notes for HHCAHPS Star Ratings. Home Health HHCAHPS Star Ratings. *https://homehealthcahps.org/Portals/0/HHCAHPS_Stars_Tech_Notes.pdf.*

robust basis on which to adjust payment while also maximizing the number of HHAs eligible for the payment adjustment.

Although those HHAs that do not meet this minimum would not be subject to payment adjustments under the expanded Model, we proposed that other applicable policies under the expanded HHVBP Model would still apply. We proposed that these HHAs would receive IPRs for any measures that meet the definition of applicable measure, and they would continue to have future opportunities to compete for payment adjustments. Based on the most recent data available at the time of the development of the proposed rule, the vast majority of HHAs are reporting on at least five applicable measures. In 2019, those with less than five applicable measures account for less than 2.4 percent of the claims made (and 2.0 percent of claims payments made) across the 9,526 HHAs delivering care nationwide.

We also proposed to codify this proposal at § 484.360(c). We sought public comment on this proposal.

Final Decision: We did not receive comments on this proposal and are finalizing our proposal as proposed, including our proposed regulation text at § 484.360(c). As previously discussed, we are finalizing CY 2023 as the first performance year and CY 2025 as the first payment year under the expanded Model. We reiterate that HHAs will not be assessed on their performance on the quality measures during the CY 2022 pre-implementation year. As noted later in this rule, we will continue to collect and evaluate data under the expanded HHVBP Model during CY 2022 and anticipate providing sample reports to HHAs, where administratively feasible and based on available data, for learning purposes only. The sample report would include the same information as an Interim Performance Report (IPR), and would be based on the same scoring methodologies and other policies as finalized in this rule for a performance year. We also anticipate providing learning support to all HHAs during CY 2022 including, for example, scenario-based performance reports and related learning events on the content of the reports and how they can be used to supplement an HHA's quality improvement efforts.

e. Weights for the Claims-Based, OASIS-Based, and HHCAHPS Survey Measures

Except for removing the New Measures category, for the expanded HHVBP Model, we generally proposed the same policies regarding the weighting of measures and the redistribution of weights when measures or measure categories are missing as under the original Model (83 FR 56536).

(1) Weighting and Re-Distribution of Weights Between the Measure Categories

In the proposed rule, we proposed to group the expanded Model proposed measures into measure categories based on their data source as indicated in Table 27: Claims-based, OASIS–based, and the HHCAHPS survey-based. We proposed that claims-based, OASIS-based, and the HHCAHPS survey-based categories would be weighted 35 percent, 35 percent, and 30 percent, respectively, when the HHA has applicable measures in all three categories and otherwise meets the minimum threshold to receive a TPS. Together, all three categories would account for 100 percent of the TPS. The measure weights reflect prioritization of the two claims-based measures because they may have a greater impact on reducing Medicare expenditures. In addition, we also place slightly more weight on the OASIS-based measures since they represent a larger variety of measures covering a range of quality topics as compared to the HHCAHPS survey measure.

We also proposed that where an HHA is missing all measures from a single measure category, the weights for the remaining two measure categories would be redistributed such that the proportional contribution remains consistent with the original weights. For instance, some smaller-volume HHAs may be missing the HHCAHPS survey measure, which would require re-distributing weights to the claims-based (otherwise weighted 35 percent) and OASIS-based (otherwise weighted 35 percent) measure categories, such that the claims-based and OASIS-based measure categories would each be weighted at 50 percent of the total TPS. Where an HHA is missing the claims-based category, the OASIS-based (otherwise weighted 35 percent) and the HHCAHPS survey (otherwise weighted 30 percent) measure categories would be reweighted to 53.85 percent for the OASIS-based measures and 46.15 percent for the HHCAHPS survey measure.[36] [37] Finally, we proposed that if two measure categories are missing, the remaining category would be weighted 100 percent. We refer readers to Table 28 for the distribution of measure category weights under various scenarios.

(2) Quality Measure Weights Within Measure Categories

Within the measure categories, we proposed to weight certain individual measures differently than other measures in the same category.

(i) HHCAHPS Survey Measure Category

For the HHCAHPS survey measure category, we proposed that all 5 components are weighted equally to determine the overall HHCAHPS survey measure percentage, which would contribute 30 percent to the overall TPS. This measure category would not require re-distribution of weights for the individual components because HHAs either meet the minimum requirement for number of completed surveys for all HHCAHPS survey measure components or they do not meet the minimum requirements.

(ii) Claims-Based Measure Category

For the claims-based measure category, we proposed to weight the ACH measure at 75 percent, and the ED Use measure at 25 percent of the total measure weight for this measure category. We proposed to place a higher weight on the ACH measure because it reflects a more severe health event and because inpatient hospitalizations generally result in more Medicare spending than the average emergency department visit that does not lead to an acute hospital admission. Like the HHCAHPS survey measure components, an HHA would either have sufficient volume for both claims-based measures to be applicable measures or it would have data for neither measure since both measures require the same minimum of 20 episodes per performance year. Consequently, re-distributing weights for either measure within the claims-based measure category should not be necessary.

(iii) OASIS-Based Measure Category

For the OASIS–based measure category, we proposed to weight both the TNC Self Care and TNC Mobility measures at 25 percent each; and the Dyspnea, Discharged to Community, and Oral Medications measures at 16.67 percent each of the total measure weight for this measure category. Both the TNC Self-Care and TNC Mobility measures are composed of several measures that are consolidated into two composite measures; because of this, we proposed to weight them slightly more than the

[36] OASIS-based measures reweighting = 35% original OASIS weight/(35% original OASIS weight + 30% original HHCAHPS weight) = 53.85% revised OASIS weight.

[37] HHCAHPS reweighting = 30% original HHCAHPS weight/(35% original OASIS weight + 30% original HHCAHPS weight) = 46.15% revised HHCAHPS weight.

other 3 measures, which are not composite measures, as under the original Model. Under this proposal, should any measures in the category be missing, we proposed to re-distribute weights across the measures such that the original proportions are maintained. For instance, should an HHA be missing both the TNC Self-Care and Dyspnea measures, the remaining measures would be weighted as 42.85 percent for the TNC Mobility measure, 28.57 percent for the Discharged to Community measure, and 28.57 percent for the Oral Medications measure, which reflects the relative ratios of 25 percent to 16.67 percent to 16.67 percent, respectively.[38] [39] [40]

See Table 27 for a comprehensive list of the proposed within-category measure weights.

TABLE 27: PROPOSED WITHIN-CATEGORY MEASURE WEIGHTS

Measure Category	Quality Measures	Within-category Weight (percentage)
OASIS	TNC Self-Care	25.00
	TNC Mobility	25.00
	Dyspnea	16.67
	Discharged to Community	16.67
	Oral Medications	16.67
Claims	ACH	75.00
	ED Use	25.00
HHCAHPS Survey	HHCAHPS Professional Care	20.00
	HHCAHPS Communication	20.00
	HHCAHPS Team Discussion	20.00
	HHCAHPS Overall Rating	20.00
	HHCAHPS Willingness to Recommend	20.00

Table 28 presents the proposed weights for the proposed measures and measure categories under various reporting scenarios.

[38] TNC Mobility reweighting = 25% original TNC Mobility weight/(25% original TNC Mobility weight + 16.67% original Discharged to Community weight + 16.67% original Oral Medications weight) = 42.85% revised TNC Mobility weight.

[39] Discharged to Community reweighting = 16.67% original Discharged to Community weight/(25% original TNC Mobility weight + 16.67% original Discharged to Community weight + 16.67% original Oral Medications weight) = 28.57% revised Discharged to Community weight.

[40] Oral Medications reweighting = 16.67% original Oral Medications weight/(25% original TNC Mobility weight + 16.67% original Discharged to Community weight + 16.67% original Oral Medications weight) = 28.57% revised Oral Medications weight.

TABLE 28: PROPOSED QUALITY MEASURE WEIGHTING AND RE-WEIGHTING SCHEDULE

	Measure Reporting Scenarios			
Measure	**All Measures**	**No HHCAHPS**	**No Claims**	**No Claims or HHCAHPS**
OASIS				
TNC Self-Care	8.75%	12.50%	13.46%	25.00%
TNC Mobility	8.75%	12.50%	13.46%	25.00%
Oral Medications	5.83%	8.33%	8.98%	16.67%
Dyspnea	5.83%	8.33%	8.98%	16.67%
Discharged to Community	5.83%	8.33%	8.98%	16.67%
Total for OASIS-based measures	*35.00%*	*50.00%*	*53.85%*	*100.00%*
Claims				
ACH	26.25%	37.50%	0.00%	0.00%
ED Use	8.75%	12.50%	0.00%	0.00%
Total for claims-based measures	*35.00%*	*50.00%*	*0.00%*	*0.00%*
HHCAHPS Survey Measure Components				
HHCAHPS Professional Care	6.00%	0.00%	9.23%	0.00%
HHCAHPS Communication	6.00%	0.00%	9.23%	0.00%
HHCAHPS Team Discussion	6.00%	0.00%	9.23%	0.00%
HHCAHPS Overall Rating	6.00%	0.00%	9.23%	0.00%
HHCAHPS Willingness to Recommend	6.00%	0.00%	9.23%	0.00%
Total for the HHCAHPS Survey-based measure	*30.00%*	*0.00%*	*46.15%*	*0.00%*

We also proposed to codify these proposals at § 484.360. We solicited public comment on these proposals.

Final Decision: We did not receive comments on these proposals and are finalizing our proposals as proposed, including our proposed regulation text at § 484.360.

f. Examples of the Total Performance Score Calculation

The following are two examples of the finalized performance score calculation, beginning with the assigned achievement vs. improvement points. The following describes the TPS calculations for HHA ''D'' and HHA ''E.''

In this first example, out of a possible 12 applicable measures, which includes two claims-based measures, five OASIS assessment-based measures, and five components that make up the HHCAHPS survey measure, HHA ''D'' has at least 20 episodes of care and received at least 40 completed HHCAHPS surveys in the 12-month performance year, which means the HHA received scores on all 12 quality measures. Under the finalized scoring methodology outlined previously, for HHA D, the measure category weights would be as follows: 35 percent for the claims-based measures, 35 percent for the OASIS assessment-based measures, and 30 percent for the HHCAHPS Survey-based measures. See Table 29 for a detailed calculation of the TPS. For each measure in column 1, HHA D receives the highest of its achievement or improvement score, which is listed in column 2. Each applicable measure's weight is listed in column 3. To determine the weighted points in column 4, multiply the measure score in column 2 by the measure's weight in column 3 and then by 10. The total performance score is the sum of all the weighted points listed in column 4. In the case of HHA D, the TPS is 46.021.

TABLE 29: HHA D TOTAL PERFORMANCE SCORE EXAMPLE

① Quality Measure	② Points for Applicable Measures	③Weight (percentage)	④ Weighted Points
OASIS			
TNC Self-care	7.661	8.75	6.703
TNC Mobility	5.299	8.75	4.637
Oral Medications	3.302	5.83	1.925
Dyspnea	4.633	5.83	2.701
Discharged to Community	0.618	5.83	0.360
Claims			
ACH	1.180	26.25	3.098
ED Use	0.000	8.75	0.000
HHCAHPS Survey Components			
HHCAHPS Professional Care	10.000	6.00	6.000
HHCAHPS Communication	10.000	6.00	6.000
HHCAHPS Team Discussion	10.000	6.00	6.000
HHCAHPS Overall Rating	5.921	6.00	3.553
HHCAHPS Willingness to Recommend	8.406	6.00	5.044
Total Performance Score		**100.00**	**46.021**

In the second example, HHA ''E'' has only seven applicable measures. Because it did not receive the minimum count of HHCAHPS surveys for all components, HHA E did not receive any scores on the HHCAHPS Survey components. Where an HHA is missing the HHCAHPS Survey components, the HHA's HHCAHPS Survey measure category is re-weighted at 0 percent and the remaining two measure categories are re-weighted such that their proportional contribution remains consistent with the original weights and the total of the weights sums to 100 percent. Based on the ratio of the original weights for the claims-based (35 percent) and the OASIS-based (35 percent) measure categories, each category contributes 50 percent to the TPS. See Table 30 for the detailed calculation of the TPS. For each applicable measure in column 1, HHA E received the highest of its achievement or improvement score, which is listed in column 2. Column 2 lists N/A for each of the HHCAHPS Survey measure components since this HHA had fewer than 40 HHCAHPS surveys in the performance year. Each applicable measure's weight is listed in column 3. To determine the weighted points in column 4, multiply the measure score in column 2 by the applicable measure's weight in column 3 and then by 10. The total performance score is the sum of all the weighted points listed in column 4. In the case of HHA E, the TPS is 27.750.

TABLE 30: HHA E TOTAL PERFORMANCE SCORE EXAMPLE

① Quality Measures	② Points for Applicable Measures	③Re-Weighting (percentage)	④ Re-Weighted Points
OASIS			
TNC Self-care	7.661	12.5	9.576
TNC Mobility	5.299	12.5	6.624
Oral Medications	3.302	8.33	2.751
Dyspnea	4.633	8.33	3.859
Discharged to Community	0.618	8.33	0.515
Claims			
ACH	1.180	37.50	4.425
ED Use	0.000	12.50	0.000
HHCAHPS Survey Components			
HHCAHPS Professional Care	N/A	0.00	N/A
HHCAHPS Communication	N/A	0.00	N/A
HHCAHPS Team Discussion	N/A	0.00	N/A
HHCAHPS Overall Rating	N/A	0.00	N/A
HHCAHPS Willingness to Recommend	N/A	0.00	N/A
Total Performance Score		**100.00**	**27.750**

8. Payment Adjustment Methodology

We finalized the use of the Linear Exchange Function (LEF) for the original Model (80 FR 68686) because it was the simplest and most straightforward option to provide the same marginal incentives to all HHAs, and we stated in the proposed rule that we believe the same to be true for the HHVBP Model expansion. The LEF is used to translate an HHA's TPS into a percentage of the value-based payment adjustment earned by each HHA. Performance measurement is based on a linear exchange function which only includes competing-HHAs.

Under the expanded HHVBP Model, we proposed to codify at § 484.370 a methodology for applying value-based payment adjustments to home health services. We proposed that payment adjustments would be made to the HH PPS final claim payment amount as calculated in accordance with HH PPS regulations at § 484.205 using a LEF, similar to the methodology utilized by the HVBP Program (76 FR 26533). We proposed the function's intercept at zero percent, meaning those HHAs that have a TPS that is average in relationship to other HHAs in their cohort would not receive any payment adjustment. Under this proposal, payment adjustments for each HHA with a score above zero percent would be determined by the slope of the LEF. We proposed to set the slope of the LEF for the given performance year so that the estimated aggregate value-based payment adjustments for that performance year are equal to 5 percent (the proposed maximum payment adjustment for CY 2024; as previously discussed, we are finalizing CY 2025 as the first payment year of the expanded Model) of the estimated aggregate base operating payment amount for the corresponding payment year, calculated separately for the larger and smaller volume cohorts nationwide. The estimated aggregate base operating payment amount is the total amount of payments made to all the HHAs by Medicare nationwide in each of the larger- and smaller-volume cohorts.

We proposed that the LEF would be calculated using the following steps, after calculating and ranking the Total Performance Score (TPS) (the range of the TPS is 0–100) for each HHA in the cohort:

- Step 1, Determine the 'Prior Year Aggregate HHA Payment Amount' that each HHA was paid in the prior year.
- Step 2, Determine the 'X-percent (the applicable payment year payment adjustment percent) Payment Reduction Amount' by multiplying the Prior Year Aggregate HHA Payment Amount per HHA by the 'X-percent Reduction Rate'; the sum of these amounts is the numerator of the LEF.
- Step 3, Determine the 'TPS Adjusted Reduction Amount' by multiplying the 'X-percent Payment Reduction Amount' by the TPS/100. The sum of these amounts is the denominator of the LEF.
- Step 4, Calculate the LEF by dividing the sum of all HHAs' 'X-percent Payment Reduction Amount' by the sum of the 'TPS Adjusted Reduction Amount'.
- Step 5, Determine the 'Final TPS Adjusted Payment Amount' by multiplying the LEF by the 'TPS Adjusted Reduction Amount' for each HHA.
- Step 6, Determine the 'Quality Adjusted Payment Rate' by dividing the 'Final TPS Adjusted Payment Amount' by the 'Prior Year Aggregate HHA Payment Amount'.
- Step 7, Determine the 'Final Percent Payment Adjustment' that will be applied to the HHA payments by subtracting the 'X-percent Reduction Rate' from the 'Quality Adjusted Payment Rate'.

Table 31 provides an example of how the LEF would be calculated and how it would be applied to calculate the percentage payment adjustment to an HHA's TPS. For this example, we applied the maximum 5-percent payment adjustment proposed for the expanded HHVBP Model for the proposed CY 2024 payment year.

Step #1 involves the calculation of the 'Prior Year Aggregate HHA Payment Amount' (C2 in Table 31) that each HHA was paid from claims data under the HH PPS in the year prior to the performance year. For the proposed CY 2024 payment year, from claims data, all payments are summed together for each HHA for CY 2021, the year prior to the proposed performance year.

Step #2 involves the calculation of the '5-percent Payment Reduction Amount' (C3 of Table 31 for each HHA, which is calculated by multiplying the 'Prior Year Aggregate HHA Payment Amount', from Step #1 by the '5-percent Payment Reduction Rate'. The aggregate of the '5-percent Payment Reduction Amount' is the numerator of the LEF.

Step #3 involves the calculation of the 'TPS Adjusted Reduction Amount' (C4 of Table 31 by multiplying the '5-percent Payment Reduction Amount' from Step #2 by the TPS (C1) divided by 100. The aggregate of the 'TPS Adjusted Reduction Amount' is the denominator of the LEF.

Step #4 involves calculating the LEF (C5 of Table 31) by dividing the sum of '5- percent Payment Reduction Amount' calculated in Step #2 by the sum of 'TPS Adjusted Reduction Amount' calculated in Step #3.

Step #5 involves the calculation of the 'Final TPS Adjusted Payment Amount' (C6 of Table 31) by multiplying the 'TPS Adjusted Reduction Amount' from Step #3 (C4) by the LEF from Step #4 (C5). The 'Final TPS Adjusted Payment Amount' is an intermediary value used to calculate 'Quality Adjusted Payment Rate'.

Step #6 involves the calculation of the 'Quality Adjusted Payment Rate' (C7 of Table 31) by dividing the 'Final TPS Adjusted Payment Amount' from Step #5 by the 'Prior Year Aggregate HHA Payment Amount' from Step #1. This is an intermediary step to determining the payment adjustment rate.

Step #7 involves the calculation of the 'Final Percent Payment Adjustment' (C8 of Table 31) by subtracting 5 percent from 'Quality Adjusted Payment Rate'. The 'Final Percent Payment Adjustment' would be applied to the HHA payments for the payment adjustment year. We proposed that the payment adjustment percentage would be capped at no more than plus or minus 5 percent for the applicable performance year and the payment adjustment would occur on the final claim payment amount for the applicable payment year.

We also proposed to codify this payment methodology policy at § 484.370. We invited comments on this proposal. We summarize in this section of this rule comments received and provide our responses.

TABLE 31: 5-PERCENT REDUCTION SAMPLE

		Step 1	Step 2	Step 3	Step 4	Step 5	Step 6	Step 7
HHA	**TPS**	**Prior Year Aggregate HHA Payment Amount***	**5-Percent Payment Reduction Amount (C2*5 percent)**	**TPS Adjusted Reduction Amount (C1/100)*C3**	**Linear Exchange Function (LEF) (Sum of C3/ Sum of C4)**	**Final TPS Adjusted Payment Amount (C4*C5)**	**Quality Adjusted Payment Rate (C6/C2)**	**Final Percent Payment Adjustment +/- (C7-5%)**
	(C1)	**(C2)**	**(C3)**	**(C4)**	**(C5)**	**(C6)**	**(C7)**	**(C8)**
HHA1	38	$100,000	$5,000	$1,900	1.931	$3,669	3.669%	-1.331%
HHA2	55	$145,000	$7,250	$3,988	1.931	$7,701	5.311%	0.311%
HHA3	22	$800,000	$40,000	$8,800	1.931	$16,995	2.124%	-2.876%
HHA4	85	$653,222	$32,661	$27,762	1.931	$53,614	8.208%	3.208%
HHA5	50	$190,000	$9,500	$4,750	1.931	$9,173	4.828%	-0.172%
HHA6	63	$340,000	$17,000	$10,710	1.931	$20,683	6.083%	1.083%
HHA7	74	$660,000	$33,000	$24,420	1.931	$47,160	7.146%	2.146%
HHA8	25	$564,000	$28,200	$7,050	1.931	$13,615	2.414%	-2.586%
Sum			$172,611	$89,379		$172,611		

*Example cases.

Comment: A commenter asked about the ''X-percent Adjustment Percentage'' and how would an HHA know this value.

Response: We believe the commenter is inquiring about the ''X-percent Payment Reduction Amount.'' The ''X-percent Payment Reduction Amount'' is the maximum payment adjustment possible for an HHA under the HHVBP expanded model for the payment year. As discussed in section III.A.5.a of this final rule, we are finalizing that the maximum payment adjustment under the expanded Model would be 5 percent for CY 2025, the first payment year under the expanded Model, and subsequent years.

Comment: A few commenters stated that there is likely no significant difference between an HHA in 45th percentile and 55th percentile, but the HHA in the 45th percentile will receive a payment reduction and the HHA in the 55th percentile will receive a payment increase. A commenter asked CMS to make it more realistic to achieve the maximum bonus or penalty. Another commenter asked CMS to re-evaluate the current payment adjustment structure because it is difficult to score within the top or bottom decile. The commenter stated that most HHAs fall in the middle of the curve and relatively neutral payment impact does not incentivize them to make significant changes. Conversely, a commenter recommended that we reward positive performance and not apply a negative adjustment to low performing HHAs.

Response: Under the original HHVBP Model, we used the LEF to translate an HHA's TPS into a percentage of the value-based payment adjustment earned by each HHA. The LEF is similar to the methodology utilized by the HVBP program. The LEF was identified by the HVBP Program as the simplest and most straightforward option to provide the same marginal incentives to all hospitals, and we found the same to be true for HHAs under the original HHVBP Model. It is true that an HHA in the 45th percentile and an HHA in the 55th percentile could have a similar TPS and one could have a small positive payment adjustment and one could have a small negative payment adjustment. The possibility of either a negative or a positive payment adjustment incentivizes HHAs to improve quality. While we agree that a majority of the HHAs fall into the middle of the pack and most do not receive the maximum positive or negative payment adjustment, we disagree that HHAs are not incentivized to make significant changes unless it is easier to receive the maximum positive or negative payment adjustment. During the original HHVBP Model, we noted improvements in quality, as noted by a decrease in unplanned hospitalizations, emergency department visits leading to inpatient admission and skilled nursing facility use, and a $604.8 million (1.3 percent) reduction of Medicare spending as noted in the HHVBP Fourth Annual Evaluation Report.[41]

Comment: A commenter expressed concern about an endless loop of rewarding the top half of HHAs and penalizing the lower half of HHAs.

Response: We appreciate the concern of the commenter, but based on our examination of the data from the original HHVBP Model, we found that many HHAs moved between negative and positive payment adjustments. Of the HHAs that received a payment adjustment under the original Model in both CY 2019 and CY 2020, 15.4 percent moved from a negative adjustment to a positive adjustment, 15.5 percent moved from a positive adjustment to a negative adjustment, 33.6 percent had a negative adjustment in both years, and 35.5 percent had a positive adjustment in both years. Accordingly, because many HHAs moved from negative adjustments to positive adjustments and vice versa under the original Model, we disagree that there would be an endless loop of rewarding the top half and penalizing the lower half of HHAs.

[41] *https://innovation.cms.gov/data-and-reports/2021/hhvbp-fourthann-rpt.*

Final Decision: After consideration of the public comments we received, we are finalizing the payment adjustment methodology as proposed, including our proposed regulation text at § 484.370.

9. Performance Feedback Reports

We proposed to use two types of reports that would provide information on performance and payment adjustments under the expanded HHVBP Model. These reports would mirror those we have distributed to HHAs under the original Model.

a. Interim Performance Report

The first report is the Interim Performance Report (IPR) that would be distributed to HHAs quarterly. The IPR would contain information on the interim quality measure performance based on the 12 most recent months of data available. The IPR would provide feedback to HHAs regarding performance relative to quality measure achievement thresholds and benchmarks and would provide competing HHAs the opportunity to assess and track their performance relative to their peers and their own past performance. HHAs would receive both a preliminary and final version of the IPR each quarter. We proposed that the Final IPR would become available, as soon as administratively feasible, after the preliminary IPR is distributed and after recalculation requests are processed, in accordance with the process discussed in section III.A.10. of this final rule (Appeal Processes).

In the proposed rule, beginning with the data collected during the first quarter of CY 2022 (that is, data for the period January 1, 2022 to March 31, 2022), and for every quarter of the expanded HHVBP Model thereafter, we proposed to provide each HHA with an IPR that contains information on its performance during the 12 most recent months of data available. We proposed to provide the 12 most recent months of data because the OASIS and claims data are available with different lag times and measures are reported in 12–month intervals on Care Compare. By using 12 months of data, we are able to remove seasonality issues and help to ensure a sufficient number of cases to provide meaningful information to HHAs. By providing HHAs with the most recent 12 months of data, the IPRs provide as close to real-time performance information as possible. We stated in the proposed rule that we expect to make the first IPR available in July 2022 and make IPRs for subsequent quarters available in October, January, and April. We stated that the July 2022 IPR would be the first IPR issued that includes CY 2022 performance year data for the first quarter quality measure performance scores on the proposed OASIS-based measures and baseline data for the HHCAHPS survey and claims-based measures. We proposed that the IPRs would include a competing HHA's expanded HHVBP Model-specific performance results with a comparison to other competing HHAs within its applicable nationwide cohort (larger- or smaller-volume). We proposed that the IPRs would be made available to each HHA through a CMS data platform, such as the Internet Quality Improvement and Evaluation System (iQIES), and would include each HHA's relative estimated ranking amongst its cohort along with measurement points and total performance score based on the 12 most recent months of data available. We noted that the IPRs would likely differ from the final data used to assess performance during a given performance year because the time periods used to develop the IPR data (the 12 most recent months) would differ from the actual performance years under the expanded Model (for example, as proposed, CY 2022 data used to determine CY 2024 payment adjustments).

These performance results would complement quality data sources provided through the iQIES and other quality tracking systems possibly being employed by HHAs to help drive quality improvement. The iQIES-generated reports would provide quality data earlier than the expanded HHVBP Model-specific performance reports (that is, IPR or Annual) because iQIES-generated reports are not limited by a quarterly run-out of data and a calculation of competing peer-rankings. The primary difference between iQIES-generated reports and expanded HHVBP Model-specific performance reports is that the Model-specific performance report we proposed would consolidate the applicable performance measures used in the expanded HHVBP Model, provide a peer-ranking to other competing HHAs within the same volume-based cohort, and provide the TPS based on the interim data. In addition, Model-specific performance reports would provide the competing HHAs with a Scorecard and TNC Change Reference. The TNC Change Reference data would help HHAs gauge their performance on the individual OASIS items included in the two composite measures. It would also tell HHAs the percentage of episodes in which there was no change, positive change, or negative change for each OASIS item. The Scorecard would help

HHAs better understand how each individual measure contributes to the TPS. For more information on the accessibility and functionality of the iQIES, please reference the iQIES manuals.[42] We noted that all quality measures, except for the TNC Mobility and TNC Self-Care measures and the HHCAHPS survey measure, in the proposed measure set for the proposed CY 2022 performance year of the expanded HHVBP Model are already made available in the iQIES. For the HHCAHPS survey measure, HHAs can access their Data Submission Reports on *https://homehealthcahps.org* under the ''For HHAs'' tab. We also suggest HHAs contact their survey vendor regarding data on the HHCAHPS survey measure.

We invited public comment on our proposals. We summarize and respond to comments on both the proposed IPRs and the proposed Annual Reports and present our final policies in the next section.

b. Annual TPS and Payment Adjustment Report

We proposed that the second report, the Annual TPS and Payment Adjustment Report (Annual Report), would be made available to each of the competing HHAs in approximately August of each year preceding the proposed payment adjustment year, expected beginning in August 2023. We proposed to make the report available via a CMS data platform, such as the iQIES. The Annual Report would focus primarily on the HHA's payment adjustment percentage for the upcoming CY and include an explanation of when the adjustment would be applied and how this adjustment was determined relative to the HHA's performance scores. Each competing HHA would receive its own confidential Annual Report viewable only to that HHA. We proposed that the Annual Report would have three versions: A Preview Annual Report, a Preliminary Annual Report (if applicable), and a Final Annual Report. We would make available to each competing HHA the Preview Annual Report in approximately August of each year preceding the calendar year for which the payment adjustment would be applied. We proposed that HHAs would have 15 days to review and request recalculations in accordance with the proposed process discussed in section III.A.10. of this final rule (Appeal Processes). For HHAs that request a recalculation, we would make available a Preliminary Annual Report as soon as administratively feasible after the recalculation request is processed. If we do not receive a recalculation request as a result of the Preview Annual Report, a Preliminary Annual Report would not be issued. We proposed that HHAs that receive a Preliminary Annual Report would have 15 days to review and submit a reconsideration request in accordance with the proposed process discussed in section III.A.10. of this final rule (Appeal Processes). As under the original Model, we proposed to make available the Final Annual Report after all reconsideration requests are processed and no later than 30 calendar days before the payment adjustment takes effect annually, both for those HHAs that requested a reconsideration and all other competing HHAs.

We stated that under this proposed approach, HHAs would be notified in advance of the first annual total performance score and payment adjustment being finalized for CY 2024. We proposed that the total performance score and payment adjustment would be based on the CY 2022 performance year (January 1, 2022 to December 31, 2022), with the first payment adjustment to be applied to each HH PPS final claim payment amount as calculated in accordance with HH PPS policies as codified at § 484.205 for HHA services furnished January 1, 2024 through December 31, 2024.

Subsequent payment adjustments would be calculated based on the applicable full calendar year of performance data from the final IPRs, with competing HHAs notified and payments adjusted, respectively, every year thereafter. We stated that as a sequential example, the second payment adjustment would apply for services furnished January 1, 2025 through December 31, 2025, based on a full 12 months of the CY 2023 performance year. We stated that notification of the second pending payment adjustment would occur in approximately August 2024 when the Preview Annual Report is issued, followed by the Preliminary (if applicable) and Final Annual Reports, as described previously.

We stated that data related to performance on quality measures would continue to be provided for the baseline year and all performance years of the expanded Model via a CMS data platform, such as the iQIES (this platform would present and might archive the previously described IPR and Annual Reports). We presented a sample timeline in Table 33 of the proposed rule showing the availability of each expanded HHVBP Model-specific performance report and the data included for the proposed CY 2022 performance year and CY 2024 payment year.

We sought public comment on our proposals related to the Interim Performance and Annual Reports. We summarize in this section of this rule comments received and provide our responses.

Comment: A commenter requested that CMS continue to provide quarterly reports to HHAs.

Response: We are committed to providing the quarterly IPRs to HHAs in the expanded HHVBP Model, just as we did in the original HHVBP Model.

Comment: A few commenters requested that performance feedback reports be completed in a timely manner. Another commenter requested that performance feedback reports be provided earlier so HHAs have the opportunity to adjust operations as early as possible. Another commenter requested that performance feedback reports be provided no later than January 2022.

Response: We are committed to providing performance feedback reports, both the quarterly IPRs and Annual Reports, as soon as administratively feasible. We understands that both the IPRs and Annual reports are important tools that HHAs use to help adjust operations to improve quality. Due to the lag time between data submission and data processing of claims, HHCAHPS, and OASIS data, CMS is unable to provide the first IPR that includes CY 2023 performance year data for the first quarter quality measure performance scores any earlier than July 2023, as detailed in Table 32. As described in section III.A.3 of this rule, We have finalized the payment adjustments for the expanded HHVBP model to start in CY 2025 instead of CY 2024. We will provide sample reports as soon as administratively feasible and learning support during CY 2022 on the content of the IPRs and Annual Reports to allow HHAs to learn how the HHVBP quarterly reports can support their quality improvement efforts and potentially make adjustments to their operations as they see fit.

Comment: A commenter requested that CMS provide the baseline report as soon as possible, another commenter suggested CMS provide the baseline report before the performance year starts and another commenter suggested publishing the baseline report with this final rule.

Response: We understand that HHAs want to have time to examine their baseline data as soon as possible and anticipate making available baseline reports using the CY 2019 baseline year data in advance of the first performance

[42] iQIES manuals are available at *https://qtso.cms.gov/software/iqies/reference-manuals.*

year under the expanded Model (CY 2023). As noted, we will also make available during the CY 2022 pre-implementation year sample reports to individual HHAs via iQIES as soon as administratively feasible. The sample reports will provide, based on the data available, achievement threshold, benchmark, improvement threshold, and quality performance data.

Comment: A commenter requested that CMS thoroughly test the iQIES system to ensure that it is capable and prepared to provide the IPRs and Annual Reports to HHAs.

Response: We note that the iQIES already provides similar functionality in providing reports to HHAs for other purposes, and we have tested iQIES for acceptance of the file format to be used for the HHVBP model-reports and the test was successful.

Final Decision: After consideration of the public comments we received, we are finalizing our proposals for the proposed IPRs and Annual TPS and Payment Adjustment Reports, with modification, to reflect that CY 2023 will be the first performance year and CY 2025 the first payment year under the expanded Model, with CY 2022 as a pre-implementation year. We will continue to collect and evaluate data under the expanded HHVBP Model during CY 2022 and anticipate providing sample reports to HHAs, where administratively feasible and based on available data, for learning purposes only. The sample report would include the same information as an IPR, and would be based on the same scoring methodologies and other policies as finalized in this rule for a performance year. We also anticipate providing learning support to all HHAs during CY 2022 including, for example, scenario-based performance reports and related learning events on the content of the reports and how they can be used to supplement an HHA's quality improvement efforts.

As noted, CY 2023 will be the first performance year and CY 2025 will be the first payment year under the expanded Model. We expect to make the first IPR available in July 2023 and make IPRs for subsequent quarters available in October, January, and April. The July 2023 IPR would be the first IPR issued that includes CY 2023 performance year data for the first quarter quality measure performance scores on the OASIS-based measures and baseline data for the HHCAHPS survey and claims-based measures. HHAs will be notified in advance of the first annual total performance score and payment adjustment being finalized for CY 2025. The total performance score and payment adjustment will be based on the CY 2023 performance year (January 1, 2023 to December 31, 2023), with the first payment adjustment to be applied to each HH PPS final claim payment amount as calculated in accordance with HH PPS policies as codified at § 484.205 for HHA services furnished January 1, 2025 through December 31, 2025.

Subsequent payment adjustments will be calculated based on the applicable full calendar year of performance data from the final IPRs, with competing HHAs notified and payments adjusted, respectively, every year thereafter. As a sequential example, the second payment adjustment would apply for services furnished January 1, 2026 through December 31, 2026, based on a full 12 months of the CY 2024 performance year. Notification of the second pending payment adjustment would occur in approximately August 2025 when the Preview Annual Report is issued, followed by the Preliminary (if applicable) and Final Annual Reports, as described previously.

We present in Table 32 a sample timeline showing the availability of each expanded HHVBP Model-specific performance report and the data included for the CY 2023 performance year and CY 2025 payment year.

TABLE 32: TIMELINE FOR CY 2023 PERFORMANCE YEAR AND CY 2025 PAYMENT YEAR BY REPORT TYPE AND DATA TYPE

Report Type (Approximate Date Issued)	OASIS-Based Measures	Claims-Based and HHCAHPS-Based Measures
July 2023 IPR (July 2023)	12 months ending 3/31/2023	Baseline data only
October 2023 IPR (Oct 2023)	12 months ending 6/30/2023	12 months ending 3/31/2023
January 2024 IPR (Jan 2024)	12 months ending 9/30/2023	12 months ending 6/30/2023
April 2024 IPR (April 2024)	12 months ending 12/31/2023	12 months ending 9/30/2023
July 2024 IPR (July 2024)	12 months ending 3/31/2024	12 months ending 12/31/2023
Annual TPS and Payment Adjustment Report (Aug 2024)*	12 months ending 12/31/2023	12 months ending 12/31/2023

*The Annual Report made available to HHAs in approximately August 2024 is the Preview Annual Report. The Final Annual Report is issued after the recalculation and reconsideration request periods and no later than 30 days prior to the calendar year which the payment adjustment will take effect.

10. Appeals Processes

As codified at § 484.335, the appeals process under the original HHVBP Model allows HHAs to submit recalculation requests for the IPRs and Annual TPS and Payment Adjustment Report. Under this process, an HHA may also make a reconsideration request if it disagrees with the results of a recalculation request for the Annual TPS and Payment Adjustment Report. We refer the reader to the CY 2017 HH

PPS final rule for further discussion of the appeals process under the original HHVBP Model (81 FR 76747 through 76750).

Under the expanded Model, we proposed to use the same appeals process as the original Model. We proposed that competing HHAs be provided the opportunity to appeal certain information provided in the IPRs and the Annual Report, as discussed in more detail in the following sections.

a. Recalculation Request Process

Under the expanded HHVBP Model, we proposed that HHAs be provided two separate opportunities to review scoring information and request recalculations.

HHAs would have the opportunity to request a recalculation if a discrepancy is identified due to a CMS error in calculations after review of their: (1) Preliminary IPRs following each quarterly posting; or (2) Preview Annual Report. Specifically, we proposed that an HHA would have 15 calendar days from the date either the Preliminary IPR or the Preview Annual Report is provided to request a recalculation of measure scores if it believes there is evidence of a discrepancy in the calculation of the measure. We proposed that we would adjust the score if it is determined that the discrepancy in the calculated measure scores was the result of our failure to follow measurement calculation protocols. An HHA would also have the opportunity to request recalculation if it wishes to dispute the application of the formula to calculate the payment adjustment percentage.

Under this proposal, for both the Preliminary IPRs and the Preview Annual Report, competing HHAs would only be permitted to request scoring recalculations or, for the Preview Annual Report, to dispute the application of the formula used to calculate the payment adjustment percentage, and must include a specific basis for the requested recalculation. Any changes to underlying measure data cannot be made. We would not provide HHAs with the underlying source data utilized to generate performance measure scores.

We proposed that HHAs that choose to request a recalculation would submit recalculation requests for both quarterly Preliminary IPRs and for the Preview Annual Reports via instructions provided on a CMS webpage. We proposed that the request form would be entered by the primary point of contact, a person who has authority to sign on behalf of the HHA.

We proposed that recalculation requests (quarterly Preliminary IPR or Preview Annual Report recalculations) must contain all of the following information:

- The provider's name, address associated with the services delivered, and CMS Certification Number (CCN).
- The basis for requesting recalculation to include the specific data that the HHA believes is inaccurate or the calculation the HHA believes is incorrect.
- Contact information for a person at the HHA with whom CMS or its agent can communicate about this request, including name, email address, telephone number, and mailing address (must include physical address, not just a post office box).
- A copy of any supporting documentation the HHA wishes to submit in electronic form via the Model-specific webpage.

Following receipt of a recalculation request, we proposed that CMS or its agent would—

- Provide an email acknowledgement, using the contact information provided in the recalculation request, to the HHA contact notifying the HHA that the request has been received;
- Review the request to determine validity, and determine whether the requested recalculation results in a score change altering performance measure scores or the HHA's TPS;
- If the recalculation request results in a performance measure score change, conduct a review of data and if an error is found, recalculate the TPS using the corrected performance data; and
- Provide a formal response to the HHA contact, using the contact information provided in the recalculation request, notifying the HHA of the outcome of the review and recalculation process. The Final IPR and Preliminary Annual Report would reflect any changes noted from recalculation process. As under the original Model, we stated that we anticipate providing this response as soon as administratively feasible following the submission of the request.

We also proposed to codify the recalculation process at § 484.375(a). We invited comment on our proposals.

Comment: A commenter requested that CMS consider 30 calendar days for HHAs to review and request recalculations.

Response: While we appreciate that HHAs may want additional time to review the IPRs and Annual Reports, we believe that this proposed timeframe for submission of reconsideration requests is needed to allow for two levels of appeal prior to the payment adjustments being applied. The original HHVBP model used the same appeal process, including the 15 calendar day period for HHAs to submit recalculation requests, to allow for recalculations of the IPRs to be completed prior to the posting of the Annual Report in August and to allow both levels of appeals to be completed prior to the generation and submission of the final data files in advance of the applicable payment year. We proposed this same timeframe for submission of recalculation requests under the expanded Model in order to complete the entire appeals process for all HHAs timely, both the recalculations and reconsideration requests, and allow the Medicare Administrative Contractors (MACs) time to update each HHA's payment adjustment before the payment adjustment year. As discussed in the proposed rule, the recalculation process allows HHAs to request scoring recalculations or address discrepancies in the payment adjustment calculation, but changes cannot be made to the underlying data. We therefore believe that 15 calendar days is a sufficient amount of time to determine whether a recalculation is needed, collect supporting data, and submit a recalculation request following the posting of the Preliminary IPRs and Preview Annual Reports.

Final Decision: After consideration of the public comments we received, we are finalizing the proposed reconsideration process. We are also finalizing our proposed regulation text at § 484.375(a).

b. Reconsideration Process

Under the expanded Model, we proposed that if we determine that the original calculation was correct and deny the recalculation request for the scores presented in the Preview Annual Report, or if the HHA otherwise disagrees with the results of a CMS recalculation as reflected in the Preliminary Annual Report, the HHA may submit a reconsideration request for the Preliminary Annual Report. We proposed that an HHA may request reconsideration of the outcome of a recalculation request for its Preliminary Annual Report only. We stated that we believe that the ability to review the IPRs and submit recalculation requests on a quarterly basis provides competing HHAs with a mechanism to address potential errors in advance of receiving their Preview Annual Report. Therefore, we stated that we expect that in many cases, the reconsideration request process proposed would result in a mechanical review of the application of the formulas for the TPS and the LEF, which could result in the determination

that a formula was not accurately applied.

Under this proposal, the reconsideration request and supporting documentation would be required to be submitted via instructions provided on the CMS webpage within 15 calendar days of CMS' notification to the HHA contact of the outcome of the recalculation request for the Preview Annual Report. This proposed timeframe would allow a decision on the reconsideration to be made prior to the generation of the final data files containing the payment adjustment percentage for each HHA and the submission of those data files to the Medicare Administrative Contractors (MACs) to update their provider files with the payment adjustment percentage. We stated that we believe that this would allow for finalization of the annual performance scores, TPS, and annual payment adjustment percentages in advance of the application of the payment adjustments for the applicable performance year. Reconsiderations would be conducted by a CMS designated official who was not involved with the original recalculation request.

We proposed that the final TPS and payment adjustment percentage be provided to competing HHAs in a Final Annual Report no later than 30 calendar days in advance of the payment adjustment taking effect to account for unforeseen delays that could occur between the time the Annual Reports are posted and the appeals process is completed.

We proposed to codify the reconsideration process at § 484.375(b).

We solicited comments on these proposals. We did not receive any comments on the proposed reconsideration process.

Final Decision: We are finalizing the reconsideration process as proposed. We are also finalizing our proposed regulation text at § 484.375(b).

11. Public Reporting Under the Expanded HHVBP Model

a. Background

Consistent with our discussions on public reporting under the original Model in prior rulemaking, in the CY 2020 HH PPS final rule (84 FR 60552), we finalized a policy to publicly report on the CMS Website the following two points of data from the final CY 2020 Annual Report for each participating HHA in the original Model that qualified for a payment adjustment for CY 2020: (1) The HHA's TPS from performance year 5; and (2) the HHA's corresponding performance year 5 TPS Percentile Ranking. We stated that these data would be reported for each such competing HHA by agency name, city, State, and by the agency's CCN (84 FR 60552 through 60553). We refer readers to section III.B.3. of this final rule, where we discuss our proposal to modify our public reporting policy for the original Model, given our proposal as discussed in section III.B.2. of this final rule to not use CY 2020 data to make payment adjustments for CY 2022.

Publicly reporting performance data under the expanded Model would enhance the current home health public reporting processes, as it would better inform beneficiaries when choosing an HHA, while also incentivizing HHAs to improve performance. It would also be consistent with our practice of publicly reporting performance data under other value-based initiatives such as the SNF VBP and HVBP Programs (42 CFR 413.338) (42 CFR 412.163). CMS publicly reports both facility-specific SNF VBP Program performance information (such as achievement scores, improvement scores, rankings, and incentive payment multipliers), as well as aggregate-level program performance information on the CMS website (42 CFR 413.338). Similarly, for the HVBP Program, CMS publicly reports quality measures, baseline and performance years used, domain scores, total performance scores, and aggregate payment adjustment amounts on the CMS website (42 CFR 412.163).

Publicly reporting performance data for the expanded HHVBP Model would also be consistent with other agency efforts to ensure transparency and publicly report performance data. For example, the HH QRP requires HHAs to submit data in accordance with 42 CFR 484.245(b)(1). Furthermore, section 1895(b)(3)(B)(v)(III) of the Act requires, in part, that the Secretary establish procedures for making certain HH QRP data available to the public. HHAs have been required to collect OASIS data since 1999 and to report HHCAHPS data since 2012 (64 FR 3764 and 76 FR 68577). These data are available to providers, consumers, beneficiaries, and other stakeholders on the *Care Compare* website.

b. Public Reporting for the Expanded Model

We stated in the proposed rule that we believe that publicly reporting performance data under the expanded HHVBP Model would be an important way of incentivizing HHAs to improve quality performance under the Model. Therefore, we proposed to publicly report performance data for the expanded HHVBP Model beginning with the proposed CY 2022 performance year/CY 2024 payment adjustment and for subsequent years. For all years of the expanded HHVBP Model, we proposed to publicly report the following information:

- Applicable measure benchmarks and achievement thresholds for each small- and large-volume cohort.
- For each HHA that qualified for a payment adjustment based on the data for the applicable performance year—
- Applicable measure results and improvement thresholds;
- The HHA's Total Performance Score (TPS);
- The HHA's TPS Percentile Ranking; and
- The HHA's payment adjustment for a given year.

We proposed to report these data by State, CCN, and agency name through a CMS website. We noted that quality measure results for many of the measures proposed to be included in the expanded HHVBP Model are already currently reported on *Care Compare;* however, we proposed to also separately publicly report applicable measure results for such measures in the expanded HHVBP Model, because the public reporting periods for the Model would differ from those used for the HH QRP public reporting on *Care Compare.* We stated that we believe this would be clear and transparent for the public. In addition, to the extent that any new measures or measures that are otherwise not included in the HH QRP and are thus not already reported on *Care Compare* are included in the expanded HHVBP Model in the future, we proposed to publicly report those measure results as well.

We stated that we would also provide definitions for the TPS and the TPS Percentile Ranking methodology, as well as descriptions of the scoring and payment adjustment methodology, on the CMS website to ensure the public understands the relevance of these data points and how they were calculated. We note that this information would include a broader range of data elements than we previously finalized to publicly report for the original HHVBP Model. We proposed a broader range of data elements for the expanded HHVBP Model for several reasons. First, this publicly reported information would align more closely with the SNF VBP and HVBP Programs, both of which publicly report a broad range of information, including measure results and payment adjustment percentages. Second, we note that measure results for those quality measures included in the HH QRP are already publicly reported on the *Care Compare* website. We stated

that we believe that publicly reporting the corresponding benchmarks for all expanded Model measures (including those aligned with the HH QRP as well as measures that may not be aligned), by cohort, and other quality performance information for the expanded HHVBP Model would further promote transparency and incentivize quality improvements under the expanded Model.

We stated in the proposed rule that we anticipate this information would be made available to the public on a CMS website on or after December 1, 2023, the date by which we stated we would intend to complete the proposed CY 2022 Annual Report appeals process and issuance of the Final Annual Report to each competing HHA. For each year thereafter, we stated that we anticipate following the same approximate timeline for publicly reporting the payment adjustment for the upcoming calendar year, as well as the related performance data as previously described.

As the expanded Model's performance data would be supplemental to the Home Health Quality of Patient Care and Patient Survey Star Ratings, and does not form a part of these or other star ratings, we intend to also include a reference to the Home Health Star Ratings available on the CMS website.

We also proposed to codify these proposals at § 484.355(c).

We sought public comment on these proposals.

Comment: A commenter expressed concern that publicly reported measure scores may be misinterpreted since non-identical results could be generated between the HHVBP and HH QRP measure sets on Care Compare due to different baseline periods and scoring methodologies. Another commenter had a similar concern related to inconsistencies between the TPS and the star rating system. Both commenters recommended CMS take extra effort in the presentation of the results in order to assist beneficiaries in understanding why the results may not be identical.

Response: As noted in the proposed rule, we will provide definitions for the TPS and the TPS Percentile Ranking methodology on the CMS website to assist in interpretation of these results. As the commenter notes, the TPS and the star rating system may have non-identical results; however, we believe this increases the information available to the beneficiary and their family, and allows for greater transparency. In consideration of the public comments we received, we are considering additional methods to clarify this publicly reported data to assist in accurate public interpretation and understanding of the data results.

Final Decision: After consideration of comments received, we are finalizing our proposal with modification. As previously described in this final rule, payment adjustments under the expanded HHVBP model will start in calendar year 2025 instead of calendar year 2024. As such, public reporting of performance data for the expanded HHVBP Model will begin with the CY 2023 performance year/CY 2025 payment adjustment and for subsequent years. We anticipate this information would be made available to the public on a CMS website on or after December 1, 2024, the date by which we would intend to complete the CY 2023 Annual Report appeals process and issuance of the Final Annual Report to each competing HHA. For each year thereafter, we anticipate following the same approximate timeline for publicly reporting the payment adjustment for the upcoming calendar year, as well as the related performance data as previously described.

We are finalizing codification of this proposal at § 484.355(c).

12. Extraordinary Circumstances Exception Policy

The nation, its communities, and its health care providers, on certain occasions, are forced to confront extreme and uncontrollable circumstances outside of their control that impact their ability to operate in the ordinary course of business for short-term, or sometimes even extended periods. The United States is currently responding to an outbreak of respiratory disease caused by a novel coronavirus, referred to as COVID–19, which creates serious public health threats that have greatly impacted the U.S. health care system, presenting significant challenges for stakeholders across the health care delivery system and supply chain. Other extraordinary events may also occur in the future that have a disruptive impact. These events may include other public health emergencies, large-scale natural disasters (such as, but not limited to, hurricanes, tornadoes, and wildfires), or other extreme and uncontrollable circumstances. Such events may strain health care resources, and CMS understands that HHAs may have limited capacity to continue normal operations and fulfill expanded HHVBP Model participation requirements. In situations such as these, we believe CMS should make adjustments to the requirements of the expanded HHVBP Model to ensure the delivery of safe and efficient health care.

Therefore, generally, we proposed to adopt an extraordinary circumstances exception (ECE) policy for the expanded HHVBP Model that aligns, to the extent possible, with the existing HH QRP exceptions and extension requirements at 42 CFR 484.245(c). Section 484.245(c) permits HHAs to request and CMS to grant an exception or extension from the reporting requirements in the event of extraordinary circumstances beyond HHAs' control.

Specifically, we proposed that for the expanded HHVBP Model, CMS may grant an exception with respect to quality data reporting requirements in the event of extraordinary circumstances beyond the control of the HHA. We proposed that CMS may grant an exception as follows:

- An HHA that wishes to request an exception with respect to quality data reporting requirements must submit its request to CMS within 90 days of the date that the extraordinary circumstances occurred. Specific requirements for submission of a request for an exception would be available on the CMS website (*cms.gov*).
- CMS may grant an exception to one or more HHAs that have not requested an exception if: CMS determines that a systemic problem with CMS data collection systems directly affected the ability of the HHA to submit data; or if CMS determines that an extraordinary circumstance has affected an entire region or locale.

We stated that we would strive to provide our formal response notifying the HHA of our decision within 90 days of receipt of the HHA's ECE request, however, the number of requests we receive and the complexity of the information provided would impact the actual timeframe to make ECE determinations. When an ECE for HHAs in the nation, region or locale is granted, CMS would communicate the decision through routine channels to HHAs and vendors, including, but not limited to, the PAC QRP listserv, Open Door Forum MLN Connects, and notices on the CMS Home Health Quality Reporting Spotlight webpage. Specific instructions for requesting exceptions or extensions would be provided on the CMS website.

We also proposed to codify our ECE policy at § 484.355(d).

We solicited public comment on our proposals.

Final Decision: We did not receive comments on this proposal and are finalizing our proposals as proposed, including our proposed regulation text at § 484.355(d).

B. Provisions Under the Home Health Value-Based Purchasing (HHVBP) Original Model

1. Background

We stated in the proposed rule that the last year of data collection for the original Model ended on December 31, 2020 and the last payment adjustment year of the original Model would end on December 31, 2022. Payment adjustments are based on each HHA's TPS in a given performance year, which is comprised of performance on: (1) A set of measures already reported via the Outcome and Assessment Information Set (OASIS),[43] 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. Payment adjustments for a given year are based on the TPS calculated for performance two years' prior. We stated that under current policy for the original Model, the CY 2022 payment adjustments would be based on CY 2020 (performance year 5) performance. The maximum payment adjustment for CY 2022 is upward or downward 8 percent.

In the interim final rule with comment period that appeared in the May 8, 2020 **Federal Register** (May 2020 COVID–19 IFC) (85 FR 27553 through 27554; 85 FR 70328 through 70330), in response to the COVID–19 PHE to assist HHAs while they direct their resources toward caring for their patients and ensuring the health and safety of patients and staff, we adopted a policy to align the original Model data submission requirements with any exceptions or extensions granted for purposes of HH QRP during the COVID–19 PHE. We also established a policy for granting exceptions to the New Measures data reporting during the COVID–19 PHE, including the codification of these changes at § 484.315(b).

The original Model utilizes some of the same quality measure data that are reported by HHAs for the HH QRP, including HHCAHPS survey data. The other measures used in the original Model are calculated using OASIS data; claims-based data; and New Measure data. In response to the COVID–19 PHE, on March 27, 2020, CMS issued public guidance (*https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf*) excepting HHAs from the requirement to report HH QRP data for Q4 2019 and Q1–Q2 2020. Under our policy to align the original Model data submission requirements with any exceptions or extensions granted for purposes of the HH QRP during the COVID–19 PHE, HHAs in the nine original Model States were not required to separately report measure data for these quarters for purposes of the original Model. Specific to the original Model, we granted an exception for reporting New Measures data for the April 2020 (data collection period October 1, 2019–March 31, 2020) and July 2020 (data collection period April 1, 2020–June 30, 2020) New Measure submission periods. We further noted that HHAs may optionally submit part or all of these data by the applicable submission deadlines.

We acknowledged that the exceptions to the HH QRP reporting requirements, as well as the modified submission deadlines for OASIS data and our exceptions for the New Measures reporting requirements, may impact the calculation of performance under the original Model for performance year 5 (CY 2020). We also noted that while we are able to extract the claims-based data from submitted Medicare FFS claims, we may need to assess the appropriateness of using the claims data submitted for the period of the COVID–19 PHE for purposes of performance calculations under the original Model. We further explained that we are evaluating possible changes to our payment methodologies for CY 2022 in light of this more limited data, such as whether we would be able to calculate payment adjustments for participating HHAs for CY 2022, including those that continue to report data during CY 2020, if the overall data is not sufficient, as well as whether we may consider a different weighting methodology given that we may have sufficient data for some measures and not others. We stated that further, we are also evaluating possible changes to our public reporting of CY 2020 performance year data. We stated that we intend to address any such changes to our payment methodologies for CY 2022 or public reporting of data in future rulemaking.

2. CY 2022 Payment Adjustments

For the reasons discussed in this section, we proposed not to use the CY 2020 (performance year 5) data for purposes of payment adjustments under the HHVBP Model and to instead end the original Model early, with the CY 2021 payment year. Specifically, we proposed that we would not use the annual TPS calculated using the performance year 5 data to apply payment adjustments for CY 2022 and to instead end the original Model early, such that HHAs in the nine original Model States would not have their HH PPS claims payments adjusted by the current maximum payment adjustment factor of upward or downward 8 percent in CY 2022.

In light of the data reporting exceptions under the HHVBP Model for Q1 and Q2 2020 in response to the COVID–19 PHE, as discussed previously, we reviewed available quality data from Q1 and Q2 2020 as compared to Q1 and Q2 2019 for the nine original Model States to determine whether it may be appropriate to use data from the time period during which data reporting exceptions were in place (Q1 and Q2 2020). The comparison showed a decrease of 8.9 percent in OASIS assessments. We could not directly compare HHCAHPS results from Q1 and Q2 because our data are calculated on a 12-month rolling basis. However, we also examined claims data during this same time period to determine whether volume and utilization patterns changed and observed a 20.2 percent decrease in claims-based home health stays in Q1 and Q2 2020 as compared to Q1 and Q2 2019. The change in volume and utilization was observed across time (that is, the change was not limited to a certain point of time during the Q1 and Q2 2020 time period) and within and across States. We stated in the proposed rule that we believe these changes could be the result of the impacts of the COVID–19 PHE, including patients avoiding care or dying, reduced discharges to the home, and increased use of telehealth in lieu of in-person home health care. We also observed a 10.5 percent decrease in New Measures data submissions for Q1 and Q2 2020 as compared to Q1 and Q2 2019, consistent with what we would expect given the New Measures reporting exceptions we issued for this time period.

Based on the patterns we observed for the first two quarters of CY 2020, we stated in the proposed rule that we do not believe it would be appropriate to utilize data from that time period to calculate a TPS for CY 2020 that would be used to make payment adjustments in CY 2022. The changes in volume and utilization could skew performance assessments on quality measures for HHAs, such that the calculated TPS may not accurately reflect the quality of care provided by the HHAs. Additionally, we stated that we are concerned that because the COVID–19 PHE has not impacted all HHAs equally,

[43] OASIS is the instrument/data collection tool used to collect and report performance data by HHAs.

implementing payment adjustments based on the impacted data for the period of the COVID–19 PHE could unfairly penalize certain HHAs.

We also considered whether to use only Q3 and Q4 CY 2020 quality measure data to calculate CY 2020 annual total performance scores for CY 2022 payment adjustments. However, we stated that we believe that using only two quarters of data may not be sufficiently representative of the care provided by the HHA during a given calendar year for purposes of calculating quality measure scores and determining payment adjustments under the Model, and could potentially disadvantage those HHAs in an area of a State more heavily affected by the pandemic in Q3 and Q4 of CY 2020. In addition, as HHAs in different States continued to be impacted by the COVID–19 PHE during the second half of CY 2020, we stated that we believe patterns of home health care may also have continued to be impacted during that timeframe, similar to the changes we observed for the Q1 and Q2 2020 time period. We stated that as more data become available from the latter half of CY 2020, we will continue to examine home health care patterns in the nine original Model States in order to determine whether the same patterns we observed in the Q1 and Q2 2020 data persisted into the latter half of the year, and to assess whether it would be appropriate to utilize such data for CY 2022 payment adjustments.

Finally, we noted that several commenters on the exceptions policies that we adopted in the May 2020 COVID–19 IFC requested that we not use any performance data from CY 2020 and terminate or suspend the original Model early (85 FR 70328 through 70330).

Based on data available for this final rule, we note that, as found in Q1 and Q2 2020, OASIS assessments and claims-based home health stays decreased in Q3 and Q4 2020 as compared to Q3 and Q4 2019. We observed a 1.3 percent decrease in OASIS assessments and a 10.2 percent decrease in claims-based home health stays when comparing Q3 and Q4 2020 to Q3 and Q4 2019.

As stated in the proposed rule, after consideration of these issues, we proposed to not apply any payment adjustments for CY 2022 of the original HHVBP Model based on data reported in CY 2020 and to instead end the original Model early, with the CY 2021 payment adjustment year. We stated that we will continue to examine data for CY 2020 as it becomes available in order to determine whether it would be appropriate to utilize such data for CY 2022 payment adjustments, in accordance with current Model policies. Based on data available for this final rule, we observed that using two quarters of 2020 data (Q3 and Q4 2020) as compared to using four quarters of 2020 data (Q1 through Q4 2020), would result in two-thirds of episodes of care being eliminated. As previously noted, data submissions in Q3 and Q4 2020 also remained lower than Q3 and Q4 2019 submissions. We stated in the proposed rule that we will also continue to provide HHAs with the Interim Performance Reports with CY 2020 performance data and the Annual Report with the calculated TPS and payment adjustment amount based on the CY 2020 performance data, consistent with our current policies. We stated that if we finalize our proposal, as previously discussed, we would not use the TPS calculated using the performance year 5 data to apply payment adjustments for CY 2022.

We noted that if we finalize this proposal to end the original Model early, the evaluation would include the period through CY 2019 (performance year 4) and CY 2021 (payment year 4). We stated that as we proposed to not use CY 2020 (performance year 5) data to calculate CY 2022 (payment year 5) payment adjustments, these years would not be evaluated. As we clarify in response to comments in this section, CMS does intend to include CY 2020 in its evaluation, during which the 6 percent payment adjustment is applied.

We stated that we believe that our proposed policy to not use CY 2020 performance year data to determine payment adjustments under the HHVBP Model would be consistent with how other quality reporting and VBP programs proposed to utilize data that has been significantly affected by circumstances caused by the COVID–19 PHE. In the FY 2022 Hospice proposed rule (86 FR 19755), we proposed to modify the HH QRP public display policy to display fewer quarters of data than what was previously finalized for certain HH QRP measures for the January 2022 through July 2024 refreshes (86 FR 19755 through 19764). For the January 2022 refresh, data for OASIS-based and certain claims-based measures would include Q3 2020 through Q1 2021 data. For HHCAHPS, data would cover the four quarters Q3 2020 through Q2 2021. We noted that Q1 2020 and Q2 2020 data would not be included in the proposed Care Compare refresh schedule for any measures. The SNF VBP program proposed in the FY 2022 SNF PPS proposed rule (86 FR 19954) to suppress the use of the SNF readmission measure (SNFRM) for scoring and payment adjustment purposes for the FY 2022 program year. The HVBP program proposed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25469 through 25496) to suppress the use of a number of measures for the FY 2022 or FY 2023 program years for purposes of scoring and payment adjustments, along with proposals to revise the baseline periods for certain measures due to the extraordinary circumstances exception we granted in response to the COVID–19 PHE.

We proposed to amend at § 484.305 the definition of ''applicable percent'' by removing paragraph (5) of the definition ((5) For CY 2022, 8 percent) to reflect our proposal not to apply any payment adjustments for FY 2022 and to end the original Model early.

We invited public comment on our proposal. We summarize in this section of this rule comments received and provide our responses.

Comment: Several commenters opposed ending the model early and stated CMS should provide the 2022 incentive payments that would otherwise be made to HHAs in the nine states. Commenters opposed ending the model early stating that the final year should be evaluated. A commenter did not support ending the original model early, stating that if there is concern with impacts to the data due to the PHE, CMS should apply a risk adjuster to account for it.

Response: As previously described, based on our analyses of the CY 2020 data for this final rule, the volume and utilization patterns we observed in the Q1 and Q2 2020 data were also observed in the data for Q3 and Q4 2020, when compared to the same time period in CY 2019. Because the COVID–19 PHE did not impact all HHAs equally, we continue to believe that implementing payment adjustments based on the impacted data could unfairly penalize certain HHAs. While we also considered using only Q3 and Q4 CY 2020 quality measure data to calculate CY 2020 annual total performance scores for CY 2022 payment adjustments, we found that, when compared to using four quarters of CY 2020 data, 13 percent of HHAs would no longer have enough data at all to receive a TPS; only one state would have enough HHAs for a small cohort (compared to four states with full year data); 15 percent of HHAs would no longer have enough claims data to contribute to their TPS; and, 22 percent of HHAs would no longer have enough HHCAHPS data to contribute to their TPS. Based on our analyses, we continue to believe that using only two quarters of data is not sufficient

representation of the care provided by the HHA in CY 2020 for purposes of calculating quality measure scores and determining payment adjustments under the Model, and would disadvantage HHAs in an area of a State more heavily affected by the pandemic in Q3 and Q4 of 2020. We also continue to believe that the changes in volume and utilization for CY 2020, which, as noted, were also observed in the Q3 and Q4 2020 data, could skew performance assessments on quality measures for HHAs such that the calculated TPSs may not accurately reflect the quality of care provided by HHAs.

In addition, not using the CY 2020 performance year data to determine payment adjustments under the HHVBP Model would be part of a larger set of policies we have adopted to deal with quality data we believe have been significantly affected by circumstances caused by the COVID–19 PHE. For example, in the FY 2022 Hospice final rule (86 FR 42590–42598), we addressed how HH QRP data affected by the PHE would be publicly displayed. We finalized a policy that will use three quarters rather than four quarters of data for the January 2022 refresh affecting OASIS-based measures. For certain claims-based measures, we will use three quarters rather than four quarters of data for refreshes between January 2022 and July 2024. Public reporting with refreshed data will begin in January 2022. For HHCAHPS, we finalized that data would cover the four quarters Q3 2020 through Q2 2021. We note that Q1 2020 and Q2 2020 data would not be included in the proposed Care Compare refresh schedule for any measures.

CMS finalized in the FY 2022 SNF PPS final rule (86 FR 19954) to suppress the Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM) for the FY 2022 SNF VBP Program Year because circumstances caused by the PHE for COVID–19 have significantly affected the measure and the ability to make fair, national comparisons of SNFs' performance scores. Under the special scoring policy CMS finalized for FY 2022, CMS will assign a performance score of zero to all participating SNFs, to mitigate the effect that PHE-impacted measure results would otherwise have on SNF performance scores and incentive payment multipliers. CMS also finalized that it would assign an identical incentive payment multiplier, resulting in no payment adjustments for SNFs in FY 2022. We would then apply the Low-Volume Adjustment policy as previously finalized in the FY 2019 SNF PPS final rule (83 FR 39278 through 39280). That is, if a SNF has fewer than 25 eligible stays during the performance period for a program year we would assign that SNF a performance score resulting in a net neutral payment incentive multiplier. SNFs will not be ranked for the FY 2022 SNF VBP Program.

CMS finalized in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45266 through 45277) that for FY 2022, it would suppress the use of measure data for a number of measures because circumstances caused by the COVID–19 PHE have affected those measures and the resulting quality scores significantly. Because calculating Total Performance Scores (TPSs) for hospitals based on the remaining measures would not result in a fair national comparison, CMS also finalized that it would not calculate a TPS for any hospital and would instead award each hospital a payment incentive multiplier that results in a value-based incentive payment that is equal to the amount withheld for the fiscal year (2 percent).

With regard to the comment that CMS should apply a risk adjustor to account for the PHE, we note that we did not propose to modify the risk adjustment methodology for the quality measures in the original Model's measure set. Regarding the comment that the final year of the Model should be evaluated, we clarify that the Model will be evaluated through the full period of performance. CY 2020 will be evaluated as this year reflects the 6 percent payment adjustment applied, based on CY 2018 performance.

Final Decision: After consideration of public comments, we are finalizing our proposal not to apply any payment adjustments for CY 2022 and to end the original Model early as proposed. We are also finalizing to amend at § 484.305 the definition of ''applicable percent'' by removing paragraph (5) of the definition ((5) For CY 2022, 8 percent) to reflect this final policy.

3. Public Reporting Under the Original Model

In the CY 2020 HHS PPS final rule (84 FR 60551 through 60553), we finalized a policy to publicly report on the CMS website the following two points of data from the final CY 2020 performance year 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 performance year 5; and (2) the HHA's corresponding performance year 5 TPS Percentile Ranking. We 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 expected that these data would be made public after December 1, 2021, the date by which we intended to complete the CY 2020 Annual Report appeals process and issuance of the final Annual Report to each HHA.

For the reasons discussed in section III.B.2. of this final rule, we proposed to not use CY 2020 data for CY 2022 payment adjustments under the HHVBP Model. Consistent with this proposal, we also proposed to modify our existing policy and not publicly report performance data for the HHAs included in the original Model. We stated that we do not believe that it would be appropriate to publicly report performance data for a time period for which HHAs would not be held financially accountable for quality, nor do we believe that reporting data for this time period would assist beneficiaries and other public stakeholders in making informed choices about HHA selection, as the patterns of care during CY 2020 may not be representative of performance under the original Model as a whole due to the COVID–19 PHE. However, as discussed in section III.A.11. of this final rule, we proposed to begin public reporting for the expanded HHVBP Model with the proposed CY 2022 performance year data, continuing for all performance years thereafter, and are finalizing to publicly report performance data under the expanded Model beginning with the CY 2023 performance year data, continuing for all performance years thereafter.

We proposed to amend § 484.315 to reflect our proposal not to publicly report performance data from the CY 2020 performance year by removing paragraph (d). We solicited comments on this proposal.

Final Decision: We received no comments on this proposal and are finalizing as proposed, including our proposed amendment to § 484.315.

IV. Home Health Quality Reporting Program (HH QRP) and Other Home Health Related Provisions

A. Vaccinations for Home Health Agency Health Care Personnel

Health Care Personnel (HCP) are at risk of carrying COVID–19 infection to patients, experiencing illness or death as a result of COVID–19 themselves, and transmitting it to their families, friends, and the general public. We believe home health agencies should educate and promote vaccination among their HCP as part of their efforts to assess and reduce the risk of transmission of COVID–19. HCP vaccination can potentially reduce illness that leads to

work absence and limit disruptions to care. Centers for Disease Control and Prevention. Overview of Influenza Vaccination among Health Care Personnel (*https://www.cdc.gov/flu/toolkit/long-term-care/why.htm*). Data from influenza vaccination demonstrates that provider uptake of the vaccine is associated with that provider recommending vaccination to patients, Measure Application Committee Coordinating Committee Meeting Presentation (*http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx*). We believe HCP COVID–19 vaccination among Home Health staff could similarly increase uptake among that patient population.

B. Advancing Health Information Exchange

The Department of Health and Human Services (HHS) has a number of initiatives designed to encourage and support the adoption of interoperable health information technology and to promote nationwide health information exchange to improve health care and patients' access to their health information. To further interoperability in post-acute care settings, CMS and the Office of the National Coordinator for Health Information Technology (ONC) participate in the Post-Acute Care Interoperability Workgroup (PACIO) (*https://pacioproject.org/*) to facilitate collaboration with industry stakeholders to develop Fast Healthcare Interoperability Resources (FHIR) standards. These standards could support the exchange and reuse of patient assessment data derived from the minimum data set (MDS), inpatient rehabilitation facility patient assessment instrument (IRF–PAI), long-term care hospital continuity assessment record and evaluation (LCDS), outcome and assessment information set (OASIS), and other sources, including the Hospice Outcome and Patient Evaluation Assessment (HOPE) if implemented in the Hospice Quality Reporting Program through future rulemaking. The PACIO Project has focused on FHIR implementation guides for functional status, cognitive status and new use cases on advance directives and speech, and language pathology. We encourage PAC provider and health IT vendor participation as these efforts advance.

The CMS Data Element Library (DEL) continues to be updated and serves as the authoritative resource for PAC assessment data elements and their associated mappings to health IT standards such as Logical Observation Identifiers Names and Codes and Systematized Nomenclature of Medicine. The DEL furthers CMS' goal of data standardization and interoperability. These interoperable data elements can reduce provider burden by allowing the use and exchange of healthcare data; supporting provider exchange of electronic health information for care coordination, person-centered care; and supporting real-time, data driven, clinical decision–making. Standards in the Data Element Library (*https://del.cms.gov/DELWeb/pubHome*) can be referenced on the CMS website and in the ONC Interoperability Standards Advisory (ISA). The 2021 ISA is available at *https://www.healthit.gov/isa.*

The 21st Century Cures Act (Cures Act) (Pub. L. 114–255, enacted December 13, 2016) requires HHS to take new steps to enable the electronic sharing of health information ensuring interoperability for providers and settings across the care continuum. The Cures Act includes a trusted exchange framework and common agreement (TEFCA) provision [44] that will enable the nationwide exchange of electronic health information across health information networks and provide an important way to enable bi-directional health information exchange in the future. For more information on current developments related to TEFCA, we refer readers to *https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement* and *https://rce.sequoiaproject.org/.*

The ONC final rule entitled ''21st Century Cures Act: Interoperability, Information Blocking and the ONC Health IT Certification Program'' (85 FR 25642) published May 1, 2020, (hereinafter ''ONC Cures Act Final Rule'') implemented policies related to information blocking required under Section 4004 of the 21st Century Cures Act. Information blocking is generally defined as a practice by a health IT developer of certified health IT, health information network, health information exchange, or health care provider that, except as required by law or specified by the Secretary of HHS as a reasonable and necessary activity that does not constitute information blocking, is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.[45] For a healthcare provider (as defined in 45 CFR 171.102), the law specifies that the provider knows that the practice is unreasonable as well as likely to interfere with, prevent, or materially discourage access (see 45 CFR 171.103), exchange, or use of electronic health information. To deter information blocking, health IT developers of certified health IT, health information networks and health information exchanges whom the HHS Inspector General determines, following an investigation, have committed information blocking, are subject to civil monetary penalties of up to $1 million per violation. Appropriate disincentives for health care providers need to be established by the Secretary through rulemaking. Stakeholders can learn more about information blocking at *https://www.healthit.gov/curesrule/final-rule-policy/information-blocking.* ONC has posted information resources including fact sheets (*https://www.healthit.gov/curesrule/resources/fact-sheets*), frequently asked questions (*https://www.healthit.gov/curesrule/resources/information-blocking-faqs*), and recorded webinars (*https://www.healthit.gov/curesrule/resources/webinars*).

We invite providers to learn more about these important developments and how they could affect HHAs.

C. Home Health Quality Reporting Program (HH QRP)

1. 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)

[44] ONC, *Draft 2 Trusted Exchange Framework and Common Agreement, https://www.healthit.gov/sites/default/files/page/2019-04/FINALTEFCAQTF41719508version.pdf.*

[45] For other types of actors (health IT developers of certified health IT and health information network or health information exchange, as defined in 45 CFR 171.102), the definition of ''information blocking'' (see 45 CFR 171.103) specifies that the actor ''knows, or should know, that such practice is likely to interfere with access, exchange, or use of electronic health information.''

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).
- CY 2020 HH PPS final rule with comment period (84 FR 60554).
- CY 2021 HH PPS final rule (85 FR 70326 through 70328).

2. 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 period (83 FR 56548 through 56550) we also finalized the factors we consider for removing previously adopted HH QRP measures.

3. Quality Measures Currently Adopted for the CY 2022 HH QRP

The HH QRP currently includes 20 measures for the CY 2022 program year, as outlined in Table 28 of the CY 2020 HH PPS final rule (84 FR 60555).[46] [47]

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TABLE 33: MEASURES CURRENTLY ADOPTED FOR THE CY 2022 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).
Pressure Ulcer/Injury	Changes in Skin Integrity Post-Acute Care
Timely Care	Timely Initiation Of Care (NQF #0526).
TOH - Provider	Transfer of Health Information to Provider-Post-Acute Care[48]
TOH - Patient	Transfer of Health Information to Patient-Post-Acute Care[49]
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)[50] - 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.

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[46] The HHCAHPS has five component questions that together are used to represent one NQF-endorsed measure.

[47] Data collection delayed due to the COVID–19 public health emergency for the TOH-Patient and TOH-Provider.

4. Changes for the HH QRP

a. Removal of the Drug Education on All Medications Provided to Patient/Caregiver Measure Beginning With the CY 2023 HH QRP

The CMS Meaningful Measures framework seeks to identify the highest priorities for quality measurement and improvement and reduce where possible the burden on providers and clinicians.[51] In line with our meaningful measures initiative, we proposed to remove the Drug Education on All Medications Provided to Patient/Caregiver During All Episodes of Care measure from the HH QRP under measure removal factor 1: Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.

In the CY 2010 HH PPS final rule (74 FR 58096), we adopted the Drug Education on all Medications Provided to Patient/Caregiver measure, an OASIS-based measure, beginning with the CY 2010 HH QRP. This process measure reports the percentage of home health quality episodes during which the patient/caregiver was instructed on how to monitor the effectiveness of drug therapy, how to recognize potential adverse effects, and how and when to report problems (at the time of or at any time since the most recent SOC/ROC assessment). This measure is calculated using data collected on OASIS Item M2016.[52]

The Drug Education on all Medications Provided to Patient/Caregiver measure has very high measure performance such that it meets our Meaningful Measure Removal Factor 1: Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made. The mean and median agency performance scores for this measure, from January 1, 2019 to December 31, 2019, were 97.1 percent and 99.2 percent, respectively. The mean and median agency performance score for this measure in 2010 were 85.4 percent and 97.0 percent respectively. This indicates that an overwhelming majority of patients (or their caregivers) in an HHA received drug education on all medications and demonstrated improvement over time. In addition, during the same timeframe, the 75th percentile measure score (99.9 percent) and the 90th percentile measure score (100 percent) were statistically indistinguishable from each other, meaning that measure scores do not meaningfully distinguish between HHAs.[53] Further, the truncated coefficient of variation for this measure was 0.03, suggesting that it is not useful to draw distinctions between individual agency performance scores for this measure.[54]

We note that the HH QRP also has another measure that we believe better addresses the Meaningful Measure area of medication management. The Improvement in Management of Oral Medications (#0176) measure is an NQF-endorsed outcome measure that assesses the percentage of home health quality episodes during which the patient improved in the ability to take their oral medications correctly. The OASIS item used for this measure (M2020) is currently collected at Start of Care, Resumption of Care, and Discharge. The M2020 Management of Oral Medications assessment item asks about the patient's current ability to prepare and take all oral medications reliably and safely, including administration of the correct dosage at the appropriate times/intervals. This measure focuses on improving medication management through medication education provided to the patient. The measure performance statistics demonstrate good variation among providers and room for improvement: From January 1, 2019 to December 31, 2019, the mean and median agency performance scores for this measure was 69.4 percent and 71.9 percent, respectively; the 75th percentile measure score (79.7 percent); the 90th percentile measure score (87 percent); and the truncated coefficient of variation for this measure was 0.17. Thus, we believe this outcome measure The Improvement in Management of Oral Medications (NQF #0176) both better addresses quality issues of medication education and has better performance measure properties than the Drug Education on all Medications Provided to Patient/Caregiver process measure. Additionally, the Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care measure was removed from the HH Quality of Patient Care Star Ratings in April 2019 (now Care Compare) and replaced by the Improvement in Management of Oral Medications measure (NQF #0176). The removal of Drug Education on All Medications Provided to Patient/Caregiver process measure from the HH Quality of Patient Care Star Ratings in April 2019 and replacement with the Improvement in Management of Oral Medications ensured that there was not a gap in this important topic area.

We proposed to remove the Drug Education on all Medications Provided to Patient/Caregiver measure under measure removal factor 1: Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made, beginning with the CY 2023 HH QRP.

If finalized as proposed, HHAs would no longer be required to submit OASIS Item M2016, Patient/Caregiver Drug Education Intervention for the purposes of this measure beginning January 1, 2023.[55] If finalized as proposed, data for this measure would be publicly reported on Care Compare through October 1, 2023, after which it would be removed from the site.

We invited public comments on these proposals.

Comment: Most commenters supported the removal of the Drug Education on all Medications Provided to Patient/Caregiver measure. They supported the rationale supporting our proposal that showed the measure was less useful to the broader public as a measure with limited variation in scores across providers.

Response: We thank commenters for their support of the proposal to remove the Drug Education on all Medications Provided to Patient/Caregiver measure from the HH QRP. We will continue assess the value of each measure in the HH QRP to ensure it provides value to patients, providers and other stakeholders.

Comment: Some commenters supported the measure removal yet expressed concerns that removal of this

[48] Data collection delayed due to the COVID–19 public health emergency for the TOH-Patient and TOH-Provider.

[49] *Ibid.*

[50] The HHCAHPS has five component questions that together are used to represent one NQF-endorsed measure.

[51] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.*

[52] Home Health Quality Reporting Program Measure Calculations and Reporting User's Manual *https://www.cms.gov/files/document/hh-qrp-qm-users-manual-v1-addendum.pdf.*

[53] Analysis of Home Health OASIS episodes from 2010 to 2019.

[54] The truncated coefficient of variation (TCV) is the ratio of the standard deviation to the mean of the distribution of all scores, excluding the 5 percent most extreme scores. A small TCV (≤0.1) indicates that the distribution of individual scores is clustered tightly around the mean value, suggesting that it is not useful to draw distinctions between individual performance scores.

[55] The removal or addition of an item from the OASIS instrument is subject to public comment and approval from OMB. We cannot cease reporting of this measure any earlier given the need to extend OASIS–D and submit another PRA package in January 2022 for OMB approval for OASIS–E beginning January 1, 2023.

measure would result in a significant impact on the drug education that HHAs have provided and requested that CMS continue to monitor drug education. A few commenters did not support the removal of the drug education measure out of concern that its removal as one of the patient safety measures would adversely affect patients.

Response: We appreciate commenters raising the issue of patient safety. We continue to prioritize patient safety regarding patient medications. We believe other measures in the HH QRP, specifically the Improvement in Management of Oral Medications measure, adequately addresses this domain of patient safety with respect to medications along with other measures such as the Drug Regimen Review measure.

Final Decision: After careful consideration of the public comments we received, we are finalizing our proposal to remove of the Drug Education on All Medications Provided to Patient/Caregiver During All Episodes of Care measure from the HH QRP under measure removal factor 1: Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made beginning January 1, 2023. HHAs will no longer be required to submit OASIS Item M2016, Patient/Caregiver Drug Education Intervention beginning January 1, 2023.[56] We are finalizing that data for this measure will be publicly reported on Care Compare through October 1, 2023, after which it would be removed from the site.

b. Replacement of the Acute Care Hospitalization During the First 60 Days of Home Health (NQF #0171) Measure and Emergency Department Use Without Hospitalization During the First 60 Days of Home Health (NQF #0173) Measure With the Home Health Within Stay Potentially Preventable Hospitalization Measure Beginning With the CY 2023 HH QRP

In the CY 2017 HH PPS final rule, we finalized a policy for replacing quality measures in the HH QRP. Specifically, we defined ''replace'' to mean adopting a different quality measure in place of a quality measure currently in the HH QRP based on one or more of the HH QRP's measure removal factors (81 FR 76754 through 76754). We proposed to replace the Acute Care Hospital During the First 60 Days of Home Health (NQF #0171) measure and the Emergency Department Use Without Hospitalization During the First 60 Days of Home Health (NQF #0173) measure under measure removal factor 6: A measure that is more strongly associated with desired patient outcomes for the particular topic is available, with the Home Health Within Stay Potentially Preventable Hospitalization Measure beginning with the CY 2023 HH QRP.

The proposed Home Health Within Stay Potentially Preventable Hospitalization (which we will refer to as the ''PPH'' measure) measure assesses the agency-level risk-adjusted rate of potentially preventable inpatient hospitalization or observation stays for Medicare fee-for-service (FFS) beneficiaries that occur within a home health (HH) stay for all eligible stays for an agency.

This proposed measure is claims-based, requiring no additional data collection or submission burden for HHAs. Our approach for defining potentially preventable hospital admissions is described in more detail in this section of this rule in the Measure Calculations section.

A HH stay is defined as a sequence of HH payment episodes that are within 2 days or fewer from an adjacent payment episode. Payment episodes separated from other HH payment episodes by greater than 2 days are considered separate stays. Full details of the PPH specifications may be found at ''Proposed PPH Measure Specifications for the CY 2022 HH QRP NPRM'' at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Home-Health-Quality-Measures*.

(1) Background

Hospitalizations among the Medicare population are common, costly, and often preventable.[57] [58] [59] The Medicare Payment Advisory Commission (MedPAC) and a study by Jencks et al. estimated that 17–20 percent of Medicare beneficiaries discharged from the hospital were readmitted within 30 days. Among these hospital readmissions, MedPAC has estimated that 76 percent were considered potentially avoidable and associated with $12 billion in Medicare expenditures.[60] [61] An analysis of data from a nationally representative sample of Medicare FFS beneficiaries receiving HH services in 2004 show that HH patients receive significant amounts of acute and post-acute services after discharge from HH care.[62] Focusing on readmissions, Madigan and colleagues studied data on 74,580 Medicare HH patients and found that the 30-day rehospitalization rate was 26 percent, with the largest proportion related to a cardiac-related diagnosis (42 percent).[63] A study of data on dually eligible Medicare and Medicaid beneficiaries hospitalizations from nursing home and home and community based services waiver programs found that 39 percent of admissions were potentially avoidable.[64]

Analysis of the home health patient population has revealed some key factors associated with hospitalizations from HH including functional disability, primary diagnoses of heart disease, and primary diagnosis of skin wounds.[65] An additional beneficiary characteristic that is associated with a potential for hospitalization is the time since a beneficiary's most recent hospitalization[66] and chronic conditions such as chronic obstructive pulmonary disease and congestive heart failure.[67] How HHAs address these factors, including how HHAs address chronic conditions present before the HH stay, can determine whether beneficiaries can successfully avoid

[56] The removal or addition of an item from the OASIS instrument is subject to public comment and approval from OMB. We cannot cease reporting of this measure any earlier given the need to extend OASIS–D and submit another PRA package in January 2022 for OMB approval for OASIS–E beginning January 1, 2023.

[57] Friedman, B. and J. Basu, The rate and cost of hospital readmissions for preventable conditions. Med Care Res Rev, 2004. 61(2): p. 225–40.

[58] Moy, E., Chang, E., and Barret, M. Potentially Preventable Hospitalizations—United States, 2001–2009. MMWR, 2013, 62(03);139–143.

[59] Jencks, S.F., M.V. Williams, and E.A. Coleman, Rehospitalizations among Patients in the Medicare Fee-for-Service Program. New England Journal of Medicine, 2009. 360(14): p. 1418–1428.

[60] *Ibid*.

[61] MedPAC, Payment policy for inpatient readmissions, in Report to the Congress: Promoting Greater Efficiency in Medicare. 2007: Washington D.C. p. 103–120.

[62] Wolff, J.L., Meadow, A., Weiss, C.O., Boyd, C.M., Leff, B. Medicare Home Health Patients' Transitions Through Acute And Post-Acute Care Settings.'' *Medicare Care* 11(46) 2008; 1188–1193.

[63] Madigan, E.A., N.H. Gordon, et al. Rehospitalization in a national population of home health care patients with heart failure.'' *Health Serv Res* 47(6): 2013; 2316–2338.

[64] Walsh, E.G., J.M. Wiener, et al. (2012). ''Potentially avoidable hospitalizations of dually eligible Medicare and Medicaid beneficiaries from nursing facility and Home- and Community-Based Services waiver programs.'' *J Am Geriatric Soc* 60(5): 821–829.

[65] Lohman MC, Cotton, BP, Zagaria, AB, Bao, Y, Greenberg, RL, Fortuna, KL, Bruce, ML Hospitalization Risk and Potentially Inappropriate Medications among Medicare Home Health Nursing Patients, (2017) J Gen Intern Med. 32(12):1301–1308.

[66] Hua M, Gong, MN, Brady J, Wunsch, H, Early and late unplanned rehospitalizations for survivors of critical illness (2015) Critical Care Medicine;43(2):430–438.

[67] Dye C, Willoughby D, Aybar-Damali B, Grady C, Oran R, Knudson A, Improving Chronic Disease Self-Management by Older Home Health Patients through Community Health Coaching (2018). Int J Environ Res Public Health. 15(4): 660.

hospitalizations.[68] Understanding these factors can help HHAs design strategies to address avoidable hospitalizations.

Observation stays are also increasing nationally and can have costly financial impacts, especially for patients.[69] [70] Patients admitted for an observation stay can often be treated in the same medical units and have similar medical needs as a patient admitted for inpatient care, but the service is billed as outpatient services and does not count as a referent patient stay in the calculations of readmissions.[71] Limitation of observation stays should be a goal of HHAs along with efforts to limit inpatient hospitalizations.

We have addressed emergency department use, hospitalizations, and readmissions with a number of home health measures. Measures including the Acute Care Hospitalization During the First 60 Days of Home Health (NQF #0171); Emergency Department Use without Hospitalization During the First 60 days of Home Health (NQF #0173); and the Potentially Preventable 30-Day Post-Discharge Readmission Measure for the HH QRP. The HH QRP has long sought to address hospitalization and emergency department use by home health patients since decreasing hospitalizations and use of the emergency department are important areas of quality to promote patient health outcomes and reduce unnecessary healthcare costs. Before the adoption of the Acute Care Hospitalization during the First 60 Days of Home Health (NQF #0171) and Emergency Department Use Without Hospitalization During the First 60 days of Home Health (NQF #0173) measures, the HH QRP utilized OASIS-based iterations of these measures. In the CY 2012 HH PPS final rule (76 FR 68526), we adopted the Emergency Department Use Without Hospitalization During the First 60 Days of Home Health claims-based measure to replace the OASIS-based Emergency Department Use Without Hospitalization measure since the claims data offered a more robust source of data for the measure. The M2300 item used to calculate OASIS-based ED Use QM was deemed to be insufficiently reliable in capturing emergency department visits. In the CY 2013 HH PPS final rule (77 FR 67902), we adopted the Acute Care Hospitalization During the First 60 Days of Home Health claims-based measure to replace the OASIS-based Acute Care Hospitalization measure since it made the determination that claims data provided a more robust data source for accurately measuring acute care hospitalizations.

The Acute Care Hospitalization During the First 60 Days of Home Health measure (NQF #0171) and Emergency Department Use Without Hospitalization During the First 60 days of Home Health (NQF #0173) measure are claims-based and were an improvement on addressing issues related to emergency department use and acute hospitalization but they also had limitations related to issues of attribution. In prior feedback from an NQF technical review panel on the Emergency Department Use Without Hospitalization During the First 60 days of Home Health (NQF #1073), concerns were raised regarding the HHAs' ability to prevent an emergency department visit, especially for visits that do not result in a hospitalization. While some evidence suggests that care coordination and HHA engagement can impact emergency department use by patients, experts raised concerns that there were several drivers of emergency department use outside the control of an HHA that could result in an emergency department visit.[72]

Concerns related to attribution were also raised by reviewers of the Acute Care Hospitalization during the First 60 Days of Home Health when the measure was reviewed for NQF endorsement by the Steering Committee at the National Voluntary Consensus Standards for Care Coordination 2012 meetings. Reviewers acknowledged the difficulty in determining appropriate attribution for hospitalization between different providers and settings, especially when evaluating all cause hospitalization that does not require the reason for hospitalization to be related to the reason for home health care.[73]

The proposed PPH measure addresses the limitations of the Emergency Department Use Without Hospitalization During the First 60 Days of Home Health (NQF #0173) and Acute Care Hospitalization During the First 60 Days of Home Health measures (NQF #0171). First, the PPH proposed measure assesses potentially preventable observation stays instead of just emergency department use. As noted previously, observation stays are costly clinical events that require a patient to be monitored by a medical team. Limiting the occurrence of avoidable observation stays would improve patient outcomes and reduce costs. The PPH measure is focused on the subset of observation stays that technical experts determined could be addressed by HHA intervention. Similarly, the PPH proposed measure focuses on the subset of inpatient hospitalizations that could be avoided by HHA intervention. We believe the proposed PPH measure will better provide an assessment on HH quality by focusing on observation stays and acute hospitalizations that could be prevented by HHA intervention.

Several general methods have been developed to assess potentially avoidable or preventable hospitalizations and readmissions for the Medicare population. These include the Agency for Healthcare Research and Quality's (AHRQ's) Prevention Quality Indicators,[74] approaches developed by MedPAC, and proprietary approaches, such as the 3MTM algorithm for potentially preventable hospitalizations.[75] [76] [77] The existing literature addresses both hospital readmissions more broadly and potentially avoidable hospitalizations for specific settings like long-term care and highlights issues relevant to the development of potentially preventable hospitalization measures for a post-acute care setting such as home health.[78] [79]

[68] Lohman MC, Cotton, BP, Zagaria, AB, Bao, Y, Greenberg, RL, Fortuna, KL, Bruce, ML Hospitalization Risk and Potentially Inappropriate Medications among Medicare Home Health Nursing Patients, (2017) J Gen Intern Med. 32(12):1301–1308.

[69] Lind KD, Noel-Miller CM, Sangaralingham LR, Shah ND, Hess EP, Morin P, Fernanda Bellolio M. Increasing Trends in the Use of Hospital Observation Services for Older Medicare Advantage and Privately Insured Patients. Med Care Res Rev. 2019. Apr;76(2):229–239.

[70] Feng Z, Wright B, Mor V. Sharp rise in Medicare enrollees being held in hospitals for observation raises concerns about causes and consequences. Health Aff (Millwood). 2012. Jun;31(6):1251–9.

[71] Sabbatini AK, Wright B. Excluding Observation Stays from Readmission Rates—What Quality Measures Are Missing, New England Journal of Medicine, 31;378(22):2062–2065.

[72] National Voluntary Consensus Standards for Care Coordination 2012 Draft Technical Report. Available from *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=70600.*

[73] Ibid.

[74] Prevention Quality Indicators Overview. Available at: *https://www.qualityindicators.ahrq.gov/modules/pqi_resources.aspx.*

[75] Goldfield, N.I., McCullough, E.C., Hughes, J.S., et al. Identifying potentially preventable readmissions. Health Care Finan. Rev. 30(1):75–91, 2008. Available from *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4195042/.*

[76] National Quality Forum: Prevention Quality Indicators Overview. 2008.

[77] MedPAC: Online Appendix C: Medicare Ambulatory Care Indicators for the Elderly. pp. 1–12, prepared for Chapter 4, 2011. Available from *http://www.medpac.gov/documents/reports/Mar11_Ch04_APPENDIX.pdf?sfvrsn=0.*

[78] Gao, J., Moran, E., Li, Y.-F., et al. Predicting potentially avoidable hospitalizations. Med. Care

Continued

(2) Stakeholder and Technical Expert Panel (TEP) Input

A TEP convened by our measure contractor provided recommendations on the technical specifications of this proposed measure, including the development of an approach to define potentially preventable hospital admission and observation stays for HH. TEP meetings were held in April, June, and December 2018. The TEP supported the definition of potentially preventable developed by the measure development team for both inpatient admissions and observation stays. The TEP further provided extensive guidance in refining the list of primary conditions that lead to the inpatient admission or observation stay that could be reasonably deemed preventable by HHA intervention. Details from the TEP meetings, including TEP members' ratings of conditions proposed as being potentially preventable, are available in the TEP summary report available on the CMS website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/PPH-TEP-Summary-Report-Final-101019.pdf*.

We also solicited stakeholder feedback on the development of this measure through a public comment period held from November 18 through December 16, 2019. The major comment received focused on considering the implication of implementation of the Patient-Driven Groupings Model (PDGM) on the specifications of this measure. CMS has undertaken a review of the implications on the new payment model on this and other claims-based QMs in the HH QRP and determined that the claims-based measures are not adversely affected by the new model.

(3) Measure Application Partnership (MAP) Review

Our pre-rulemaking process includes making publicly available a list of quality and efficiency measures, called the Measures under Consideration (MUC) List that the Secretary is considering adopting through the Federal rulemaking process for use in Medicare programs. This allows multi-stakeholder groups to provide recommendations to the Secretary on the measures included on the list. The PPH quality measure was published in the 2019 MUC list for the HH QRP.[80]

The PPH quality measure was presented to the 2019 NQF-convened Measure Application Process (MAP) Post-Acute Care/Long-Term Care (PAC–LTC) workgroup and the MAP recommended conditional support for rulemaking for a single measure under consideration for the HH QRP, MUC2019–34 PPH. The MAP conditionally supported MUC2019–34 PPH, pending NQF review and endorsement. CMS clarified that it intends to eventually replace related measures, NQF 0171 Acute Care Hospitalization during the First 60 Days of Home Health and NQF 0173 Emergency Department Use (ED Use) Without Hospitalization During the First 60 days of Home Health with the PPH measure under consideration.

The MAP agreed that the PPH measure adds value to the HH QRP's measure set by adding measurement of potentially preventable hospitalizations and observation stays that may occur at any point in the home health stay. No measure in the program currently provides this information.

The MAP encouraged the consideration of including Medicare Advantage patients in future iterations of the measure. CMS is supportive of this suggestion when reliable Medicare Advantage data is available nationally. The MAP also encouraged the NQF All-Cause Admissions and Readmissions Standing Committee to consider the definition for preventable hospitalization to ensure HHAs can take adequate steps to improve these outcomes. The issue of what could be determined to be potentially preventable by HHAs was discussed extensively at multiple TEP meetings. The TEP adopted a listing of conditions that could be prevented by standard care HHAs are required to provide. The MAP encouraged CMS to provide detailed performance feedback to providers to help providers differentiate the causes of hospitalizations for quality improvement purposes. More information about the MAP's recommendations for this measure is available at *https://www.qualityforum.org/Publications/2020/02/MAP_2020_Considerations_for_Implementing_Measures_Final_Report_-_PAC_LTC.aspx*.

At the time of the MAP, the initial risk-adjustment model tested measure validity and reliability as identified in the measure specifications document, as previously provided. Testing results were very strong and showed more robust results than outcome measures previously finalized through rulemaking including the Acute Care Hospitalization During the First 60 Days of Home Health (NQF #0171) measure and the Emergency Department Use Without Hospitalization During the First 60 days of Home Health (NQF #0173) measure.

(4) Quality Measure Calculation

We reviewed established scientific research, analyzed home health claims data, and obtained input from a technical expert panel (TEP) to develop a definition and list of conditions for which types of hospital admissions are potentially preventable. The defining of potentially preventable hospitalization relies on the previously developed conceptual framework that certain diagnoses, proper management, and care of the condition by the home health agency, combined with appropriate, clearly explained, and implemented discharge instructions and referrals, can potentially prevent a patient's admission to the hospital. On the basis of this framework, the team followed the working conceptual definition for potentially preventable hospitalizations for home health created during the development of the HH QRP measure Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH Quality Reporting Program. Although not specific to PAC or hospitalizations, the team used AHRQ Prevention Quality Indicators (PQIs) and Ambulatory Care Sensitive Conditions (ACSCs) as a starting point for this work. The list of ACSCs consists of conditions for which hospitalization can potentially be prevented, given good outpatient care and early intervention.[81]

We also performed analyses on Medicare claims data to identify the most frequent diagnoses associated with admissions among home health beneficiaries, and then applied the conceptual potentially preventable hospitalization definition to evaluate whether these common conditions for a hospitalization may be considered potentially preventable. This list of conditions identified from literature and claims analysis formed the preliminary potentially preventable hospitalization definition. We grouped these conditions based on clinical rationale, and the major groups are: (1) Inadequate management of chronic conditions; (2)

52(2):164–171, 2014. doi:10.1097/MLR.0000000000000041.

[79] Walsh, E.G., Wiener, J.M., Haber, S., et al. Potentially avoidable hospitalizations of dually eligible Medicare and Medicaid beneficiaries from nursing facility and home-and community-based services waiver programs. J. Am. Geriatr. Soc. 60(5):821–829, 2012. doi:10.1111/j.1532–5415.2012.03920.

[80] *https://www.cms.gov/files/document/2019muc-listclearancerpt.pdf*.

[81] Agency for Healthcare Research and Quality: AHRQ Quality Indicators—Guide to Prevention Quality Indicators: Hospital Admission for Ambulatory Care Sensitive Conditions. AHRQ Pub. No. 02–R0203. Rockville, MD. Agency for Healthcare Research and Quality, 2001.

Inadequate management of infections; (3) Inadequate management of other unplanned events; and (4) Inadequate injury prevention.

Additional details regarding the definition for potentially preventable hospitalizations are available in the document titled ''Proposed PPH Measure Specification for the CY 2022 HH QRP NPRM'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Home-Health-Quality-Measures*.

This proposed PPH measure is focused on inpatient admissions or observation stays that are potentially preventable (PP) and unplanned. Thus, planned admissions are not counted in the numerator. Planned inpatient admissions and observation stays are defined largely by the definition used for the Hospital Wide Readmission [82] and Potentially Preventable Within Stay Readmission Measure for Inpatient Rehabilitation Facilities [83] measures.

The process for classifying a planned inpatient admission or observation stay is determined based on the following parameters. If an inpatient or outpatient claim contains a code for a procedure that is frequently a planned procedure, then that inpatient admission or observation stay is designated a planned inpatient admission or observation stay and is not included in the numerator. Similarly, if an inpatient or outpatient claim contains a code for a diagnosis that is frequently associated with a planned admission, then that inpatient admission or observation stay is designated to be a planned inpatient admission or observation stay and also not included in the numerator. However, the planned inpatient admission or observation stay is reclassified as unplanned if the claim also contains a code indicating one or more acute diagnoses from a specified list that is included in the criteria material described in the next sentence. Full details on the planned admissions criteria used, including the CMS Planned Readmission Algorithm and additional procedures considered planned for post-acute care, can be found in the document titled ''Proposed PPH Measure Specification for the CY 2022 HH QRP NPRM'' at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Home-Health-Quality-Measures.*

The risk adjustment modeling estimates the effects of patient characteristics, comorbidities, and select health care variables on the probability of potentially preventable inpatient hospital admission or observation stay. More specifically, the risk-adjustment model for HHAs entails the following:

- Demographic characteristics (age, sex, original reason for Medicare entitlement).
- Care received during prior proximal hospitalization [84] (if applicable) (including the length of the hospitalization and principal diagnoses during the prior proximal hospitalization).
- Other care received within a year of stay (including number of prior acute discharges, number of outpatient emergency department visits, number of skilled nursing visits, number of inpatient rehabilitation facility visits, number of long term care hospital visits, and comorbidities from a prior proximal hospitalization [if applicable] or other visits in the last year).

The proposed measure is calculated using a calendar year of Medicare FFS data. In addition, we proposed a minimum of 20 eligible HH stays as defined in the introduction to this proposal for public reporting of the proposed measure. All HH stays during the year time window, except those that meet the exclusion criteria, would be included in the measure. The PPH observation window begins from the start of HH stay and spans to 1 day after discharge. Data from all HH stays beginning from 1/1/2016–12/31/2016, was used for the PPH measure development. For technical information about this proposed measure including information about the measure calculation, risk adjustment, and exclusions, we refer readers to our Proposed PPH Measure Specification for the CY 2022 HH QRP NPRM at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Home-Health-Quality-Measures*.

To meet the requirements of the CMS Meaningful Measures framework which seeks to identify the highest priorities for quality measurement and improvement and to reduce where possible the burden on providers and clinicians,[85] we proposed to remove the Acute Care Hospitalization During the First 60 Days of Home Health (NQF #0171) measure and the Emergency Department Use Without Hospitalization During the First 60 Days of Home Health (NQF #0173) measure and replace them with the PPH measure. We proposed to remove these two measures from the HH QRP beginning with the CY 2023 HH QRP under our measure removal Factor 6: A measure that is more strongly associated with desired patient outcomes for the particular topic is available.

The Acute Care Hospitalization During the First 60 Days of Home Health (NQF #0171) and Emergency Department Use Without Hospitalization During the First 60 Days of Home Health (NQF #0173) measures are both claims-based and have some notable limitations related to appropriate attribution of the acute hospitalization or emergency department visit to an HHA. These measures focus on hospitalization regardless of whether a HHA could provide care that could prevent the visit whereas the proposed PPH measure addresses the limitations of these measures by focusing on inpatient admissions and observation stays that research establishes could be prevented by HHA care provided to patients they serve.

We proposed to remove the Acute Care Hospitalization during the First 60 Days of Home Health (NQF #0171) measure and Emergency Department Use Without Hospitalization During the First 60 Days of Home Health (NQF #0173) measure and replace them with the Home Health Within-Stay Potentially Preventable Hospitalization claims-based measures beginning with the CY 2023 HH QRP.

We invited public comments on this proposal.

Comment: Most commenters supported our proposal to Replace the Acute Care Hospitalization During the First 60 Days of Home Health (NQF #1071) measure and Emergency Department Use Without Hospitalization During the First 60 Days of Home Health (NQF #0173) measure with the Home Health Within Stay Potentially Preventable Hospitalization measure beginning with the CY 2023 HH QRP.

Response: We thank commenters for their support of the proposal to replace the Acute Care Hospitalization During the First 60 Days of Home Health (NQF #1071) measure and Emergency Department Use Without Hospitalization During the First 60 Days of Home Health (NQF #0173) measure with the Home Health Within Stay Potentially Preventable Hospitalization

[82] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

[83] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

[84] Prior proximal hospitalizations for this measure are defined as inpatient stays within 30 days prior to home health admission.

[85] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.*

measure. We regularly strive to improve domains of quality and this policy seeks to improve how hospitalizations are addressed in home health.

Comment: Some commenters supported the PPH measure replacement with a condition that providers be given some time to adjust before it is added to either the HH QRP or HHVBP program.

Response: We disagree with the commenters recommendation to be given additional time to adjust under the HH QRP. We interpret the comment to convey that finalization of this policy in the CY 2022 rule, confidential feedback to providers in October 2022, and reporting commencing no sooner than October 1, 2023, is too soon. We contend that HHAs would have more than a year after finalization of this policy to review their PPH measure scores and implement quality improvement measures if needed.

At the present time, we only proposed the PPH measure under the HH QRP. We will note that where possible, CMS does seek alignment across our post-acute care quality programs.

Comment: A few commenters supported the PPH replacement of the ACH and ED Use measures but had suggested modification to the PPH measure specification, including the removal of the observation stays from the numerator, addition of ED use to the numerator, and a strengthening of the risk adjustment model for the measure. Commenters were concerned with the launch of OASIS E and use of items associated with the HH Patient-Driven Groupings Model (PDGM) implemented January 2020 and concurrent with the development of the PPH measure.

Response: With respect to modifications of the PPH measure, we continually seek improvement to the specifications of measures and anticipates a robust risk adjustment approach consistent with other claims-based outcome measures currently under the HH QRP. As is our practice, we will assess the appropriateness of inclusion of any new assessment items available for use to improve risk adjustment as those items are available. We have also assessed the importance of the inclusion of observation stays in the PPH measure and do believe that addressing preventable observation stays as well as inpatient stays are important aspects of quality improvement based on clinical research showing the trends of observation stays in inpatient settings and an improvement on addressing only ED use in the numerator. Observation stays are an important form of hospitalization and in the process of assessing for observation stays, ED use is also captured. As with other claims-based measures in the HH QRP, CMS will assess the impact of PDGM implementation on measure specification and update measure details as necessary.

Comment: Some commenters suggested that it is important for the PPH measure to obtain NQF endorsement if the measure is to be added to the HH QRP.

Response: We intend to submit the PPH measure for NQF endorsement.

Final Decision: After careful consideration of the public comments we received, we are finalizing the replacement of the Acute Care Hospital During the First 60 Days of Home Health (NQF #0171) measure and the Emergency Department Use Without Hospitalization During the First 60 Days of Home Health (NQF #0173) measures under measure removal factor 6: A measure that is more strongly associated with desired patient outcomes for the particular topic is available, with the Home Health Within Stay Potentially Preventable Hospitalization Measure beginning with the CY 2023 HH QRP.

c. Schedule for Publicly Reporting Quality Measures Beginning With the CY 2022 HH QRP

Section 1899B(g)(1) of the Act requires, in part, that the Secretary provide for public reporting of PAC provider performance, including HHAs, on quality measures under section 1899B(c)(1) of the Act, including by establishing procedures for making available to the public information regarding the performance of individual PAC providers with respect to such measures. Section 1899B(g)(2) of the Act requires, in part, that CMS give HHAs opportunity to review and submit corrections to the data and information to be made public under section 1899B(g)(1) of the Act prior to such data being made public. Section 1899B(g)(3) of the Act requires that such procedures provide that the data and information with respect to a measure and PAC provider is made publicly available beginning not later than 2 years after the applicable specified application date applicable to such measure and provider.

In the CY 2018 HH PPS final rule, we adopted the Percent of Residents Experiencing One or More Falls with Major Injury measure beginning with the CY 2020 HH QRP under section 1899B(c)(1)(D) of the Act (82 FR 51727 through 51730). Under section 1899B(a)(2)(E)(i)(IV)(bb) of the Act, the specified application date for HH QRP measures adopted under section 1899B(c)(1)(D) of the Act is January 1, 2019; two years after this date is January 1, 2021.

We also adopted in the CY 2018 HH PPS final rule the Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment measure beginning with the CY 2020 HH QRP (82 FR 51722 through 51727) under section 1899B(c)(1)(A) of the Act. Under section 1899B(a)(2)(E)(i)(I)(cc) of the Act, the specified application date for HH QRP measures adopted under section 1899B(c)(1)(A) of the Act is January 1, 2019; 2 years after this date is January 1, 2021.

We proposed to publicly report the Percent of Residents Experiencing One or More Major Falls with Injury measure and 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) measure beginning in April 2022.

As required by section 1899B(g)(2) of the Act, to date CMS has made these two measures available for review by HHAs the HH confidential feedback reports. The Percent of Residents Experiencing One or More Major Falls with Injury measure was added to the HHA Review and Correct Report effective 04/01/2019, and the HHA Outcome Measures Report effective 01/01/2020. 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) was added to the HHA Review and Correct Report effective 04/01/2019, and the HHA Process Measures Report effective 01/01/2020. HHAs' HH QRP measure scores for these two measures would additionally be made available for review on the HH Provider Preview Report, which would be issued in January 2022, 3 months in advance of the inaugural display of these measures on Care Compare.

We invited public comments on our proposed schedule to publicly display these measures.

Comment: A few commenters requested clarification regarding what could be considered a major injury resulting from a fall for the Percent of Residents Experiencing One or More Major Falls with Injury measure.

Response: We refer readers to the measure details outlined in the CY 2018 HH PPS final rule (82 FR 51727 through 51730) for the Percent of Residents Experiencing One or More Major Falls with Injury measure.

Final Decision: We are finalizing our proposal to publicly report the Percent

of Residents Experiencing One or More Major Falls with Injury measure and 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) measure beginning in April 2022.

d. Revised Compliance Date for Certain HH QRP Reporting Requirements

(1) Background

In the May 8, 2020 **Federal Register** (85 FR 27550), we published an interim final rule with comment period titled ''Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program'' (which we will refer to as ''IFC–2''). In IFC–2, we delayed the compliance date for certain reporting requirements under the HH QRP (85 FR 27595 through 27596). Specifically, we delayed the requirement for HHAs to begin reporting the Transfer of Health (TOH) Information to PAC and the TOH Information to Patient-PAC measures and the requirement for HHAs to begin reporting certain Standardized Patient Assessment Data Elements to January 1st of the year that is at least one full calendar year after the end of the COVID–19 Public Health Emergency (PHE). CMS also delayed the adoption of the updated version of the Outcome and Assessment Information Set (OASIS) assessment instrument (OASIS–E) for which HHAs would report the Transfer of Health (TOH) measures and certain Standardized Patient Assessment Data Elements.

Under IFC–2, HHAs must use OASIS–E to begin collecting data on the two TOH Information measures beginning with discharges and transfers on January 1st of the year that is at least one full calendar year after the end of the COVID–19 PHE. HHAs must also begin collecting data on certain Standardized Patient Assessment Data Elements on the OASIS–E, beginning with the start of care, resumption of care, and discharges (except for the hearing, vision, race, and ethnicity Standardized Patient Assessment Data Elements, which would be collected at the start of care only) on January 1st of the year that is at least 1 full calendar year after the end of the COVID–19 PHE. The delay to begin collecting data for these measures was to provide relief to HHAs from the added burden of implementing an updated instrument during the COVID–19 PHE. We wanted to provide maximum flexibilities for HHAs to respond to the public health threats posed by the COVID–19 PHE, and to reduce the burden in administrative efforts associated with attending trainings, training their staff, and working with their vendors to incorporate the updated assessment instruments into their operations.

At the time we finalized the policy in the IFC–2, we believed that the delay in collection of the TOH Information measures and Standardized Patient Assessment Data Elements would not have a significant impact on the HH QRP. However, the COVID–19 PHE showed the important need for these TOH Information measures and Standardized Patient Assessment Data Elements under the HH QRP. The PHE's disproportionate impact on minority populations demonstrates the importance of analyzing this impact and the needs for these populations to improve quality of care within HHAs, especially during a public health emergency.

(2) Current Assessment of HHAs

To accommodate the COVID–19 PHE, CMS has provided additional guidance and as a result HHAs have adopted new processes as well as modified existing processes. For example, HHAs currently have the option to complete what was required to be a face-to-face encounter to qualify for home health via telehealth and the completion of aspects of required comprehensive assessments via telehealth.[86] CMS also supported PAC providers, including HHAs, by providing requested flexibilities in the delivery of care in response to the PHE. In addition, we assisted providers by conducting sessions for HHAs to share best practices that agencies have identified to address many of the challenges posed by the PHE.

Based upon other flexibilities such as the examples provided and the adoption of best practices, and since finalizing IFC–2, HHAs are in a better position to accommodate reporting of the TOH measures and certain Standardized Patient Assessment Data Elements. Also, recent reports (not available at the time CMS IFC–2 was finalized) suggest that HHAs have the capacity to begin reporting the TOH measures and certain Social Determinant of Health (SDOH) Standardized Patient Assessment Data Elements.[87] Since IFC–2 was finalized, the industry has identified a growing demand for home health services and has noted their ability to meet this demand.[88] [89] [90] [91]

In addition, after evaluating the impact of the compliance date under IFC–2, feasibility around data collection by HHAs, and the support needs of providers during the COVID–19 PHE, we have determined that HHAs now have the administrative capacity to attend trainings, train their staff, and work with their vendors to incorporate the updated assessment instrument, the OASIS–E into their operations.

We now believe that based upon the processes adopted by HHAs, as previously described, the flexibilities afforded to HHAs since the beginning of the COVID–19 PHE, and the importance of the data to the HH QRP, it would be appropriate to modify the compliance date finalized in IFC–2. This may support future activities under Executive Order 13985, entitled ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,'' issued January 20, 2021 (*https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government*).

3. Collection of the Transfer of Health Information to Provider-PAC Measure, the Transfer of Health Information to Patient-PAC Measure, and Certain Standardized Patient Assessment Data Elements Beginning January 1, 2023

We proposed to revise the compliance date from IFC–2 to January 1, 2023. This revised date would begin the collection of data on the Transfer of Health Information to Provider-PAC measure and Transfer of Health Information to Patient-PAC measure, and certain Standardized Patient Assessment Data Elements on the updated version of the OASIS assessment instrument referred to as OASIS–E. This revised date of January 1, 2023, which is a 2-year delay from this original compliance date finalized in the CY 2020 HH PPS final rule (84 FR 60557 through 60610), balances the support that HHAs needed during much of the COVID–19 PHE as

[86] *https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf.*

[87] *https://www.healthaffairs.org/do/10.1377/hblog20201214.543463/full/.*

[88] *https://www.hartfordbusiness.com/article/demand-for-home-health-care-surges-amid-covid-19-shifting-industry-landscape.*

[89] *https://www.forbes.com/sites/sethjoseph/2020/08/05/home-health-care-is-a-bright-light-during-covid-19-with-an-even-brighter-future/?sh=2bfa2c513891.*

[90] *https://www.wsj.com/articles/demand-for-in-home-care-rises-during-coronavirus-11588003076.*

[91] *https://www.csbj.com/premier/businessnews/healthcare/covid-19-boosts-demand-for-home-health-care/article_c65d2b4e-3b17-11eb-a46e-97a2079b065f.html.*

CMS provided flexibilities to support HHAs along with the need to collect this important data.

The need for the Standardized Patient Assessment Data Elements and Transfer of Health data have shown to be even more pressing with issues of inequities that the COVID–19 PHE laid bare. This data that includes addressing SDOH provides information that is expected to improve quality of care for all. Consequently, we proposed to revise the compliance date to reflect this balance and assure that this data collection begins on January 1, 2023.

As stated in the CY 2020 HH PPS final rule, CMS will provide the training and education for HHAs to be prepared for this implementation (84 FR 60554). In addition, if CMS adopts a January 1, 2023 compliance date, CMS would release a draft of the updated version of the OASIS instrument, OASIS–E, in early 2022.

Based upon our evaluation, we proposed that HHAs would collect the Transfer of Health Information to Provider Post-Acute Care measure, the Transfer of Health Information to Patient-PAC measure, and certain Standardized Patient Assessment Data Elements beginning January 1, 2023. We proposed that, accordingly, HHAs would begin collecting data on the two TOH measures beginning with discharges and transfers on January 1, 2023 on the OASIS–E. We also proposed that HHAs would begin collecting data on the six categories of Standardized Patient Assessment Data Elements on the OASIS–E, with the start of care, resumption of care, and discharges (except for the hearing, vision, race, and ethnicity Standardized Patient Assessment Data Elements, which would be collected at the start of care only) beginning on January 1, 2023.

We invited public comment on these proposals.

Comment: Most commenters supported our plan to establishing the OASIS–E effective January 1, 2023 for the corresponding collection of transfer and standardized patient data elements on the assessment tool.

Response: We thank commenters for their support.

Comment: Many commenters who were supportive of this proposal requested that CMS consider the overall burden associated with OASIS–E and to consider ways to mitigate the burden of reporting additional OASIS–E items.

Response: We appreciate the importance of avoiding unnecessary burden on HHAs and will continue to evaluate and consider any burden associated with changes to the OASIS. We have taken into consideration any new burden that our proposals might place on HHAs outlined in the CY 2020 HH PPS final rule (84 FR 60566 through 60608).

Comment: Some commenters did not support the launch of OASIS–E in January 1, 2023, citing the ongoing PHE and the additional burdens an assessment tool launch would incur.

Response: We considered the ongoing impact of the PHE, provisions implemented to support HHAs, in managing the PHE impacts, and management of care provision since the start of the PHE (86 FR 35955 through 35955). Based on a review of the current impacts of the PHE on HHAs nationally, we believe HHAs are well-positioned to successfully implement OASIS–E beginning January 1, 2023.

Comment: Most commenters supported the collection of the Transfer of Health Information to Provider Post-Acute Care and Transfer of Health Information to Patient Post–Acute Care measures and certain standardized patient assessment data elements beginning in January 1, 2023, highlighting the importance of these measures and items in support of CMS quality efforts.

Response: We thank the commenters for their support of this proposal and outcome of these data collection efforts to further build on our ability to assess quality in HHAs.

Comment: Some commenters did not support our proposal to revise the compliance date for the Standardized Patient Assessment Data Elements while the PHE continued, and suggested that CMS defer collection until after the conclusion of the PHE.

Response: We considered the ongoing impact of the PHE, provisions implemented to support providers, including HHAs, in managing the PHE impacts and HHA management of care provision since the start of the PHE. Based on a review of the current impacts of the PHE on HHAs nationally, we believe HHAs are well-positioned to successfully collect these Standardized Patient Assessment Data Elements.

Final Decision: After consideration of the public comments, we are finalizing our proposal that HHAs will collect the Transfer of Health Information to Provider Post-Acute Care measure, the Transfer of Health Information to Patient-PAC measure, and certain Standardized Patient Assessment Data Elements beginning January 1, 2023. We are finalizing that HHAs will begin collecting data on the two TOH measures beginning with discharges and transfers on January 1, 2023 on the OASIS–E. We are also finalizing that HHAs will collect data on the six categories of Standardized Patient Assessment Data Elements on the OASIS–E, with the start of care, resumption of care, and discharges (except for the hearing, vision, race, and ethnicity Standardized Patient Assessment Data Elements, which would be collected at the start of care only) beginning on January 1, 2023.

D. Changes to the Home Health Conditions of Participation

1. Background and Statutory Authority

Since March 2020, CMS has issued a number of regulatory waivers in response to the COVID–19 PHE under the statutory authority granted the Secretary by section 1135 of the Act. That statute permits the Secretary to waive certain statutes and regulations during a public health emergency declared by the President, in order to expand healthcare system capacity while continuing to maintain public and patient safety, and to hold harmless providers and suppliers who may be unable to comply with existing regulations after a good faith effort. Specifically, the Secretary may temporarily waive or modify certain Medicare, Medicaid, and Children's Health Insurance Program (CHIP) requirements (and associated provisions in Title XI) to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in Medicare, Medicaid and CHIP in the emergency area during the emergency period. In such circumstances, providers can be reimbursed and exempted from sanctions under these programs (absent any determination of fraud or abuse).

We have issued HHAs a variety of regulatory waivers. Sections 1861(o) and 1891 of the Act authorize the Secretary to establish the requirements that an HHA must meet to participate in the Medicare Program, and these conditions of participation (CoPs) are set forth in regulations at 42 CFR part 484. We waived selected requirements for HHAs within part 484 for the duration of the PHE. While some of these waivers simply delay certain administrative deadlines, others directly impact the provision of patient care. We have identified waivers related to the requirements for the supervision of home health aides at § 484.80(h)(1) and (2) that we believe will be appropriate as permanent policy. These proposed changes and their respective background information are discussed in detail below.

In addition, in order to implement section 115 of Division CC of the CAA 2021, we proposed to modify the

requirements for the home health initial assessment visit and comprehensive assessment. This statutorily-required modification allows an occupational therapist to complete the initial and comprehensive assessments for Medicare patients when occupational therapy is ordered with another rehabilitation therapy service (speech language pathology or physical therapy) that establishes program eligibility. This would only be permitted if skilled nursing services have not been ordered.

2. Regulatory Provisions

We proposed the following revisions to the HHA CoPs.

a. Home Health Aide Supervision

Home health aides deliver a significant portion of direct home health care. Ensuring that aide services are meeting the patient's needs is a critical part in maintaining safe, quality care. At § 484.80(h)(1) and (2), we differentiate aide supervision requirements based on the level of care required by the patient. Aides caring for a patient receiving skilled care from nurses or therapists must currently have an on-site supervisory visit every 14 days, while aides caring for a patient who is not receiving skilled care must have an on-site supervisory visit every 60 days.

We believe the current 14-day on-site supervisory visit requirement when a patient is receiving skilled services is an important component to assessing the quality of care and services provided by the HHA aide, and to ensure that aide services are meeting the patient's needs. Currently, the regulations require that the 14-day supervisory assessment be conducted by the registered nurse (RN) or other appropriate skilled professional who is familiar with the patient, the patient's plan of care and the written care instructions as described in § 484.80(g). However, we believe it is important to permit HHAs to complete this assessment virtually, in the rare circumstance that an onsite visit cannot be coordinated within the 14-day time period.

We proposed that HHAs be permitted to use interactive telecommunications systems for purposes of aide supervision, on occasion, not to exceed 2 virtual supervisory assessments per HHA in a 60–day period. We proposed to revise the language at § 484.80(h)(1)(i) to require that if a patient is receiving skilled care (that is, skilled nursing, physical or occupational therapy, or speech language pathology services), the home health aide supervisor (RN or other appropriate skilled professional) must complete a supervisory assessment of the aide services being provided, either onsite (that is, an in person visit) or by using interactive telecommunications systems to ensure aides are furnishing care in a safe and effective manner, no less frequently than every 14 days. The home health aide does not need to be present during this supervisory assessment. As outlined in regulation at § 484.80(h)(4), the home health aide supervisory assessment is required to ensure that the aide is furnishing care in a safe and effective manner, such as: Following the patient's plan of care for completion of tasks assigned to the home health aide; maintaining an open communication process with the patient, representatives, caregivers, and family; demonstrating competency with assigned tasks; complying with infection prevention and control policies and procedures; reporting changes in the patient's condition; and honoring the patient's rights. We proposed to define interactive telecommunications systems as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner. The use of interactive telecommunications systems for the aide supervisory assessment could not exceed 2 virtual supervisory assessments per HHA in a 60–day period, regardless of the number of aides or patients associated with a given HHA. If the supervising individual noted an area of concern during the 14-day supervisory assessment, the supervising individual would have to make an on-site in-person visit to the location where the patient was receiving care while the aide performed care, in order to observe and assess the aide, as required at § 484.80(h)(1)(ii) and (iii).

While we proposed to allow this flexibility, we expect that in most instances, the HHAs would plan to conduct the 14-day supervisory assessment during an on-site, in person visit, and that the HHA would use interactive telecommunications systems option only for unplanned occurrences that would otherwise interrupt scheduled in-person visits. Examples of circumstances in which a scheduled on-site in-person visit might not be able to be rescheduled timely within the 14-day window could include a severe weather occurrence, a patient requests to change the date of the scheduled visit, or unexpected staff illness or absence on the planned day for the visit.

We did not propose changes to the requirements for annual aide assessments at § 484.80(h)(1)(iii). In addition to the regularly-scheduled 14-day supervisory assessment and as–needed observation visits for aides providing care to patients receiving skilled services, HHAs are required to make an annual on-site, in person, visit to a patient's home to directly observe and assess each home health aide while he or she is performing patient care activities. The HHA is required to observe each home health aide annually with at least one patient.

We also proposed revisions to the supervisory assessment requirements for aides providing care to patients who are not receiving skilled care services. At § 484.80(h)(2), we currently require that if home health aide services are provided to a patient who is not receiving skilled care, the RN must make an on-site visit to the location where the patient is receiving care from such aide. Such visits must occur at least once every 60 days in order to observe and assess each home health aide while he or she is providing care. This supervisory visit must be performed by a RN because these patients are not otherwise receiving HHA services from other professionals, such as therapists. We continue to receive feedback that this requirement is overly burdensome for the patient and the HHA if multiple home health aides provide care to the same patient. For instance, if a patient has three different home health aides providing care, the nurse is currently required to observe and assess each of the three home health aides while the aide is giving care to the patient. This circumstance would entail three separate nursing supervision visits on the same patient every 60 days. While we believe that the HHA's observation of an aide providing direct care to the patient is important to ensure quality, requiring a patient to receive three separate supervision visits every 60 days may be onerous on the patient and the HHA.

We proposed to maintain the first part of this requirement, that the registered nurse must make a visit in person every 60 days, but would remove the requirement that the RN must directly observe the aide in person during those visits. We would accomplish this by removing the language from 42 CFR 484.80(h)(2) that states, ''in order to observe and assess each home health aide while he or she is performing care,'' and replacing it with ''to assess the quality of care and services provided by the home health aide and to ensure that services meet the patient's needs''. In addition, we proposed to further revise the requirement to state that the home health aide would not need to be present during this visit. We believe that these proposed revisions from an on-site

(direct) observation of each aide while performing care, to an indirect supervision visit to assess the adequacy of the aide care plan, the patient's perception of services provided, and hear any concerns from the patient, may better support the patients' needs by allowing for open communication between the nurse and patient. If the assessment found deficiencies in the aide's performance, the agency would have to conduct (and the home health aide would have to complete) retraining and a competency evaluation for the deficient and all related skills.

In order to ensure appropriate RN supervision of HHA aides caring for patients who are not receiving skilled services, we proposed to add a new requirement to 42 CFR 484.80(h)(2) that would require the RN to make a semi-annual on-site visit to the location where a patient is receiving care in order to directly observe and assess each home health aide while he or she is performing care. This semi-annual in-person assessment would occur twice yearly for each aide, regardless of the number of patients cared for by that aide.

Supervisory visits allow professionals to evaluate whether aides are providing appropriate care as ordered by the patient's plan of care. When RNs or qualified professionals identify a deficiency in aide services, § 484.80(h)(3) requires that the agency conduct, and the home health aide complete, retraining and a competency evaluation related to the deficient skill(s).

We proposed to maintain this requirement at § 484.80(h)(3), but to modify it by adding ''and all related skills.'' We believe that when a deficient area(s) in the aide's care are assessed and verified by the RN, additional related competencies may reflect deficient practice areas that should be addressed. For example, if the patient informs the nurse that they almost fell when the aide was transferring them from bed to a chair, the nurse should assess the aide's technique for transferring a patient in other circumstances beyond transfer to a chair, such as transferring from a bed to bedside commode or to a shower chair.

We requested public comment on our proposed changes to allow virtual supervisory assessments of home health aides for patients receiving skilled care at § 484.80(h)(1)(i), and for the proposed changes to supervision, competency assessment, and retraining for aides providing care to patients receiving all levels of HHA care. We especially welcomed comments from patients and caregivers who have experienced virtual supervisory assessments of home health aides during the PHE.

Comment: Some commenters recommended that CMS eliminate the 14-day home health supervisory visit entirely. However, these commenters did not provide rationale for this recommendation.

Response: We did not propose any changes to the 14-day home health aide supervisory visit at § 484.80(h)(1) other than permitting this visit to be conducted virtually, via interactive telecommunications systems, in the rare circumstance that an onsite visit cannot be coordinated within the 14-day time period. The supervisory visits are conducted when patients are receiving aide services in conjunction with skilled home health services such as skilled nursing, occupational therapy, physical therapy, and speech language pathology services. These visits are the opportunity to verify the aide is following the patient's plan of care; effectively communicating with the patient; demonstrating competency with assigned tasks; complying with infection prevention and control policies and procedures; reporting changes in the patient's condition; and honoring patient rights. We believe these visits are an important component to ensuring that aides furnish care in a safe and effective manner.

Comment: Commenters overwhelming supported the proposed change to permit the 14–day home health aide supervisory visit to be conducted virtually, via interactive telecommunications systems, in the rare circumstance that an onsite visit cannot be coordinated within the 14-day time period. However, some of these commenters expressed concerns regarding the frequency that HHAs would be permitted to exercise this flexibility. Commenters indicated that it would be difficult, if not impossible, for home health agencies to track these visits at the agency level to ensure compliance. Many commenters recommended that CMS apply the frequency so that the virtual visits would be permissible at the patient-level rather than the agency-level. Some comments recommended a specific frequency for each patient, such as one or two per patient per 60-day episode.

Response: In proposing the limit on HHA utilization of virtual home health aide supervisory visits at § 484.80(h)(1), we sought to balance the need for in-person visits with flexibility for unplanned circumstances that may prevent an HHA from complying with this requirement. However, many commenters have indicated that the requirement, as proposed, would be difficult to track and monitor making it ineffective, especially for large agencies. We do believe it important to have this flexibility without creating additional burden for agencies. We are therefore revising the requirement to implement the change at the patient-level. However, we believe the in-person visits are an important component to ensuring that aides furnish care in a safe and effective manner. Therefore, we intend to limit this virtual nurse aide supervisory visit to one per patient per 60-day episode and only in the rare circumstance, from an unplanned occurrence, that an onsite visit cannot be coordinated within the 14-day time period. In our proposed rule, we stated such occurrences may be from items such as, but not limited to, severe weather, a patient requesting to change the date of the scheduled visit, or unexpected staff illness or absence on the planned day for the visit. We believe these examples still apply. However, if the HHA finds it necessary to utilize this virtual option, the HHA will need to document in the patients record the rationale for the virtual visit.

Comment: Several commenters recommended conducting all aide supervisory visits virtually. A commenter recommended removing any artificial cap the number and letting the HHA decide on which visits would be appropriate to be conducted in-person and which would be appropriate for virtual supervision.

Response: We believe the home health services 14-day supervisory visit for aide services at § 484.80(h)(1) should be conducted in-person to ensure that patients are receiving care in a safe and effective manner. Replacing this requirement with completely virtual supervisory visits would reduce oversight of key aspects of care provided by aides.

Comment: A commenter opposed the changes in home health aide supervisory visits permitting a virtual visit in rare circumstances at § 484.80(h)(1), stating that the proposed change is inconsistent with the provision of quality care and limits the ability of HHAs to assess aides. This commenter suggested more evaluation and study be conducted before making the change permanent. Another commenter indicated that virtual visits are subject to numerous problems that may hinder effective home health aide supervision. This commenter indicated that there are frequently technical and economic barriers to virtual visits. They also indicated that many patients prefer in-person visits and that these forge a strong relationship with patients. Finally, the commenter indicated that

virtual aide supervision would hinder the nurse from assessing for changes in the patient's condition that would otherwise be detected with an in–person visit.

Response: We appreciate these comments and the concern for patient safety and quality of care. However, we are proposed this flexibility to facilitate compliance with this requirement in the rare circumstance that an HHA cannot complete the requirement due to unplanned occurrences. Therefore, we expect HHAs to exercise this provision rarely and not more than once per patient every 60-day episode of care. Additionally, we do not expect to see this provision exercised for every patient during every 60-day period. We expect that home health surveyors would investigate such instances while conducting inspection of the home agency and seek supporting narrative in the home health patient record describing why a virtual visit was conducted in each instance. In instances when barriers prevent a virtual supervisory visit via a 2-way audio-visual telecommunications system, such as no internet service or the patient is unable to utilize the telecommunications system, the agency would be non-compliant with the supervisory visit requirement and would need to complete an in-person visit as soon as possible. Finally, the primary purpose of the aide supervisory visit at § 484.80(h)(1) is to assess the aide care plan and services provided by the aide rather than an assessment of the patient that occurs during the skilled visit. The discussion that occurs between the nurse and the patient during this visit allows for open dialogue regarding the aide's services outlined in the plan of care and services carried out by the aide. If in the conversation the nurse notes a potential issue with the aide's care, a competency skills check will be triggered. Therefore, we believe the type and frequency of patient visits provided the necessary supervision to support quality care.

Comment: Several commenters recommended CMS remove the 2-way audio-visual requirement as part of the proposed virtual aide supervisory visit.

Response: We appreciate the requests to remove the proposed language regarding 2-way audio-visual requirement as part of the virtual aide supervisory visit. While we understand some patients may not have access to the internet or the ability to use such technology; we believe it is imperative for the clinician to be able to see the patient during these 2-way audio-visual communications. Utilizing only the phone for audio communications does not allow the clinician to visualize the patient and assess areas such as wounds, mobility and circulation. In regards to the patient using audio-visual technology, being able to visualize the clinician they are speaking with assists in fostering and maintaining the patient and clinician relationship. If the patient does not have access to 2-way audio-visual technology, the agency would be non-compliant with the supervisory visit requirement and would need to complete an in-person visit. Therefore, we are finalizing the use of interactive telecommunications systems as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real–time interactive communication between the patient and distant site physician or practitioner. The use of interactive telecommunications systems for the aide supervisory assessment must not exceed 1 virtual supervisory assessment per patient in a 60-day period, regardless of the number of aides or patients associated with a given HHA.

Comment: Many commenters were supportive of the proposed provision at § 484.80(h)(2) revising the supervisory assessment requirements for aides providing care to patients who are not receiving skilled care services, indicating that the change would significantly reduce burden for HHAs. These commenters stated that the on-site and virtual visits would provide the appropriate balance of supervision for this requirement. However, these same commenters also recommended that CMS monitor the feasibility for HHAs to conduct a semi–annual onsite, aide present, supervisory visit on their non-skilled patients. They stated that they have concerns with the logistics of conducting a semi-annual onsite visit, aide present, for all home health aides.

Response: We appreciate the opportunity to clarify this requirement. CMS has previously received feedback that the prior requirement of an onsite visit every 60 days for each aide providing services to non-skilled patients was overly burdensome for the patient and the HHA if multiple home health aides provide care to the same patient. Retaining the 60-day frequency but changing the requirement for the in-person direct observation of the aide to biannually will decrease the amount of times the HHA must observe each aide in-person. For instance, over the course of 180 days, an HHA providing aide services to a patient receiving care from three aides would be required to coordinate and provide a total of nine supervisor visits with both the nurse and the aide present. Under the new requirement, the HHA would still be required to conduct nine supervisory visits but would only have to coordinate as few as three in-person supervisory with both the nurse and the aide present. Although this will require some coordination and planning on the part of the HHA, we believe this will provide for more efficient planning and scheduling for HHAs from the prior requirements while still maintaining oversight to ensure adequate supervision of the services provided.

Comment: A commenter opposed the proposed change to aide supervision at § 484.80(h)(2) for patients that are not receiving skilled services, permitting this supervisor visit to be conducted without the aide present. The commenter suggested that more evaluation and study be conducted before making the change permanent. Another commenter stated the proposed change results in the RN's assessment and observation of a home health aide occurring three times less frequently. The commenter stated that lack of frequent direct assessment of the home health aide by an RN could jeopardize a patient's health, safety, and ability to recover their highest level of function.

Response: We appreciate these comments regarding the health and safety of patients and concerns for ensuring home health aides provide quality care. An important component to addressing these concerns is ensuring that home health aides enter the workforce meeting minimum qualifications that includes training and competency evaluation. We have extensive requirements specifying the content and duration of home health aide classroom and supervised practical training at § 484.80(b), competency evaluation requirements at § 484.80(c), annual in-service training requirement at § 484.80(d), qualifications for instructors conducting classroom and supervised practical training at § 484.80(e), and eligibility requirements for training and competency evaluation organizations at § 484.80(g). These aspects are critical components to ensuring the aide workforce is adequately trained and qualified to provide home health aide services. Aides are assigned to specific patients with written care instructions for the services they will be providing. Additionally, they will be provided periodic supervision by one of the HHA skilled professionals. Therefore, we do not believe the extensive direct supervision requirements for patients receiving non-skilled services only are necessary and believe these have been overly burdensome for HHAs. Regardless, we do believe that direct

observation of the aide while providing services is an important component of supervision. However, we also believe that patients should also have the opportunity to speak with the skilled professional without the aide present to provide the patient the opportunity to speak freely about any concerns they may have. We believe this is also an important aspect of the supervision component in hearing directly from the patient where some patients may be more reserved in sharing concerns if the aide were present. However, we do acknowledge the commenters concerns regarding the frequency of oversight that has been proposed. We had proposed that each aide receive one direct observation every 6 months for one non-skilled patients for which the aide is providing services. We are revising this requirement so that the aide receives a direct observation every 6 months for each patient to whom the aide is providing services. This is a significant decrease in the planning and coordination for HHAs from the previous requirement of a direct observation supervisory visit for each patient every 60 days. However, it provides an increase in supervisory visits over what was originally proposed. We believe this strikes a balance is reducing burden while providing necessary direct observation in ensuring the health and safety of patients receiving home health aide services.

Comment: Several commenters requested clarification on the skills that would be considered related when a deficient skill was assessed during an aide supervisory visit. While other commenters requested additional examples, to promote consistency for applying this requirement and that CMS align the requirements with the hospice requirements.

Response: We appreciate the commenters support on this issue and the request for clarification. We believe that when a deficient area(s) in the aide's care are assessed and verified by the RN, additional related competencies may reflect deficient practice areas that should be addressed. For example, if the patient informs the nurse that they almost fell when the aide was transferring them from bed to a chair, the nurse should assess the aide's technique for transferring a patient in other circumstances beyond transfer to a chair, such as transferring from a bed to bedside commode or to a shower chair. We believe this is not a one size fits all in determining what is related. Every patient and aide presents a unique dynamic. Ultimately it is the supervising nurse's clinical judgement on a case by case basis to determine what additional competency areas are related.

Final Decision: After consideration of the public comments received, we are finalizing the 14-day aide supervisor visit at § 484.80(h)(1) with modification. Based on public comment, we intend to apply the changes at patient-level rather than the agency-level. Therefore, we will permit the one virtual supervisory visit per patient per 60-day episode. This visit must only be done in rare instances for circumstances outside the HHA's control and must have documentation in the medical record detailing such circumstances. At § 484.80(h)(2) we are finalizing the supervisory visit requirements for non-skilled patients with modification. We are modifying the semi-annual onsite visit to require that this visit be conducted on ''each'' patient the aide is providing services to rather than ''a'' patient. Lastly, after consideration of the public comments we received at § 484.80(h)(3), we are finalizing the assessment of deficient skills as proposed.

b. Permitting Occupational Therapists To Conduct the Initial Assessment Visit and Complete the Comprehensive Assessment for Home Health Agencies Under the Medicare Program

On December 27, 2020, the CAA, 2021 was signed into law. Division CC, section 115 of the CAA 2021 requires CMS to permit an occupational therapist to conduct the initial assessment visit and complete the comprehensive assessment under the Medicare program, but only when occupational therapy is on the home health plan of care with either physical therapy or speech therapy and skilled nursing services are not initially on the plan of care. We proposed to conforming regulation text changes at § 484.55(a)(2) and (b)(3), respectively to implement this provision.

Currently, the requirement at § 484.55(a)(2) provide that when rehabilitation therapy service (speech language pathology, physical therapy, or occupational therapy) is the only service ordered by the physician or allowed practitioner who is responsible for the home health plan of care, and if the need for that service establishes program eligibility, the initial assessment visit may be made by the appropriate rehabilitation skilled professional. We proposed to add new language that allows the occupational therapist to complete the initial assessment for Medicare patients when skilled nursing is not initially on the plan of care, but occupational therapy is ordered with another rehabilitation therapy service (speech language pathology or physical therapy) that establishes program eligibility. This is necessary because a need for occupational therapy alone cannot initially establish program eligibility under the Medicare home health benefit (see section 1814(a)(2)(c) and 1835(a)(2)(A) of the Act). Similarly, at § 484.55(b)(3), we proposed to modify our regulatory language to allow an occupational therapist to complete the comprehensive assessment for Medicare patients when ordered with another qualifying rehabilitation therapy service (speech language pathology or physical therapy) that establishes program eligibility and when skilled nursing is not initially part of the plan of care. It should be noted that the statutory requirements for establishing Medicare program eligibility have not changed. Therefore, only the need for skilled nursing, physical therapy or speech language pathology services can initially establish eligibility for Medicare home health care. However, occupational therapy can maintain eligibility for Medicare home health care after the need for skilled nursing, physical therapy, and speech language pathology services have ceased (see sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act).

Comment: Many commenters were appreciative of the change proposing to permit occupational therapists to conduct the initial assessment visit and the comprehensive assessment for home health services but questioned why occupational therapy alone does not establish program eligibility. A commenter stated that occupational therapists address a wide range of patient populations and diagnoses with a focus on individual patient goals. The commenter stated that occupational therapy is often the most appropriate discipline to assess and evaluate the patient in their home environment and provide interventions to ensure that the patient is able to safely perform the activities and routines they need and want to do while in their home. This commenter requested that CMS support any Federal legislation to make occupational therapy a qualifying service. Another commenter questioned why CMS did not modify the Social Security Act to allow the need for occupational therapy to establish eligibility for home health services.

Response: We appreciate the commenters' support. The eligibility requirements for the coverage of home health services is specified at sections 1814(a)(2)(c) and 1835(a)(2)(A) of the Act. The statute permits payment for

home health services when a patient is confined to a home and has a need for skilled nursing care (other than solely venipuncture for the purpose of obtaining a blood sample) on an intermittent basis or physical or speech therapy. Additionally, payment may also be made when a patient no longer has a need for these services but continues to need occupational therapy. Therefore, occupational therapy alone does not establish initial program eligibility. CMS does not have the statutory authority to permit occupational therapy to be a qualifying service. An act of Congress would be needed to change the statute.

Comment: Many commenters recommended that all rehabilitation therapists (occupational therapists, physical therapist, and speech language pathologists) be permitted to conduct the initial assessment visit and the comprehensive assessment for home health services, even when ordered concurrently with skilled nursing services. Commenters stated that this change would facilitate more timely access to home health services.

Response: The requirements for conducting the initial assessment visit and the comprehensive assessment for home health services are based on sections 1814(a)(2)(c) and 1835(a)(2)(A) of the Act regarding eligibility and payment for home health services. The requirements for these assessments are based on the professional disciplines that will be involved in, and coordinating, care for the patient. Therefore, when nursing is assigned to the case, it is likely the patient will have a greater need for nursing services than other services so we believe that skilled nurses should conduct the initial assessment visit and initiate the comprehensive assessment. In therapy-only cases, it would be appropriate for the therapist to conduct the initial assessment visit and the comprehensive assessment. We did not propose changes beyond those authorized under Division CC, Section 115 of The Consolidated Appropriations Act of 2021, but will consider this issue in future rulemaking.

Comment: A commenter sought clarification on the sequence of services between qualifying services and other Medicare covered services, specifically occupational therapy. The commenter requested clarification on whether or not the sequencing of disciplines providing services, as described in the Medicare Benefits Policy Manual (CMS Pub 100–02), Chapter 7, Section 30.2.11, would be irrelevant following the proposed changes permitting occupational therapists to conduct the initial assessment visit and comprehensive assessment. The commenter wanted to know if occupational therapists would be able to conduct these tasks before other therapy disciplines.

Response: We appreciate the opportunity to clarify this policy. The change implementing Division CC, Section 115 of The Consolidated Appropriations Act of 2021 permits occupational therapists to conduct the initial assessment visit and comprehensive assessment in ''therapy-only'' cases. This is when occupational therapy is on the home health plan of care along with physical therapy and/or speech therapy, but skilled nursing services are not initially on the plan of care. If the physician-ordered plan of care contains orders for a qualifying service other than skilled nursing services (physical therapy and/or speech language pathology services), then occupational therapy may conduct the initial assessment visit and comprehensive assessment prior to the visits from other therapy disciplines; however, the occupational therapist will be required to determine eligibility for the Medicare home health benefit, including homebound status, as part of the initial assessment and comprehensive assessment. In ''therapy-only'' cases for Medicare patients, the sequence in the delivery of the type of therapy is irrelevant as long as the need for a qualifying service is established during the initial assessment visit and when the comprehensive assessment of the patient is completed in accordance with the regulations at § 484.55.

Final Decision: After consideration of the public comments we received, we are finalizing this provision as proposed.

c. Adequacy of Aide Staffing

As stated earlier, ensuring that aide services are meeting the patient's needs is a critical part in maintaining safe, quality care. However, in 2019 MedPAC reported that between 1998 and 2017 home health visits declined by 88 percent. We sought information about the adequacy of aide staffing and solicited comments on the following:

- Whether home health agencies employ or arrange for (under contract) home health aides to provide aide services.
- The number of home health aides per home health agency (both directly employed and under contract), and whether the number has increased or decreased over the past 5 to 10 years.
- The average number of aide hours per beneficiary with aide service ordered on the plan of care.
- The effect of the public health emergency on the ability of HHAs to employ home health aides or arrange for (under contract) the provision of home health aide services.

Comment: Several commenters provided feedback regarding the adequacy of aide staffing. Some of these commenters stated they are experiencing a severe shortage of nurses. While other commenters stated they are experiencing shortages in all disciplines, RN, PT, OT, ST, social worker, and aide staffing. A commenter noted that there had been a 50 percent decrease in the number of aides and professional staff applying for positions. The commenter also stated that ''the pandemic has caused many professionals to change course to stay at home with families, look for remote work opportunities, and remain employed in facilities where they feel safer due to the controlled environment''. Commenters also stated that field safety has become more of concern because of recent social unrest and the pandemic leaving some of our most vulnerable patient service areas under-staffed. A commenter stated that ''agencies are increasingly not staffing for home health aides (current COVID-related circumstances aside). Instead of providing home health aides, agencies refer patients to their non-Medicare, private pay ''affiliates'' for related services, or cost-shift home health aides for patients dually enrolled in Medicare and Medicaid to Medicaid. In the case of Medicare Advantage, many plans simply do not allow home health aide services to be delivered. Denying access to Medicare-covered home health aides for help with activities of daily living as critical as bathing, toileting, grooming, skin care, walking, transferring, and assistance with self-administered medications, puts enrollees at risk of being hospitalized or entering a nursing home because they do not get the support they need to stay safely at home. These practices are costly for Medicare and detrimental to the enrollee's health and wellbeing''. Other commenters suggested that CMS should ensure that Medicare home health agencies serving beneficiaries who require Medicare-covered home health aide services meet the statutorily defined limit of 28 to 35 hours a week and that robust oversight is necessary to ensure that agencies provide necessary care.

Response: We appreciate the robust comments in response to the adequacy of aide staffing questions. Ensuring home health workforce staffing adequacy is an important concern and we take reported shortages seriously.

We will continue to review the information received as we consider ways to ensure that aide services are meeting the patient's needs as such services are a critical part in maintaining safe, quality care.

d. Technical Correction (§ 484.50(d)(5))

In the May 2020 COVID–19 IFC (85 FR 27550), we amended the home health regulations by adding ''or allowed practitioner(s)'' to the CoPs.

Comment: A commenter noted that the ''allowed practitioner'' language is missing from § 484.50(d)(5).

Response: We did not propose this change in the proposed rule. However, we believe making this change in the final rule constitutes a minor technical change to our regulation, which conforms our rule to the statutory language. Therefore, we are making the suggested correction to § 484.50(d)(5).

V. Home Infusion Therapy Services: Annual Payment Updates for CY 2022

A. Home Infusion Therapy Payment Categories

Section 5012 of the 21st Century Cures Act (''the Cures Act'') (Pub. L. 114–255), which amended sections 1834(u), 1861(s)(2) and 1861(iii) of the Act, established a new Medicare home infusion therapy services benefit, effective January 1, 2021. The Medicare home infusion therapy services benefit covers the professional services, including nursing services, furnished in accordance with the plan of care, patient training and education not otherwise covered under the durable medical equipment benefit, remote monitoring, and monitoring services for the provision of home infusion therapy furnished by a qualified home infusion therapy supplier.

Section 50401 of the Bipartisan Budget Act (BBA) of 2018 amended section 1834(u) of the Act by adding a new paragraph (7) that established a home infusion therapy services temporary transitional payment for eligible home infusion suppliers for certain items and services furnished in coordination with the furnishing of transitional home infusion drugs beginning January 1, 2019. The temporary transitional payment began on January 1, 2019 and ended the day before the full implementation of the home infusion therapy services benefit on January 1, 2021.

For the full implementation of the home infusion therapy services benefit on January 1, 2021, we established a unit of single payment for each infusion drug administration calendar day in the individual's home. In accordance with section 1834(u)(1)(A)(ii) of the Act, a unit of single payment must be established for different types of infusion therapy, taking into account variation in utilization of nursing services by therapy type. Furthermore, section 1834(u)(1)(B)(ii) of the Act required that the single payment amount reflect factors such as patient acuity and complexity of drug administration. In the CY 2020 HH PPS final rule with comment period (84 FR 60628), we finalized our proposal to maintain the three payment categories that were utilized under the temporary transitional payments for home infusion therapy services. The three payment categories group home infusion drugs by J-code based on therapy type. The single payment amount for each payment category varies by utilization of nursing services and reflects patient acuity and complexity of drug administration, and; therefore, ultimately reflects variations in infusion drug administration services. Payment category 1 comprises 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 comprises subcutaneous infusions for therapy or prophylaxis, including certain subcutaneous immunotherapy infusions. Payment category 3 comprises intravenous chemotherapy infusions and other highly complex intravenous infusions. We did not propose to make any changes to the three payment categories in CY 2022.

The categories and associated J-codes can be found in the MLN Matters article entitled ''Billing for Home Infusion Therapy Services on or After January 1, 2021'' (MM11880).[92] This list will be updated as new drugs and biologicals are added to the DME LCD and determined to be ''home infusion drugs.'' The list of home infusion drugs and their respective payment categories do not need to be updated through rulemaking when a new drug is added to the DME LCD for External Infusion Pumps (L33794).[93] The payment category may be determined by the DME MAC for any subsequent home infusion drug additions to the DME LCD for External Infusion Pumps (L33794)[94] as identified by the following NOC codes: J7799 (Not otherwise classified drugs, other than inhalation drugs, administered through DME) and J7999 (Compounded drug, not otherwise classified). Payment category 1 would include any appropriate subsequent intravenous infusion drug additions, payment category 2 would include any appropriate subsequent subcutaneous infusion drug additions, and payment category 3 would include any appropriate subsequent intravenous chemotherapy or other highly complex drug or biologic infusion additions.

Section 1861(iii)(3)(C) of the Act defines a home infusion drug as a parenteral drug or biological administered intravenously or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of DME. Such term does not include the following: (1) Insulin pump systems; and (2) a self-administered drug or biological on a self-administered drug (SAD) exclusion list. Division CC, section 117 of CAA 2021 amended section 1861(iii)(3)(C) of the Act so that the previously detailed SAD exclusion in the definition of home infusion drug would not apply to a self-administered drug or biological on a SAD exclusion list if such drug or biological was included as a transitional home infusion drug under subparagraph (A)(iii) of section 1834(u)(7), and was identified by a HCPCS code described in subparagraph (C)(ii) of such section.

In the CY 2021 HH PPS final rule (85 FR 70337), we stated that Hizentra®, a subcutaneous immunoglobulin, was not included in the definition of ''home infusion drugs'' under the benefit beginning January 1, 2021, because it was listed on a SAD exclusion list maintained by the Medicare Administrative Contractors (MACs). We also stated that if it is removed from all the SAD exclusion lists, Hizentra® could be added to the home infusion drugs list in the future. After publication of the CY 2021 HH PPS final rule on November 4, 2020, CAA 2021 was signed into law on December 27, 2020. Division CC, section 117 of CAA 2021 amended the definition of home infusion drugs in section 1861(iii)(3)(C) of the Act as previously noted.

Hizentra® was included as a transitional home infusion drug according to the definition of such drug in section 1834(u)(7)(A)(iii) of the Act, and was identified by a HCPCS code (J1559) described in subparagraph (C)(ii) of such section of the Act. Therefore, consistent with the statutorily amended definition of ''home infusion drug'', the home infusion therapy services related

[92] Billing for Home Infusion Therapy Services on or After January 1, 2021 (MM11880). *https://www.cms.gov/files/document/mm11880.pdf.*

[93] Local Coverage Determination (LCD): External Infusion Pumps (L33794). *https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33794.*

[94] Local Coverage Determination (LCD): External Infusion Pumps (L33794). *https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33794.*

to the administration of Hizentra® are covered under payment category 2 under both the temporary transitional payment from 2019 to 2020, and the permanent benefit beginning January 1, 2021. The DME MACs maintain and update the list of home infusion drugs and their respective payment categories for purposes of the home infusion therapy services benefit under the DME LCD for External Infusion Pumps (L33794). For these routine updates, we will implement such changes through the subregulatory change request process.

B. Payment Adjustments for CY 2022 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 CY 2020 HH PPS final rule with comment period (84 FR 60629) we finalized the use of the geographic adjustment factor (GAF) to adjust home infusion therapy payments for differences in geographic area wages rates based on the location of the beneficiary. We reminded stakeholders that the GAFs are a weighted composite of each Physician Fee Schedule (PFS) localities work, practice expense (PE) and malpractice (MP) expense geographic practice cost indices (GPCIs) using the national GPCI cost share weights. The periodic review and adjustment of GPCIs is mandated by section 1848(e)(1)(C) of the Act. At each update, the proposed GPCIs are published in the PFS proposed rule to provide an opportunity for public comment and further revisions in response to comments prior to implementation. The GPCIs and the GAFs are updated triennially with a 2-year phase in and were last updated in the CY 2020 PFS final rule. The next full update to the GPCIs and the GAFs will be in the CY 2023 PFS proposed rule. For CY 2022, there will be changes to the GAF values for the majority of localities located in California because CY 2022 is the last year of a 5-year incremental transition for the majority of the California localities implemented in 2017 in accordance with the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93) (PAMA 2014). The CY 2022 PFS proposed GAFs are available on the PFS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched*.

In the CY 2020 HH PPS final rule with comment period (84 FR 60628), we stated that the application of the GAF would be budget-neutral, therefore there is no overall cost impact by applying a budget-neutrality factor. We proposed to continue this practice and apply the GAF budget-neutrality factor to the home infusion therapy service payment rates whenever there are changes to the GAFs in order to eliminate the aggregate effect of variations in the GAFs. For CY 2022, the GAF standardization factor would equal the ratio of the estimated national spending total using the CY 2021 GAF to the estimated national spending total using the CY 2022 GAF. Estimates of national spending totals would use home infusion therapy benefit utilization data for CY 2020. We did not receive any comments on the proposal to use the CY 2022 GAFs to wage adjust home infusion therapy payments nor the proposal to continue the application of the GAF standardization factor.

Final Decision: We are finalizing the proposal to use the CY 2022 GAFs to wage adjust home infusion therapy payments for CY 2022. We are also finalizing our proposal to continue the apply a GAF budget neutrality factor to home infusion therapy payments whenever there are changes to the GAFs in order to eliminate the aggregate effect of variations in the GAFS. The CY 2022 GAF standardization factor that will be used in updating the payment amounts for CY 2022 will be 1.0001. The final CY 2022 GAF values will be posted as an addendum on the PFS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched* under the supporting documentation section of the CY 2022 Medicare Physician Fee Schedule Final Rule and posted on the Home Infusion Therapy Billing and Rates webpage.[95]

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 are required to increase the single payment amount from the prior year (that is, CY 2021) by the percentage 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 a productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act as the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity. Section 1834(u)(3) of the Act further states that the application of the productivity adjustment may result in a percentage being less than 0.0 for 1-year, and may result in payment being less than such payment rates for the preceding year.

The CPI–U for the 12-month period ending in June of 2021 is 5.4 percent and the corresponding productivity adjustment is 0.3 percent. Therefore, the final home infusion therapy payment rate update for CY 2022 is 5.1 percent.

3. Initial and Subsequent Visit Adjustment

In the CY 2020 HH PPS final rule with comment period (84 FR 60627), we finalized our policy that the payment amounts for each of the three payment categories for the first home infusion therapy visit by the qualified home infusion therapy supplier in the patient's home will be increased by the average difference between the PFS amounts for E/M existing patient visits and new patient visits for a given year, resulting in a small decrease to the payment amounts for the second and subsequent visits, using a budget neutrality factor. We reminded stakeholders that effective January 1, 2021 there were changes to the office/outpatient E/M visit code set (CPT codes 99201,99215) used to calculate the initial and subsequent visit payment amounts for home infusion therapy. These changes were adopted from the new coding, prefatory language, and interpretive guidance framework that has been issued by the AMA's CPT Editorial Panel (see *https://www.ama-assn.org/practice-management/cpt/cpt-evaluation-and-management*) and include the deletion of code 99201 (Level 1 office/outpatient visit, new patient), and new values for CPT codes 99202 through 99215. The initial visit percentage increase will still be calculated using the average difference between the PFS amounts for E/M existing patient visits and new patient visits for a given year; however, only new patient E/M codes 99202 through 99205 were used in the calculation, as the final policy indicates that the calculation is based on the relative difference between the average of the new and existing patient E/M codes. For CY 2021, the initial visit percentage increase was calculated using the average difference between the CY 2021 PFS amounts for office/outpatient E/M existing patient visits (99211 through 99215) and the CY 2021 PFS amounts for office/outpatient E/M new patient visits (99202 through 99205). In the CY

[95] Home Infusion Therapy Services Billing and Rates. *https://www.cms.gov/medicare/home-infusion-therapy-services/billing-and-rates.*

2021 HH PPS final rule (85 FR 70340), we estimated a 19 percent increase in the first visit payment amount and a 1.18 percent decrease in subsequent visit amounts based on the average difference between the CY 2021 proposed PFS E/M codes amounts for new and existing patients. The percent increase remained 19 percent for the first visit payment amount and the percent decrease remained 1.18 percent for subsequent visit amounts using the final PFS E/M rates for new and existing patients.

Division N, section 101 of CAA 2021 added section 1848(t)(1) of the Act applied a 3.75 percent increase in PFS payment amounts only for CY 2021.[96] Division CC, section 113 of CAA 2021 also delayed the implementation of an add-on E/M code G2211 until CY 2024. Because the PFS relative value units (RVUs) are budget neutral, this delay in the implementation of the add-on code changed the RVUs for all codes under the PFS, including the E/M codes used to calculate the home infusion therapy service payment initial visit percent increase. The updated RVUs and conversion factor after the changes implemented by the CAA 2021 were used to recalculate the CY 2021 payment amounts for home infusion therapy services, and the percent difference used to calculate the initial visit percentage increase. As a result, the initial home infusion therapy service visits increase was updated to 20 percent and the decrease for subsequent visits was updated to 1.33 percent. We noted that the change in the percent increase for initial visits was driven by the delay of the code G2211. While the updated payment amounts (after the changes implemented by the CAA 2021) for the office/outpatient E/M codes were used to recalculate the initial visit increase, removing the 3.75 percent does not impact the average difference between the office/outpatient E/M codes for new patient visits and existing patient because the increase was applied equally. Therefore, after removing the adjustment, the percent increase remains 20 percent for the initial visit payment amounts and a 1.33 percent decrease for all subsequent visit payment amounts.

In the CY 2021 HH PPS final rule (85 FR 70339) we also stated that we would increase the payment amounts for each of the three payment categories for the first home infusion therapy visit by the qualified home infusion therapy supplier in the patient's home by the average difference between the PFS amounts for E/M existing patient visits and new patient visits for a given year. Section 1834 (u)(3) of the Act requires the rates from the previous year to be updated by the percentage increase in the CPI–U for the 12-month period ending in June of the preceding year reduced by a productivity adjustment beginning in 2022. Therefore, we are to update the established payment rates for CY 2021 by the percentage increase in the CPI–U reduced by the productivity adjustment without recalculating the percent difference each year using the updated values for the PFS E/M codes for CY 2022 payment purposes. For CY 2022, we proposed to maintain the 20 percent increase calculated for the initial home infusion therapy service visits and the 1.33 percent decrease calculated for subsequent visits after implementation of the changes mandated by the CAA 2021, which we previously noted did not impact these percentages. Table 34 shows the updated E/M visit codes and the final unadjusted PFS payment amounts (without the 3.75 percent increase implemented by the CAA 2021) for CY 2021, for both new and existing patients, used to determine the increased payment amount for the first visit. We invited comments on our proposal to maintain the percentages calculated for initial and subsequent home infusion therapy service visits calculated after implementing the changes mandated by the CAA 2021. We did not receive any comments on our proposal to maintain the percentages for the initial and subsequent visits.

[96] Medicare Learning Network Connects ''Special Edition: Physician Fee Schedule Update'' (Jan 7, 2021). *https://www.cms.gov/files/document/2021-01-07-mlnc-se.pdf.*

TABLE 34: AVERAGE PERCENT DIFFERENCE BETWEEN PFS E/M CODES FOR NEW AND EXISTING PATIENTS

New Patient E/M Code	Unadjusted CY 2021 PFS Rates	Existing Patient E/M Code	Unadjusted CY 2021 PFS Rates	Percent Difference
		99211	$22.20	NA
99202	$71.30	99212	$54.82	30%
99203	$109.64	99213	$89.12	23%
99204	$163.79	99214	$126.46	30%
99205	$216.25	99215	$176.57	22%
Total	$560.98		$469.17	20%

Source: The unadjusted CY 2021 PFS rates are calculated based on the updated CY 2021 RVUs which were recalculated after the removal of code G2211 and the unadjusted PFS Conversion Factor which is calculated by removing the 3.75 percent increase in PFS payments for CY 2021. The RVUs used to calculate the unadjusted CY 2021 rates e are taken from CY 2021 PFS Final Rule Addendum B, version dated December 29, 2020 (Available at: https://www.cms.gov/files/zip/cy-2021-pfs-final-rule-addenda-updated-12292020.zip; Accessed on 3/17/2021).

Final Decision: We are finalizing the proposal to maintain the 20 percent increase calculated for the initial home infusion therapy service visits and the 1.33 percent decrease calculated for subsequent visits after implementation of the changes mandated by the CAA 2021, which we previously noted did not impact these percentages.

C. CY 2022 Payment Amounts for Home Infusion Therapy Services

As noted previously, Division N, section 101 of CAA 2021 amended added section 1848(t)(1) of the Act, which applied and modified the CY 2021 PFS rates by providing a 3.75 percent increase in PFS payment amounts only for CY 2021.[97] For CY 2022, we will remove the 3.75 percent increase from the PFS amounts used to establish the CY 2021 home infusion therapy payment rates and use the unadjusted CY 2021 rates for the CY 2022 home infusion therapy services payment amounts. Table E2 shows the CY 2021 unadjusted payment rates after removing the 3.75 percent increase. The unadjusted CY 2021 rates will be updated for CY 2022 in accordance with section 1834(u)(3) of the Act using the 5.4 percentage increase in the CPI–U for the 12-month period ending in June of 2021 reduced by the productivity adjustment of 0.3 percent, which results in a 5.1 percent increase.

The unadjusted CY 2021 national home infusion therapy rates are located in Table 35. The final CY 2022 national home infusion therapy services 5-hour payment amounts are located in Table 36.

TABLE 35: CY 2021 UNADJUSTED PAYMENT RATES

HCPCS	Description	CY 2021 National Final Payment Rates	CY 2022 Rate Step Down Adjustment	CY 2021 National Unadjusted Payment Rates
G0068	Adm iv infusion drug in home	$160.18	÷ 1.0375	$154.39
G0069	Adm sq infusion drug in home	$216.43	÷ 1.0375	$208.61
G0070	Adm of chemo drug in home	$269.25	÷ 1.0375	$259.52
G0088	Adm iv drug 1st home visit	$194.81	÷ 1.0375	$187.77
G0089	Adm subq drug 1st home visit	$263.21	÷ 1.0375	$253.70
G0090	Adm iv chemo 1st home visit	$327.46	÷ 1.0375	$315.62

Source: The unadjusted CY 2021 PFS rates are calculated based on the updated CY 2021 RVUs which were recalculated after the removal of code G2211 and the unadjusted PFS Conversion Factor which is calculated by removing the 3.75 percent increase in PFS payments for CY 2021.

[97] Medicare Learning Network Connects ''Special Edition: Physician Fee Schedule Update'' (January 7, 2021). *https://www.cms.gov/files/document/2021-01-07-mlnc-se.pdf.*

TABLE 36: FINAL CY 2022 NATIONAL HOME INFUSION THERAPY SERVICES 5-HOUR PAYMENT AMOUNTS

HCPCS	Description	CY 2021 National Unadjusted Payment Rates	GAF Standardization Factor	CPI-U Reduced by Productivity Adjustment	Final 2022 HIT Payment Amount
G0068	Adm iv infusion drug in home	$154.39	X 1.0001	X 1.0510	$162.28
G0069	Adm sq infusion drug in home	$208.61	X 1.0001	X 1.0510	$219.27
G0070	Adm of chemo drug in home	$259.52	X 1.0001	X 1.0510	$272.78
G0088	Adm iv drug 1st home visit	$187.77	X 1.0001	X 1.0510	$197.37
G0089	Adm subq drug 1st home visit	$253.70	X 1.0001	X 1.0510	$266.67
G0090	Adm iv chemo 1st home visit	$315.62	X 1.0001	X 1.0510	$331.75

Source: The unadjusted CY 2021 PFS rates are calculated based on the updated CY 2021 RVUs which were recalculated after the removal of code G2211 and the unadjusted PFS Conversion Factor which is calculated by removing the 3.75 percent increase in PFS payments for CY 2021.

The geographically adjusted home infusion therapy services payment rates will be released in a forthcoming change request CR and posted on the Home Infusion Therapy Services Billing and Rates webpage.[98] For more in-depth information regarding the finalized policies associated with the scope of the home infusion therapy services benefit and conditions for payment, we refer readers to the CY 2020 HH PPS final rule with comment period (84 FR 60544). While we did not include CY 2022 payment amounts in the proposed rule, we did not receive comments on the approach used to calculate these rates.

Final Decision: The unadjusted CY 2021 rates will be updated for CY 2022 in accordance with section 1834(u)(3) of the Act using the 5.4 percentage increase in the CPI–U for the 12-month period ending in June of 2021 reduced by the productivity adjustment of 0.3 percentage point, which results in a 5.1 percent increase.

VI. Medicare Provider and Supplier Enrollment Changes

A. Background—Provider and Supplier Enrollment Process

1. General Discussion

Section 1866(j)(1)(A) of the Act requires the Secretary to establish a process for the enrollment of providers and suppliers in the Medicare program. The overarching purpose of the enrollment process is to help CMS confirm that providers and suppliers seeking to bill Medicare for services and items furnished to Medicare beneficiaries meet Federal and state requirements to do so. The process is, to an extent, a ''gatekeeper'' that helps prevent unqualified and potentially fraudulent individuals and entities from being able to enter and inappropriately bill Medicare.

Since 2006, we have taken various steps via rulemaking to outline our enrollment procedures. These regulations are generally incorporated in 42 CFR part 424, subpart P (currently §§ 424.500 through 424.570 and hereafter occasionally referenced as subpart P). They address, among other things, requirements that providers and suppliers must meet to obtain and maintain Medicare billing privileges. One such requirement (outlined in § 424.510) is that the provider or supplier must complete, sign, and submit to its assigned Medicare Administrative Contractor (MAC) (hereafter occasionally referenced as ''Medicare contractor'' or simply ''contractor'') the appropriate enrollment application, typically the Form CMS–855 (OMB Control No. 0938–0685). The Form CMS–855, which can be submitted via paper or electronically through the Internet-based Provider Enrollment, Chain, and Ownership System (PECOS) process (SORN: 09–70–0532, Provider Enrollment, Chain, and Ownership System) collects important information about the provider or supplier; such data includes, but is not limited to, general identifying information (for example, legal business name), licensure and/or certification data, and practice locations. After receiving the provider's or supplier's initial enrollment application, CMS or the MAC will review and confirm the information thereon and determine whether the provider or supplier meets all applicable Medicare requirements. We believe this screening process has greatly assisted CMS in executing its responsibility to prevent Medicare fraud, waste, and abuse.

The previously-referenced regulations we have issued since 2006 clarified and strengthened certain components of the enrollment process. Moreover, they enabled us to take further action against providers and suppliers: (1) Engaging (or potentially engaging) in fraudulent or abusive behavior; (2) presenting a risk of harm to Medicare beneficiaries or the Medicare Trust Funds; or (3) that are otherwise unqualified to furnish Medicare services or items. Consistent therewith, and as further discussed in section VI.B. of this final rule, we proposed several changes to our existing provider enrollment regulations in the proposed rule.

2. Legal Authorities

There were two principal sources of legal authority for our proposed provider enrollment provisions. Section 1866(j) of the Act provides specific authority with respect to the enrollment process for providers and suppliers. Sections 1102 and 1871 of the Act furnish general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.

B. Provisions

1. Effective Dates

We proposed to codify in regulation certain effective date practices discussed in CMS Publication 100–08, Program Integrity Manual (PIM) (or in other subregulatory guidance). We believed that incorporating these topics into 42 CFR part 424 would furnish needed clarification and allow the

[98] Home Infusion Therapy Services Billing and Rates. *https://www.cms.gov/medicare/home-infusion-therapy-services/billing-and-rates.*

provider community to furnish public comments thereon.

a. Effective Date of Billing Privileges

Section 424.520 outlines the effective date of billing privileges for provider and supplier types that are eligible to enroll in Medicare. Paragraph (d) thereof sets forth the applicable effective date for physicians, non-physician practitioners (NPP), physician organizations, NPP organizations, ambulance suppliers, opioid treatment programs, and home infusion therapy suppliers. This effective date is the later of: (1) The date of filing of a Medicare enrollment application that a Medicare contractor subsequently approved; or (2) the date that the provider or supplier first began furnishing services at a new practice location. In a similar vein, § 424.521(a) states that the seven aforementioned provider and supplier types can retrospectively bill for services when they have met all program requirements (including state licensure requirements), and services were provided at the enrolled practice location for up to—

- Thirty days prior to their effective date if circumstances precluded enrollment in advance of providing services to Medicare beneficiaries; or
- Ninety days prior to their effective date if a Presidentially-declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Pub. L. 100–707, enacted November 23, 1988), 42 U.S.C. 5121–5206 (Stafford Act), precluded enrollment in advance of providing services to Medicare beneficiaries.

Under the applicable PIM guidance, CMS had applied the effective date policies in §§ 424.520(d) and 424.521(a) to the following additional supplier types: (1) Part B hospital departments; (2) Clinical Laboratory Improvement Amendment labs; (3) intensive cardiac rehabilitation facilities; (4) mammography centers; (5) mass immunizers/pharmacies; (6) radiation therapy centers; (7) physical therapists; (8) occupational therapists; and (9) speech language pathologists.

We proposed to add these nine supplier types to the scope of §§ 424.520(d) and 424.521(a). Our specific regulatory changes were as follows:

First, we proposed in the title and opening paragraph of § 424.520(d) to replace the current enumeration of all seven provider and supplier types therein with a simpler, more generic reference to the ''provider and supplier types'' identified in paragraph (d)(2). This proposed classification would include the aforementioned seven provider and supplier types as well as the nine we proposed to add to § 424.520(d). Consistent with this change, we further proposed to:

- Redesignate existing § 424.520(d)(1) and (2) as, respectively, new § 424.520(d)(1)(i) and (ii).
- List the 16 previously referenced provider and supplier types as new § 424.520(d)(2)(i) through (xvi).

Second, and similar to our change to § 424.520(d), we proposed to revise the title and opening language of § 424.521 to broadly encapsulate the 16 affected provider and supplier types (for example, the title would list them as ''certain provider and supplier types'') rather than to individually list all 16 of them in the title and opening paragraph. As part of this, we also proposed to—

- Redesignate existing § 424.521(a)(1) and (2) as, respectively, new § 424.521(a)(1)(i) and (ii); and
- List the 16 previously discussed provider and supplier types as new § 424.521(a)(2)(i) through (xvi).

b. Effective Dates of Reassignments and Form CMS–855O Enrollments

(1) Reassignments

A Form CMS–855R application (OMB Control No. 0938–0685) must be completed for any individual supplier (reassignor) who wishes to reassign his or her Part B benefits to an eligible entity or individual (reassignee) under § 424.80. Under the applicable PIM guidance, CMS applied the basic principles of §§ 424.520(d) and 424.521(a) to Form CMS–855R reassignments when establishing the effective date of the latter. To codify this in regulation, we proposed to add a new § 424.522, the title of which would state: ''Additional effective dates.'' Paragraph (a) of § 424.522 would specify that a reassignment of benefits under § 424.80 is effective beginning 30 days before the Form CMS–855R is submitted if all applicable requirements during that period were otherwise met.

(2) Practitioner Enrolling Solely To Order or Certify via Form CMS–855O

Under § 424.507, a physician or other eligible professional (as that term is defined in § 424.506(a)) who orders or certifies covered—(1) imaging services; (2) clinical laboratory services; (3) durable medical equipment, prosthetics, orthotics, and supplies; and/or (4) home health services must be enrolled in or validly opted-out of Medicare for the resulting claim to be eligible for payment. There are situations where a physician or other eligible professional indeed wishes to enroll to order and/or certify these services and/or items but is not seeking Medicare billing privileges. In this scenario, he or she will complete the Form CMS–855O (''Medicare Enrollment Application: Enrollment for Eligible Ordering, Certifying and Prescribing Physicians and Eligible Professionals; OMB Control #: 0935–1135). CMS or MAC approval of this application does not grant billing privileges but only permits the individual to order/certify the aforementioned services and/or items.

The PIM states that a Form CMS–855O enrollment effective date is the date on which the Medicare contractor received the application (as opposed to, for instance, the date the contractor approves the application). This permitted the individual to order/certify these services and items for a limited period prior to enrollment. To incorporate this in regulation, we proposed to state in new § 424.522(b) that the effective date of a Form CMS–855O enrollment is the date on which the Medicare contractor received the Form CMS–855O application if all other requirements are met.

c. Comments on Effective Date Proposals

We did not receive specific comments on the foregoing effective date proposals and are therefore finalizing them as proposed and without modification.

2. Rejections and Returns

a. Background and Distinction

Per § 424.525(a), CMS may reject a provider's or supplier's enrollment application for any of the following reasons:

- The prospective provider or supplier fails to furnish complete information on the provider/supplier enrollment application within 30 calendar days from the date of the Medicare contractor's request for the missing information.
- The prospective provider or supplier fails to furnish all required supporting documentation within 30 calendar days of submitting the enrollment application.
- The prospective institutional provider (as defined in § 424.502) does not submit the application fee (in accordance with § 424.514) in the designated amount or a hardship waiver request with the Medicare enrollment application at the time of filing.

The PIM outlines additional factual situations in which an application could have been rejected.

The return of provider enrollment applications, too, is discussed in the PIM. In general, an application has been returned when one of the return

grounds outlined in the PIM applied. These grounds typically involve situations where the provider's or supplier's submission constitutes, in essence, a non-application. This is different from a rejected application in that the latter: (1) Does not automatically involve an invalid submission yet the application, for instance, failed to include certain information or documentation or contains erroneous data; and (2) can be remedied prior to any rejection via the provider's or supplier's submission of a corrected, revised, supplemented, or complete application.

As there has been uncertainty within the provider community regarding the difference between application rejections and returns as well as the grounds for both actions, we proposed to revise § 424.525 and to add a new § 424.526.

b. Rejection and Return Policies

(1) Rejections

The three previously discussed reasons in § 424.525(a) for rejecting an application are currently designated as, respectively, paragraphs (a)(1), (2), and (3). We proposed to include the following ten rejection scenarios (almost all of which had been identified as reasons for rejection in the PIM) within the larger § 424.525(a)(1) category. This means that rejection in these ten situations would only occur if the provider or supplier failed to comply with the requirements of paragraph (a)(1) (for instance, furnishing correct and complete data) within the 30-day period stated therein. The scenarios in question would be designated as § 424.525(a)(1)(i) through (x) and are as follows:

- The application is missing data required by CMS or the Medicare contractor to process the application (such as, but not limited to, names, social security number, contact information, and practice location information).
- The application is unsigned or undated.
- The application contains a copied or stamped signature.
- The application is signed more than 120 days prior to the date on which the Medicare contractor received the application.
- The application is signed by a person unauthorized to do so under 42 CFR part 424, subpart P.
- For paper applications, the required certification statement is missing.
- The paper application is completed in pencil.
- The application is submitted via fax or e-mail when the provider or supplier was not otherwise permitted to do so.
- The provider or supplier failed to submit all of the forms needed to process a Form CMS–855 reassignment package within 30 days of receipt. (For example, a newly enrolling physician who will be reassigning her benefits to a group practice submits a Form CMS–855R application but fails to submit an accompanying Form CMS–855I application.)
- The provider or supplier submitted the incorrect Form CMS–855 application. (For example, the provider submitted a Form CMS–855B when a Form CMS–855A application (Medicare Enrollment Application; Institutional Providers; OMB # 0938–0685) was required.)

Existing § 424.525(b), (c), and (d) address various operational aspects of our rejection policy. We did not propose to revise them. However, and to clarify the scope of § 424.525, we proposed in new § 424.525(e) that § 424.525 applies to all CMS provider enrollment application submissions, including: (1) Form CMS–855 initial applications, change of information requests, changes of ownership (CHOWs), revalidations, and reactivations; (2) Form CMS–588 (Electronic Funds Transfer (EFT) Authorization Agreement; OMB # 0938–0626) submissions; (3) Form CMS–20134 submissions; and (4) any electronic or successor versions of the forms identified in § 424.525(e)(1) through (3). Concomitant with this change, we proposed to remove the word ''prospective'' from § 424.525(a)(1), (2), and (3) and (b). This would clarify that these three rejection grounds apply to enrolled providers and suppliers and not simply to prospective enrollees.

(2) Returns

We proposed in new § 424.526(a) that the following situations constitute grounds for CMS' or the contractor's return of the provider's or supplier's application to the provider or supplier. These grounds, which were discussed in the PIM, would be designated as § 424.526(a)(1) through (13)—

- The provider or supplier sent its paper Form CMS–855, Form CMS–588, or Form CMS–20134 application to the incorrect Medicare contractor for processing. (For example, the application was sent to Contractor X instead of Contractor Y.)
- The Medicare contractor received the application more than 60 days prior to the effective date listed on the application. (This would not apply to: (1) Providers and suppliers submitting a Form CMS–855A application; (2) ambulatory surgical centers; or (3) portable x–ray suppliers.)
- The seller or buyer in a change of ownership submitted its Form CMS–855A or Form CMS–855B application more than 90 days prior to the anticipated date of the sale.
- The Medicare contractor received an initial application more than 180 days prior to the effective date listed on the application from: (1) A Provider or supplier submitting a Form CMS–855A application; (2) an ambulatory surgical center; or (3) a portable x-ray supplier.
- The Medicare contractor confirms that the provider or supplier submitted an initial enrollment application prior to the expiration of the time period in which it is entitled to appeal the denial of its previously submitted application.
- The provider or supplier submitted an initial enrollment application prior to the expiration of their existing reenrollment bar under § 424.535 or reapplication bar under § 424.530(f).
- The application is not needed for (or is inapplicable to) the transaction in question.
- The provider or supplier submitted a revalidation application more than 7 months prior to the provider's or supplier's revalidation due date.
- A Medicare Diabetes Prevention Program (MDPP) supplier submitted an application with a coach start date more than 30 days in the future. (That is, the application lists an MDPP coach who will commence his or her services beginning at least 31 days after the date the Medicare contractor receives the application.)
- The provider or supplier requests that their application be withdrawn prior to or during the Medicare contractor's processing thereof.
- The provider or supplier submits an application that is an exact duplicate of an application that: (1) Has already been processed or (2) is currently being processed or is pending processing.
- The provider or supplier submits a paper Form CMS–855 or Form CMS–20134 application that is outdated and/or has been superseded by a revised version.
- The provider or supplier submits a Form CMS–855A or Form CMS–855B initial enrollment application followed by a Form CMS–855A or Form CMS–855B CHOW application. If the Medicare contractor has done either of the following:

++ Not yet made a recommendation for approval concerning the initial application, both applications may be returned in this scenario.

++ Made a recommendation for approval concerning the initial

application, the Medicare contractor may return the CHOW application. If, per the Medicare contractor's written request, the provider or supplier fails to submit a new initial Form CMS–855A or Form CMS–855B application containing the new owner's information within 30 days of the date of the letter, the Medicare contractor may return the originally submitted initial Form CMS–855A or Form CMS–855B application.

We also proposed in § 424.526 to explain certain operational components of our return policy. First, we proposed in § 424.526(b) that a provider or supplier may not appeal a return of their enrollment application. (Section 424.525(d) contains a similar provision for rejections.) Second, we proposed to effectively duplicate proposed § 424.525(e) in new proposed § 424.526(c) in order to clarify the types of enrollment applications and transactions to which § 424.526 would apply.

(3) Comments on Rejection and Return Proposals

We did not receive specific comments on the foregoing rejection and return proposals and are therefore finalizing them as proposed and without modification.

3. Deactivation

(a) Background

Regulatory policies regarding the provider enrollment concept of deactivation are addressed in § 424.540. Deactivation means that the provider's or supplier's billing privileges are stopped but can be restored (or ''reactivated'') upon the submission of information required under § 424.540. As stated in § 424.540(c), deactivation is intended to protect the provider or supplier from the misuse of its billing number and to protect the Medicare Trust Funds from unnecessary overpayments. A deactivated provider or supplier is not revoked from Medicare and remains enrolled in the program; also, per § 424.540(c), deactivation does not impact the provider's or supplier's existing provider or supplier agreement. However, the provider's or supplier's ability to bill Medicare is halted pending its compliance with § 424.540's requirements for reactivation.

There are currently three grounds for deactivation under § 424.540(a), listed as, respectively, paragraphs (a)(1), (2), and (3):

- The provider or supplier does not submit any Medicare claims for 12 consecutive calendar months.
- The provider or supplier does not report a change in its enrollment information within 90 calendar days of the change. (Changes in ownership or control must be reported within 30 calendar days.)
- The provider or supplier does not furnish complete and accurate information and all supporting documentation within 90 calendar days of receipt of notification from CMS to submit a revalidation application in accordance with § 424.515. (In addition, § 424.550(b) permits deactivation if the prospective new owner in a CHOW fails to submit a new enrollment application containing information concerning the new owner within 30 days of the CHOW. CMS may also deactivate in a CHOW situation if: (1) An incomplete CHOW application is submitted containing material omissions; or (2) CMS has information that makes it question whether the provider agreement will be transferred to the new owner.)

To reactivate one's billing privileges, § 424.540(b) states that the provider or supplier must: (1) Recertify that their enrollment information currently on file with Medicare is correct and furnish any missing information as appropriate; or (2) submit a complete Form CMS–855 application if required by CMS.

We constantly examine the effectiveness of our deactivation processes from both a program integrity and a provider impact perspective. Based on this monitoring, we proposed several changes to § 424.540 that we believed were necessary.

(b) Deactivation Grounds, Deactivation Effective Dates, and Reactivations

First, existing § 424.540(a) contains an opening clause followed by the three existing deactivation reasons, codified as paragraphs (a)(1), (2), and (3). We proposed to add several new deactivation grounds as paragraphs (a)(4) through (8); respectively, they would be as follows:

- The provider or supplier is not in compliance with all enrollment requirements in title 42.
- The provider's or supplier's practice location is non-operational or otherwise invalid.
- The provider or supplier is deceased.
- The provider or supplier is voluntarily withdrawing from Medicare.
- The provider is the seller in an HHA change of ownership under § 424.550(b)(1).

Second, we proposed to revise § 424.540(b)(1) to state that for a deactivated provider or supplier to reactivate its Medicare billing privileges, the provider or supplier must recertify that its enrollment information currently on file with Medicare is correct, furnish any missing information as appropriate, and be in compliance with all applicable enrollment requirements in title 42.

Third, and consistent with existing policy, we proposed in new paragraph (d)(1)(i) to specify that, except as provided in § 424.540(d)(1)(ii), the effective date of a deactivation is the date on which the deactivation is imposed. In paragraph (d)(1)(ii), we proposed that CMS may apply a retroactive deactivation effective date—based on the date that the provider's or supplier's action or non-compliance occurred or commenced (as applicable)—in the following instances (which would include our proposed new deactivation grounds, discussed previously):

++ For deactivation reasons § 424.540(a)(2), (3), and (4), the effective date would be the date on which the provider or supplier became non-compliant (for example, the expiration of the period in which the provider was required to report a change in its enrollment information).

++ For deactivation reason § 424.540(a)(5), the date on which the provider's or supplier's practice location became non-operational or otherwise invalid.

++ For deactivation reason § 424.540(a)(6), the date of death of the provider or supplier.

++ For deactivation reason § 424.540(a)(7), the date on which the provider or supplier voluntarily withdrew from Medicare.

++ For deactivation reason § 424.540(a)(8), the date of the sale.

(c) Payment Prohibition

We also proposed in new § 424.540(e) that a provider or supplier may not receive payment for services or items furnished while deactivated under § 424.540(a). We recognize that the PIM has permitted retroactive payment (once the provider or supplier is reactivated) for services furnished during the period of deactivation; current subregulatory guidance permits the provider or supplier to bill for services or items furnished up to 30 days prior to the effective date of the reactivation. After careful reflection, however, we believed that the most sensible approach from a program integrity perspective is to prohibit such payments altogether. In our view, a provider or supplier should not be effectively rewarded for its non-adherence to enrollment requirements (for example, failing to respond to a revalidation request or failing to timely report enrollment information changes) by receiving payment for services or

items furnished while out of compliance. We stated that proposed § 424.540(e) would not only be an important payment safeguard in this regard but also would: (1) Clarify this important issue (which has created some confusion within the provider community); and (2) allow the public to furnish feedback on the topic.

(d) Additional Revisions

We also proposed three additional clarifications to the deactivation provisions in § 424.540.

First, the opening sentence of § 424.540(c) states that deactivation is considered an action to protect the provider or supplier from misuse of its billing number and to protect the Medicare Trust Funds from unnecessary overpayments. We believed this sentence was too restrictive in that it did not address other reasons for our deactivation policy. Therefore, we proposed to delete it. (The existing second sentence of § 424.540(c) was to remain intact and comprise the whole of revised paragraph (c).)

Second, and as alluded to previously, the concluding sentence of existing § 424.540(a)(2) states that changes in ownership or control must be reported within 30 calendar days as specified in §§ 424.520(b) and 424.550(b). We proposed to clarify that our existing deactivation authority under § 424.540(a)(2) applies to both the changes that must be reported within 90 days and those within 30 days. Thus, we proposed to delete the existing version of this paragraph and stated that deactivation is permitted if the provider or supplier does not report a change to the information supplied on the enrollment application within the applicable time period required under Title 42.

Third, under the applicable PIM guidance, the effective date of a reactivation is generally the date on which the Medicare contractor received the application that was processed to completion. To clarify this policy in regulation, we proposed to add it as new § 424.540(d)(2) with one modification, in that the word ''completion'' would be replaced with ''approval.'' This would make clear that the contractor would have to actually approve the application (rather than merely complete the processing thereof) in order for the reactivation to become effective.

(e) Comments on Deactivation Proposals

We did not receive specific comments on the foregoing deactivation proposals and are therefore finalizing them as proposed and without modification.

4. HHA Capitalization

Under §§ 489.28(a) and 424.510(d)(9), an HHA entering the Medicare program—including a new HHA resulting from a change of ownership if the latter results in a new provider number being issued—must have sufficient funds (known as initial reserve operating funds) available: (1) At the time of application submission; and (2) at all times during the enrollment process, to operate the HHA for the 3-month period after the Medicare contractor conveys billing privileges (exclusive of actual or projected accounts receivable from Medicare). This means that the HHA must also have available sufficient initial reserve operating funds during the 3-month period following the conveyance of Medicare billing privileges.

To enable CMS or the MAC to verify compliance with the requirements of §§ 489.28(a) and 424.510(d)(9), the HHA must submit adequate proof of the availability of initial reserve operating funds. Section 489.28(d) states that such proof must include, at a minimum, a copy of the statement(s) of the HHA's savings, checking, or other account(s) that contains the funds, accompanied by an attestation from an officer of the bank or other financial institution that the funds are in the account(s) and that the funds are immediately available to the HHA. With respect to borrowed funds, § 489.28(e) states that if such funds are not in the same account(s) as the HHA's own non-borrowed funds, the HHA must provide proof that the borrowed funds are available for use in operating the HHA, by providing, at a minimum, a statement similar to the bank/financial institution officer attestation referenced in § 489.28(d).

CMS has recently learned that several national bank chains are no longer providing these attestation statements, thus hindering the ability of HHAs to comply with § 489.28(d) or (e). To remedy this, we proposed to insert the phrase ''(if the financial institution offers such attestations)'' after the term ''financial institution'' as used § 489.28(d) and (e).

We did not receive specific comments on this proposal and are therefore finalizing it as proposed and without modification.

5. HHA Changes of Ownership

Section 424.550(b) states that if there is a change in majority ownership of an HHA by sale within 36 months after the effective date of the HHA's initial enrollment in Medicare or within 36 months after the HHA's most recent change in majority ownership, the HHA's provider agreement and Medicare billing privileges do not convey to the new owner (hereafter occasionally referenced as the ''36-month rule''). Instead, the prospective provider/owner of the HHA must: (1) Enroll in Medicare as a new (initial) HHA; and (2) obtain a state survey or accreditation.

Section § 424.550(b) contains several exceptions to the previously referenced requirement to enroll as a new HHA. One exception (identified in § 424.550(b)(2)(i)) is that the HHA has submitted 2 consecutive years of full cost reports. There has been uncertainty within the provider community as to whether this particular exception applies only to the 2-year cost report period after initial enrollment or also to 2-year cost report periods after the HHA's previous change in majority ownership. To clarify this, we proposed to revise the first sentence of § 424.550(b)(2)(i) to specify that the HHA submitted 2 consecutive years of full cost reports since initial enrollment or the last change in majority ownership, whichever is later. (The second sentence of § 424.550(b)(2)(i), which clarifies that low utilization or no utilization cost reports do not qualify as full cost reports for purposes of § 424.550(b)(2)(i), would remain intact.)

We did not receive specific comments on this proposal and are therefore finalizing it as proposed and without modification.

C. Miscellaneous Comments

We received the following three comments from stakeholders concerning our proposed enrollment provisions as a whole.

Comment: A few commenters expressed support for the codification into regulation of the previously-discussed sub-regulatory guidance. However, one of these commenters requested that CMS: (1) Update the paper enrollment forms to mirror the PECOS system; and (2) explain when paper forms are required instead of submission via Internet-based PECOS.

Response: We appreciate the commenters' support for our proposed codifications. However, we believe that the commenter's two requests are outside the scope of this rule.

Comment: A commenter requested that CMS permit hospitals to update their Form CMS–855A enrollment to furnish home infusion therapy (HIT) and to provide durable medical equipment (DME) to support HIT. The commenter did not believe that hospitals should have to separately enroll as a HIT supplier or DME

supplier to provide these services and items.

Response: We appreciate this comment but believe it is outside the scope of this rule.

VII. Survey and Enforcement Requirements for Hospice Programs

A. Background

Hospice care, as referenced in our regulations at § 418.3, means a comprehensive set of services described in section 1861(dd)(1) of the Act. These services are identified and coordinated by an interdisciplinary group to provide for the physical, psychosocial, spiritual, and emotional needs of a terminally ill patient and/or family members, as delineated in a specific patient plan of care that is individualized and person-centered. Hospice care is a comprehensive, holistic approach to treatment that recognizes the impending death of a terminally ill individual and warrants a change in the focus from curative care to palliative care for the relief of pain and symptom management. Medicare regulations at § 418.3 define ''palliative care'' as patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, emotional, social, and spiritual needs and facilitating patient autonomy, access to information, and choice. Palliative care that is patient-centered and individualized is at the core of hospice philosophy and care practices, and is a critical component of the Medicare hospice benefit.

The goal of hospice care is to help terminally ill individuals continue life with minimal disruption to normal activities while remaining primarily in the home environment. A hospice program uses an interdisciplinary approach to deliver medical, nursing, social, psychological, emotional, and spiritual services through a collaboration of professionals and other caregivers, to make the beneficiary as physically and emotionally comfortable as possible.

As referenced in hospice program regulations at § 418.22(b)(1), to be eligible for Medicare hospice program services, the patient's attending physician (if any) and the hospice program medical director must certify that the individual is ''terminally ill,'' as defined in section 1861(dd)(3)(A) of the Act and our regulations at § 418.3. Under this definition, an individual has a medical prognosis that his or her life expectancy is 6 months or less if the illness runs its normal course. Under the Medicare hospice program benefit, the election of hospice program care is a patient choice and once a terminally ill patient elects to receive hospice care, a hospice interdisciplinary group (IDG) is essential in the seamless provision of primarily home-based services.

As noted in § 489.10(b), in order to be certified in the Medicare program, hospice programs must comply with applicable civil rights laws,[99] including section 504 of the Rehabilitation Act of 1973 and the Americans with Disabilities Act, under which covered entities must take appropriate steps to ensure effective communication with patients and patient care representatives with disabilities, including the provisions of auxiliary aids and services. Additionally, they must take reasonable steps to ensure meaningful access for individuals with limited English proficiency, consistent with Title VI of the Civil Rights Act of 1964. Further information about these requirements may be found at: *http://www.hhs.gov/ocr/civilrights*.

1. Medicare Participation and Survey Activity

Sections 1812(d), 1813(a)(4), 1814(a)(7), 1814(i), and 1861(dd) of the Act, and the implementing regulations in 42 CFR part 418, establish eligibility requirements, payment standards, and procedures; define covered services; and delineate the conditions a hospice program must meet to be approved for participation as a provider in the Medicare program. Part 418, subpart G, provides for a per diem payment based on one of four prospectively-determined rate categories of hospice care (routine home care, continuous home care, inpatient respite care, and general inpatient care), based on each day a qualified Medicare beneficiary is under hospice care (once the individual has elected). This per diem payment is meant to cover all of the hospice services and items needed to manage the beneficiary's care, as required by section 1861(dd)(1) of the Act.

Section 1864(a) of the Act authorizes the State survey agencies (SAs) or other appropriate local agencies, under an agreement with CMS, to perform surveys of health care providers and suppliers to assess their compliance with the applicable Medicare conditions. There are several types of surveys conducted, including initial surveys (to receive initial certification), recertification surveys (to maintain certification), complaint surveys (to investigate complaints), and surveys for validation of the results of accrediting organization (AO) surveys. Only the SA or we may survey certain provider types because a CMS-approved AO option does not exist for their type, while others cannot be surveyed by SAs in accordance with the statute but can only be accredited by a CMS-approved AO (such as providers of the technical component of advanced diagnostic imaging). Based on the SA recommendations from survey findings, we determine whether the provider or supplier qualifies, or continues to qualify, for participation in the Medicare program.

2. CMS Requirements for AOs Approved To Deem Hospice Programs

Section 1865(a) of the Act allows most health care facilities to demonstrate their compliance with the Medicare conditions through accreditation by a CMS-approved program of an AO, instead of being surveyed by SAs for certification. Currently, CMS-approved accreditation programs for facilities under section 1865(a) of the Act include ambulatory surgical centers (ASCs); hospitals; critical access hospitals (CAHs); home health agencies (HHAs); hospices; outpatient physical therapy (OPT) facilities; end-stage renal disease (ESRD) facilities; and rural health clinics (RHCs). This is referred to as ''deeming'' accreditation. This is because CMS-approved AOs are recognized by the Secretary as having programs with accreditation standards that meet or exceed those of Medicare. Therefore, any provider or supplier that is accredited by an AO under a CMS-approved accreditation program is deemed by CMS to have also complied with the applicable Medicare conditions or requirements. Accreditation by an AO is generally voluntary on the part of the providers and suppliers, as they have the choice to seek accreditation from an approved AO or seek Medicare certification through the SA.

CMS is responsible for—(1) providing continuous oversight of the AOs' accreditation programs to ensure that providers or suppliers accredited by the AOs meet the required Medicare conditions or requirements; (2) ensuring that the AOs have formalized procedures to determine whether the health care facilities deemed under their accreditation programs meet the AO's accreditation standards (which must meet or exceed the applicable Medicare program requirements); and (3) ensuring that the AO's accreditation standards and practices for surveying providers

[99] Hospices are also subject to additional Federal civil rights laws, including the Age Discrimination Act, section 1557 of the Affordable Care Act, and conscience and religious freedom laws.

and suppliers meet or exceed the Medicare conditions and practices for approving.

The current regulations at § 488.4 set forth the general provisions for CMS-approved accreditation programs for providers and suppliers. The requirements at § 488.5 set out application and re-application procedures for national AOs that seek to obtain CMS approval of their accreditation programs, often called ''deeming authority.'' These regulations task CMS with the responsibilities of approval and oversight of the AOs' accreditation programs.

As of March 2021, there are three AOs with CMS-approved hospice accreditation programs: Accreditation Commission for Health Care, Inc. (ACHC), Community Health Accreditation Partner (CHAP), and The Joint Commission (TJC). These three AOs survey approximately half of the over 5,000 Medicare-certified hospice programs, while the SAs survey the remaining half.

B. Regulatory Provisions

1. Overview

Division CC, section 407 of the CAA 2021, amended Part A of Title XVIII of Act to add a new section 1822 to the Act, and amended sections 1864(a) and 1865(b) of the Act, establishing new hospice program survey and enforcement requirements. There are nine new survey and enforcement provisions. The law requires public reporting of hospice program surveys conducted by SAs and AOs, as well as enforcement actions taken as a result of these surveys, on the CMS website in a manner that is prominent, easily accessible, searchable, and presented in a readily understandable format. It also removes the prohibition at section 1865(b) of the Act of public disclosure of hospice surveys performed by AOs, requiring that AOs use the same survey deficiency reports as SAs (Form CMS–2567, ''Statement of Deficiencies'' or a successor form) to report survey findings. The law requires programs to measure and reduce inconsistency in the application of survey results among all surveyors. The law requires the Secretary to provide comprehensive training and testing of SA and AO hospice program surveyors, including training with respect to review of written plans of care. The statute prohibits SA surveyors from surveying hospice programs for which they have worked in the last 2 years or in which they have a financial interest, requires hospice program SAs and AOs to use a multidisciplinary team of individuals for surveys conducted with more than one surveyor (to include at least one registered nurse (RN)), and provides that each SA must establish a dedicated toll-free hotline to collect, maintain, and update information on hospice programs and to receive complaints. Finally, the law directs the Secretary to create a Special Focus Program (SFP) for poor-performing hospice programs, sets out authority for imposing enforcement remedies for noncompliant hospice programs, and requires the development and implementation of a range of remedies as well as procedures for appealing determinations regarding these remedies. These enforcement remedies can be imposed instead of, or in addition to, termination of the hospice program's participation in the Medicare program. These remedies include civil money penalties (CMPs), suspension of all or part of payments, and appointment of temporary management to oversee operations.

The provision requiring a new hospice program hotline is effective 1 year after the CAA 2021 enactment (that is, December 27, 2021). Most other provisions are effective on October 1, 2021, including the following—the requirement to use multidisciplinary survey teams, the prohibition of conflicts of interest, expanding CMS-based surveyor training to AOs, and the requirement for AOs with CMS-approved hospice accreditation programs to begin use of the Form CMS–2567 (or a successor form). The public disclosure of survey information and the requirement to develop and implement a range of enforcement remedies is effective no later than October 1, 2022. The other provisions in the legislation were effective upon enactment of the CAA 2021.

In the proposed rule, we proposed a comprehensive strategy to enhance the hospice program survey process, increase accountability for hospice programs, and provide increased transparency to the public. Our goals include: (1) Maintaining the public trust through addressing conflicts of interest and improving survey transparency; (2) addressing inconsistency within the survey process through training and survey team composition and use of common hospice program deficiency reporting mechanisms; and (3) ensuring hospice programs are held accountable for addressing identified health and safety issues. The statutory requirements outlined in the CAA 2021 will address CMS' goals and are in the best interest of patients who receive care in Medicare-participating hospice programs.

We proposed to add new subparts M and N to 42 CFR part 488 to implement the CAA 2021 requirements. Subpart M would provide survey and certification processes while subpart N would provide the enforcement remedies for hospice programs with deficiencies that are not in compliance with Medicare participation requirements. The proposed enforcement remedies for hospice programs with deficiencies are similar to the alternative enforcement sanctions available for HHAs with deficiencies. We proposed to amend §§ 488.2 and 488.28, where appropriate, to include the reference to a hospice program. In addition, we proposed to amend termination and appeal requirements in 42 CFR parts 489 and 498 based on the proposed enforcement remedies.

We received 35 timely pieces of correspondence from hospice industry associations, patient advocacy organizations, AOs with hospice programs, and individuals.

Comment: Multiple commenters expressed support for the steps Congress and CMS are taking to ensure high-quality hospice care and consistent hospice program survey process throughout the nation.

Response: We appreciate the support from the public and agree that ensuring high-quality, safe care for all patients in Medicare-certified hospice programs is paramount and that a consistent survey and enforcement process will help ensure quality.

2. Subpart A—General Provisions

a. Statutory Basis (§§ 488.2 and 498.1)

The CAA 2021 amended Part A of title XVIII of the Act to add section 1822 of the Act on hospice program survey and enforcement procedures. We proposed to amend the requirement at §§ 488.2 and at 498.1 to include this statutory reference to hospice program services. We received no public comments on these provisions, and we are finalizing the regulations at § 488.2 and at § 498.1 as proposed.

b. Application and Re-Application Procedures for National Accrediting Organizations (§ 488.5)

We proposed at § 488.5(a)(4)(x) to require the AOs, as part of a hospice program AO's application and reapplication process, to submit a statement acknowledging that the AO will include a statement of deficiencies (that is, the Form CMS–2567 or a successor form) to document findings of the hospice program Medicare CoPs under section 1822(a)(2)(A)(ii) of the Act and will submit such in a manner specified by CMS.

Currently, the regulations under § 488.5 do not require AOs to utilize the same forms as SA surveyors when documenting survey findings of noncompliance. Specifically, § 488.5(a)(4)(ii) in part states that AOs with CMS-approved programs must submit documentation demonstrating the comparability of the organization's survey process and surveyor guidance to those required for State survey agencies conducting Federal Medicare surveys for the same provider or supplier type. Therefore, AOs are not required to and do not utilize the Form CMS–2567 to report their survey findings, nor do they use the same software system used by SAs to capture the information. Each of the three AOs with CMS-approved hospice program deeming authority has a unique software system that is proprietary to the organization and develops a unique survey report for their deemed hospice organizations. These systems are platforms for AO/client communication as well as document storage and are unique to the AOs standards and process, which may meet or exceed those of CMS. The AO's survey reports, provided to hospice program clients, set out the deficiencies related to CMS requirements, as well as any additional AO standards combined into one report.

The Form CMS–2567 Statement of Deficiencies and Plan of Correction [100] is the legal, documentary basis for how SAs and CMS Federal surveyors note findings of compliance or noncompliance (deficiencies) resulting from an inspection of Medicare-participating providers and suppliers. Our regulations at § 488.18 require that SAs document all deficiency findings on a statement of deficiencies, which is the Form CMS–2567.

Additionally, §§ 488.26 and 488.28 further delineate how findings must be recorded and that CMS prescribed forms must be used. The Form CMS–2567 is used to state concisely and in a standard format, whether or not any deficiencies were identified during a survey, including the evidence to support each finding. Following the survey, the provider/supplier will use the form to document their plan for correcting the identified deficiencies.

The completed Form CMS–2567 exists in PDF format and is also compiled by the CMS Automated Survey Processing Environment (ASPEN) survey software, which is the current national database, designed to help SAs collect and manage healthcare provider data. CMS is in the process of transitioning the ASPEN software system to a new, web-based Internet Quality Improvement and Evaluation System (iQIES).[101] In mid-2021, CMS began transitioning to the new software system on a program-specific implementation schedule, starting with HHAs. It may take several years to fully transition all programs to the new technology platform, and CMS will continue to evaluate documentation needs, make necessary system adjustments with each program that transitions, and train surveyors on system use.

Currently, AOs are able to access the online PDF version of the Form CMS–2567 but do not have access to the CMS ASPEN system, as this software was only designed and distributed for use by SAs and CMS employees. CMS and the AOs must therefore determine the systems process for the inclusion and subsequent collection of the Form CMS–2567 as part of all deemed hospice program surveys completed by AOs. CMS already requires all AO survey reports to identify the comparable Medicare CoPs for each finding of noncompliance with accreditation standards (§ 488.5(a)(4)(iv)). Therefore, in order to meet the new statutory requirement for hospice program AOs to also use the Form CMS–2567 (or a successor form), each of the three CMS-approved hospice program AOs must now develop a way to incorporate this form into their data systems.

As required by § 488.5(a)(11)(ii), AOs submit their survey findings to CMS. The database, *Accrediting Organization System for Storing User Recorded Experiences* (ASSURE), is currently used by AOs to provide CMS with survey data from its deemed facilities. The ASSURE system requires the AO to match its specific survey findings and comparable AO standards to the Medicare conditions or requirements by uploading a spreadsheet text file, designed based on the data fields in the system, or by manually inputting the information. At this time, the ASSURE system does not and cannot develop a statement of deficiencies Form CMS–2567, as ASPEN does for SA surveyors because ASSURE was designed to capture survey details and findings based on the requirements for AOs at § 488.5.

CMS is continuing to assess the systems revisions needed for each of the three database options (ASPEN, ASSURE, and iQIES) to determine if one of the systems could be a future vehicle for hospice program AOs to document their survey findings in the same manner as SAs and subsequently have those forms easily captured by CMS for reporting purposes. Since ASPEN and ASSURE are nearing the end of their lifecycle, as CMS transitions to iQIES, it may not be prudent for CMS to invest resources and redistribute funding intended to update the future system to update legacy systems. At this time, it is most important for AOs to develop a way of incorporating the Form CMS–2567 into their documentation systems. As their systems are proprietary, CMS is unable to tell the AOs exactly how to incorporate the Form CMS–2567, but we will work with the AOs to determine how their version can be submitted to CMS via electronic data exchange.

Separately from the systems issues, the existing format of the Form CMS–2567 must be modified, as it does not currently have a place for the name of the AO that is performing the survey as this form was historically only used by SAs. Consequently, the form directions do not refer to AOs. Since this is a public document that is frequently used by consumers, advocacy groups, and the public as a source of information about the quality of care and facility compliance, CMS must make updates to the form to include AO information so it is clear who performed the survey. CMS sought Office of Management and Budget (OMB) approval of this revised form for information collection, in accordance with provisions of the Paperwork Reduction Act (PRA). For further discussion on PRA implications and timeline, see the collection of information requirements in section XI of this final rule.

We sought public comment on how AOs can customize their proprietary systems to incorporate a version of the Form CMS–2567 and then submit it to CMS via electronic data exchange.

Comment: Several commenters supported the requirement for AOs to utilize the same forms as SA surveyors when documenting survey findings of noncompliance and noted it will promote consistency and standardization.

Response: We thank the public for their support and believe this is one step to ensuring consistency and transparency for the survey process.

Comment: Several commenters asked that CMS engage stakeholders when revising the Form CMS–2567. A suggestion was also made that CMS create and offer an electronic version of the form to all states and AOs.

Response: Given the timeline mandated by the CAA 2021 and the timing of this final rule, CMS needed to quickly revise the existing Form CMS–

[100] CMS–2567 available at: *https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS2567.pdf.*

[101] iQIES is available at: *https://iqies.cms.gov/.*

2567 in order for AOs to integrate it into their documentation systems for use. As required by the Paperwork Reduction Act of 1995 (PRA) requirements, CMS posted public notice of the proposed form changes for a 30-day comment period beginning July 13, 2021. 86 FR 36751. We received one comment on the Form CMS–2567 which was outside the scope of the information collection request. We made the necessary minimal updates to the form, that were needed for AO use, which we described in the proposed rule, 86 FR 35969, 35988, and in the public notice of proposed form changes, 86 FR 35874. If CMS decides to make further revisions to the form, it will go through public notice process again as required by the PRA.

Additionally, as noted in the proposed rule discussion, CMS has begun transitioning to the new software system on a program-specific implementation schedule, starting with HHAs. While it may take several years to fully transition all programs to the new technology platform, SAs and AOs will have access to this system. The Form CMS–2567 is currently generated electronically through the CMS software system and will continue to be as we transition systems and provide additional user access. As the rule notes, the requirement is for the inclusion of a statement of deficiencies, which means the Form CMS–2567 or a successor form. CMS will communicate with stakeholders if we move away from the Form CMS–2567 to a different format.

Comment: A few commenters noted that AO standards contain requirements that exceed those of CMS. The commenters believe that CMS should only require Medicare CoP requirements on the Form CMS–2567 because any additional AO requirements that exceed Medicare CoPs are proprietary standards. In addition, commenters believed it could be confusing to the public if different requirements were listed for each AO and reported on for hospices. Similar to the comment regarding AO standards that exceed CMS requirements, a commenter also questioned whether Form CMS–2567s would also include state licensure requirements.

Response: We explained in the proposed rule that changes to the Form CMS–2567 would require OMB approval via notice and comment, and that process would be separate from the rulemaking for this rule. 86 FR 35988. As noted above, CMS has recently updated the Form CMS–2567 pursuant to the process required by the PRA, including posting the proposed changes for public comment. We made minimal changes to the form, and we have no plans to update the form again to include any AO- or State-specific requirements.

We note that including the Form CMS–2567 in AO reports of survey findings is required by the statute and is one step towards providing hospice patients and families information needed to make decisions on where they wish to receive care, and we want that information to be as clear and useful as possible. Since Medicare participation is partially based on the findings of compliance surveys, which are used to determine whether a hospice program meets the Medicare CoPs, we noted in the proposed regulation, that AOs must include a statement of deficiencies (that is, the Form CMS–2567 or a successor form) to document survey findings for the hospice Medicare CoPs. Although AOs are required to include the Form CMS–2567 in their reports to CMS, this regulation does not require AO surveyors to use the form. For example, while one AO may require its surveyors to use the Form CMS–2567 to record survey findings, another AO may continue to allow its surveyors to use its proprietary survey forms and then translate the survey findings to Medicare CoPs on the Form CMS–2567.

Section 1865(a)(1) of the Act requires that for most provider entities, including hospices, if the Secretary finds that the requirements for accreditation from an AO demonstrate that a provider entity meets or exceeds all applicable conditions, the Secretary must deem such requirements to be met. The statutory language of ''meets or exceeds'' currently allows AOs to develop additional standards that differ from those of Medicare. When an AO applies for ''deeming authority,'' we determine whether its standards meet or exceed ours. With the required inclusion of the Form CMS–2567, we are not restricting AOs from using accreditation standards that exceed the Medicare CoPs. However, including the AO findings of the Medicare hospice CoPs on the Form CMS–2567 allows CMS to post hospice program survey reports from SAs and AOs in a manner that is standardized across both types of surveying entities. We believe that including only CMS requirements, and not state-specific licensure or AO-specific requirements that vary across states and AOs, provides for consistency and avoids confusion. AOs may still use additional standards that exceed the Medicare CoPs, but documentation of whether hospice programs meet those additional standards would not be on the Form CMS–2567.

Comment: A commenter expressed concern that incorporation of the Form CMS–2567 into AO data systems could result in the duplication of data.

Response: AO data systems are proprietary and therefore CMS is not able to address specifics of how AOs will implement the Form CMS–2567 into in their systems. However, as part of the existing regulations at § 488.5(a)(4)(iv), AO survey reports must identify for each finding of non-compliance with accreditation standards, the comparable Medicare CoP, conditions for coverage, conditions for certification, or requirements. Therefore, this data already exists in some form with each AO survey report. Adding the requirement to include the Form CMS–2567 (or a successor form) only changes the format and not the data included. Additionally, we are not restricting the AO from reporting survey findings in their existing AO format to their accredited facilities. AOs would only need to extract the data related to the Medicare CoPs into the Form CMS–2567 (or a successor form) for our purposes. Ultimately, the information will align and be mirrored, but not duplicative.

Comment: A commenter asked if there would be an opportunity for hospice programs to preview the forms before they are submitted to CMS to verify the accuracy of the reported information and to use internally to act to correct the issues. Additionally, the commenter asked what would happen if a deficiency is corrected during the survey process.

Response: We thank the commenter for their clarifying questions and note that this rule does not change the existing survey process outlined in the State Operations Manual at Chapter 2 and Appendix M related to completing the statement of deficiencies and submitting it to the facility for review and response.

Comment: A few commenters requested that CMS clarify if AOs were required to also have facilities use the form to submit their plan of correction (POC) for identified non-compliance. They stated the Form CMS–2567 formatting is antiquated and that AOs have electronic or customer portal POC formats that guide the hospice to create a strong POC, inclusive of all specific actions to be taken, date correction to be completed, and individual responsible for correction process to prevent recurrence with monitoring of corrective actions to ensure they effectively prevent a recurrence. Commenters encouraged CMS to allow AOs to continue the use of their electronic POCs and not require POC

documentation on the Form CMS–2567 itself.

Response: The Form CMS–2567 has a section for listing the deficiencies and another section for providers to document their POC. In 2017, CMS indicated that providers may document POCs in a separate document instead of on the form itself. Stakeholders may refer to CMS memorandum S&C:17–34–ALL which can be found at *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-17-34.pdf*. Hospice programs have the flexibility to document their POCs in their preferred format, including the format currently used by an AO. It is important to note that all elements of an acceptable POC, as outlined in the State Operations Manual, Chapter 2, Section 2728B, are still required regardless of which format or document is used.

Comment: Most commenters expressed serious concerns about the October 1, 2021, statutory deadline and urged CMS to provide enough time for AOs to adapt their technology systems to include the use of the Form CMS–2567. Specifically, AOs with hospice programs stated that the proposed rule did not provide critical information on the process and timing for submitting the Form CMS–2567 and therefore they do not have the information necessary to build their data systems for reporting purposes. AOs reported their need to analyze specifications, design solutions, create new processes, and then perform testing on their systems. Several commenters also noted the need to provide training to familiarize surveyors and other staff with any new processes and procedures that allow for completion and submission of the Form CMS–2567 to CMS. The AOs and several commenters stated CMS should either ask Congress for an extension of the October 1, 2021, statutory deadline or delay at least 3 to 6 months for inclusion and use of the form.

Response: We appreciate the concern and understands that it takes time for AOs to adapt their systems to include the requisite form and then submit it in a manner specified by CMS. We thank commenters for their detailed feedback and note that CMS will develop associated guidance to address many of the concerns raised by commenters regarding the October 1, 2021, deadline, submission, and formatting/reporting. In accordance with § 488.8(b), CMS specifies in a written notice any changes that affect accrediting organizations and provides a timeframe to submit its proposed equivalent changes.

Final Decision: After consideration of the public comments we received, we are finalizing the regulation at § 488.5(a)(4)(x) as proposed.

c. Release and Use of Accreditation Surveys (§ 488.7)

We proposed to add a new § 488.7(c), which would require the posting of the Form CMS–2567 in a manner that is prominent, easily accessible, readily understandable, and searchable for the general public and allows for timely updates. Prior to the CAA 2021, CMS did not have the authority to publish AO surveys for deemed hospice programs except to the extent that the AO survey and its survey information are related to an enforcement action taken by CMS against the provider. However, CMS may post State agency complaints or validation survey results of deemed hospice providers; CMS utilizes the Quality, Oversight, and Certification Reports (QCOR) [102] public website for this purpose.

As mentioned in section VII.B.1.b of this final rule, CMS recognizes there are challenges related to the system implications for use of the Form CMS–2567 by the AOs. However, Congress removed the prohibition that previously allowed AO hospice program survey reports to be considered confidential and proprietary. We proposed to require that AOs release deficiency reports for hospice program surveys conducted under their respective deeming authority to increase transparency among the hospice beneficiary community.

CMS will need to address various system integrations and updates to integrate AO survey results on the Form CMS–2567 as mentioned in section VII.B.2.b of this final rule. Furthermore, CMS recognizes there are limitations and additional data system changes to consider for survey results from the Form CMS–2567 to be displayed in a meaningful and useful format.

We sought public comments as to how data elements from the Form CMS–2567 may be utilized and displayed, and other recommendations of relevant provider information, to assist the public in obtaining a more comprehensive understanding of a hospice program's overall performance. The CAA 2021 requires that CMS publish survey information from the Form CMS–2567 in a way that is readily understandable and useable by the public in a meaningful way. We anticipate the need for us to develop some type of a standard framework that would identify salient survey findings in addition to other relevant data about the hospices' performance. We recognize that the implications of releasing national survey data would require collaboration with industry stakeholders to assure the development is fair and equitable across all hospice programs.

Comment: Many commenters recommended that CMS establish a Technical Expert Panel (TEP) that focuses on the display of survey findings, which should include a wide array of stakeholders. Furthermore, they believe this TEP should be responsible for identifying a comprehensive algorithm to include salient Form CMS–2567 findings related to the scope and severity of deficiencies and additional metrics that will provide a more comprehensive overview of the hospice provider.

Response: The CAA 2021 mandates that survey findings be ''prominent, easily accessible, readily understandable, and searchable for the general public and allows for timely updates.'' CMS recognizes that a metric or algorithm would help to accomplish this goal, which could integrate salient findings from the Form CMS–2567 that may be utilized by the general public to adequately compare hospice providers' services. CMS considers the publication of the Form CMS–2567 to be a first step in meeting the intent of this provision. CMS remains committed to continuing collaboration with hospice stakeholders after this rule is finalized; we appreciate and are considering commenters' suggestion to convene a TEP or other vehicle for gathering stakeholders' input on ways to define a more comprehensive metric or algorithm for public display in guidance.

Final Decision: After consideration of the public comments we received, we are finalizing our proposal at § 488.7(c) with one technical change. We are modifying the regulatory text at § 488.7(c) by changing ''accreditation organization'' to ''accrediting organization'' for internal consistency within § 488.7.

d. Providers or Suppliers, Other Than SNFs, NFs, HHAs, and Hospice Programs With Deficiencies (§ 488.28)

Currently, the regulation at § 488.28 states that if a provider or supplier is deficient in one or more of the standards set out in such provider's or supplier's CoPs, it must submit an acceptable plan of correction (POC) for achieving compliance. An acceptable POC must be received within a reasonable time acceptable to CMS to continue Medicare participation. If it is determined during

[102] Quality, Certification and Oversight Reports (QCOR)

a survey that a provider or supplier is not in compliance with one or more of the standards in the CoPs, it is granted a ''reasonable time'' to achieve compliance. The amount of time depends upon the nature of the deficiency and the survey agency's judgment as to whether the facility can provide adequate and safe care. Ordinarily, a provider or supplier is expected to take the steps needed to achieve compliance within 60 days of being notified of the deficiencies. However, the SA may recommend additional time be granted based on individual situations if it is not reasonable to expect compliance within 60 days. The regulation exempts SNFs, NFs, and HHAs from this requirement; instead, similar provisions are separately set out in the regulations relating to those specific provider types.

Section 1822(c) of the Act authorizes the Secretary to take actions to ensure the removal and correction of condition-level deficiencies in a hospice program through an enforcement remedy or termination or both. The enforcement remedy requirements for hospice programs are outlined in the proposed new subpart N. Regardless of which remedy is applied, a non-compliant hospice program must still submit a POC for approval by the SA or CMS. The POC is a plan developed by the hospice program and approved by the SA or CMS. However, only CMS can impose an enforcement remedy or termination or both. It is the hospice program's written response to survey findings detailing corrective actions to cited deficiencies and the hospice program specifies the date by which those deficiencies will be corrected. We proposed revising the heading for § 488.28 to indicate that hospice programs would also be exempt from the requirements set out in that section because we proposed POC provisions for hospice programs with deficiencies in new subpart N, as discussed in section VII.B.4 of this final rule.

Final Decision: We did not receive comments on this proposal and therefore are finalizing this provision without modification.

3. New Subpart M—Survey and Certification of Hospice Programs

a. Basis and Scope (§ 488.1100)

We proposed at § 488.1100 to specify the statutory authority and general scope of the hospice program. As stated in the proposed rule, this rule is generally based on the rulemaking authority in section 1822 of the Act as well as specific statutory provisions identified in the preamble where appropriate. We received no public comments on this provision and we are finalizing it as proposed.

b. Definitions (§ 488.1105)

We proposed to add definitions at § 488.1105 for survey and enforcement terms for hospice programs. The definitions proposed for hospice programs include the following:

- *Abbreviated standard survey* would mean a focused survey other than a standard survey that gathers information on hospice program's compliance with specific standards or CoPs. An abbreviated standard survey may be based on complaints received or other indicators of specific concern. Examples of other indicators include media reports or findings of government oversight activities, such as OIG investigations.
- *Complaint survey* would mean a survey that is conducted to investigate substantial allegations of noncompliance as defined in § 488.1.
- *Condition-level deficiency* would mean noncompliance as described in § 488.24.
- *Deficiency* would mean a violation of the Act and regulations contained in 42 CFR part 418, subparts C and D, is determined as part of a survey, and can be either standard or condition-level.
- *Noncompliance* would mean any deficiency found at the condition-level or standard-level.
- *Standard-level deficiency* would mean noncompliance with one or more of the standards that make up each condition of participation for hospice programs.
- *Standard survey* would mean a survey conducted in which the surveyor reviews the hospice program's compliance with a select number of standards and/or CoPs to determine the quality of care and services furnished by a hospice program.
- *Substantial compliance* would mean compliance with all condition-level requirements, as determined by CMS or the State.

Comment: An AO commenter stated that they do not conduct what CMS references as a standard level survey, but all initial and renewal reviews are comprehensive surveys.

Response: We acknowledge that the terminology of ''standard survey'' may vary with AOs and that the AOs are still required under Section 1865 of the Act to meet or exceed Medicare requirements and survey procedures. We also note that the new requirement at § 488.1110(a) requires a hospice standard survey (initial, recertification, or renewal) to be conducted not later than 36 months after the date of the previous standard survey. While the regulation at § 488.5(a)(4)(i) provides a timeframe for AOs of no later than 36 months after the prior accreditation effective date, or shorter if there is a statutorily mandated survey interval of fewer than 36 months, we expect hospice AOs to follow the new requirement for hospice surveys at § 488.1110(a) to be comparable with the requirements outlined for SAs. Therefore, the new hospice requirement at § 488.1110(a) would supersede the AO requirement at § 488.5(a)(4)(i) for hospice surveys.

After consideration of the public comments we received, we are finalizing this section as proposed.

c. Hospice Program Surveys and Hospice Program Hotline (§ 488.1110)

At proposed § 488.1110(a), a standard survey would have to be conducted not later than 36 months after the date of the previous standard survey, as specified in section 1822(a)(1) of the Act. A survey could be conducted more frequently than 36 months to assure that the delivery of quality hospice services complies with the CoPs and confirm that the hospice program corrected deficiencies that were previously cited. At proposed § 488.1110(b)(1), a standard or abbreviated standard survey would have to be conducted when complaint allegations against the hospice program were reported to CMS, the State, or local agency. Additionally, we recognize that for AOs with hospice deeming programs, the proposed 36-month surveys would mirror the requirements for AOs to describe the frequency of surveys as part of the AO application process at existing § 488.5(a)(4)(i). That provision requires AOs to agree to survey and re-survey every accredited provider or supplier, through unannounced surveys, no later than 36 months after the prior accreditation effective date, or shorter if there is a statutorily mandated survey interval of fewer than 36 months.

Prior to the amendments made by CAA 2021, section 1864(a) of the Act required that agreements between the Secretary and the State, under which SAs carry out the Medicare certification process, shall provide for the appropriate State or local agency to establish and maintain a toll-free hotline for HHAs. The CAA 2021 amended this requirement to include hospice programs. The provision now requires that a hotline must be maintained: (1) To collect, maintain, and continually update information on HHAs and hospice programs located in the State or locality that are certified to participate in the program established under this

title; and (2) to receive complaints (and answer questions) with respect to HHAs and hospice programs in the State or locality. Section 1864(a) of the Act also provides that such agreements shall provide for the State or local agency to maintain a unit for investigating such complaints that possesses enforcement authority and has access to survey and certification reports, information gathered by any private accreditation agency utilized by the Secretary under section 1865 of the Act, and consumer medical records (but only with the consent of the consumer or his or her legal representative). We proposed to build on these same requirements for hospice programs consistent with the amendments made to section 1864(a) of the Act by CAA 2021.

Therefore, at § 488.1110(b)(2) we proposed that the State or local agency is responsible for establishing and maintaining a toll-free hotline to receive complaints (and answer questions) with respect to hospice programs in the State or locality and for maintaining a unit to investigate such complaints. The requirement for the hotline would be described in the annual CMS Quality, Safety and Oversight Group's Mission and Priority Document (MPD) that serves as the scope of work to which State Agencies are bound contractually via section 1864 of the Act (42 U.S.C. 1395aa).

As we plan for the implementation of the hospice toll-free hotline to streamline and enhance the complaint process for hospice program beneficiaries, we sought public comment on current experiences with the HHA toll-free hotline as required by section 1864(a) of the Act. We sought this information to inform CMS of potential future enhancements to the toll-free hotline. Specifically, what data elements and processes should be included to assure confidentiality and immediate communication with relevant SAs in order to permit them to respond promptly.

Comment: Several commenters were in support of the CAA 2021, which makes permanent the requirement that hospice programs receive recertification surveys no less frequently than once every 36 months. A commenter recommended that CMS clarify the implementation dates related to the hospice surveys.

Response: The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 114–185) initially amended section 1861(dd)(4) of the Act to provide that hospice programs will be subject to a standard survey every 36 months beginning six months from enactment through September 2025. The CAA 2021 amends Title XVIII of the Act to permanently continue this provision. CMS is codifying this mandate into regulation. Hospice programs will continue to be surveyed not later than 36 months after the date of the previous survey.

Comment: A commenter stated that CMS should establish a 6-month timeframe in which surveyors must conduct complaint surveys once an allegation is reported.

Response: We currently maintain a national complaint tracking and prioritization system which prioritizes complaints according to the level of risk for a hospice program's patients. Complaints that indicate the possibility of an immediate jeopardy situation are given the highest priority and investigated by the State as soon as possible. The State Operations Manual, chapter 5, specifies the timeframes and procedures by which all types of complaints should be investigated.

Comment: A commenter stated serious concerns about the ability of SAs and AOs to increase staffing to support more frequent surveys. The commenter states that the Department of Health and Human Services and the Office of the Inspector General (OIG) have documented a substantial backlog of standard surveys, with roughly 71 percent of nursing homes that have gone at least 16 months without a standard survey as of May 31, 2021.

Response: The requirement to survey hospice programs every three years was initially established in the *Improving Medicare Post-Acute Care Transformation Act of 2014* (IMPACT Act) and the CAA 2021 establishes permanency of the continuation of this requirement. We are codifying this mandate into regulation. The AOs are currently required in regulations to survey hospice programs every three years, which is the same as the legislative requirement. Hospice programs will continue to be surveyed not later than 36 months after the date of the previous survey by the SA or AO.

The comment regarding the substantial backlog of nursing home surveys referenced is outside the scope of this rule.

Comment: Several commenters support codifying and making uniform throughout the United States a dedicated toll-free hospice hotlines, each maintained by the appropriate State or local agency. The commenters supported the proposed use of hotlines to collect, maintain, and continually update information, as well as to receive complaints, on hospice programs located in the State or locality that are certified to participate in the Medicare program. Commenters noted that the State or local agency must also maintain a unit for investigating such complaints and that many State or local agencies have existing hotlines for home health agencies.

Response: We appreciate the support. State or local agencies that have existing toll-free hotlines for home health agency complaints can utilize this hotline to also collect and maintain information on hospice programs. However, the State or local agency may decide to establish a separate toll-free hotline specific to hospice programs.

Comment: A commenter recommends that the State or local agency staff the hospice hotline with individuals who are appropriately trained on hospice care and the hospice philosophy.

Response: We believe that the hospice hotline staff decision should be left to the State or local agency. The State or local agency follows the MPD that discusses survey and certification functions as well as the Medicare funding allocation process for states, which directly impacts the work prioritization and planning for the required survey workload in the fiscal year the MPD is issued.

Final Decision: After consideration of the public comments we received, we are finalizing this section as proposed.

d. Surveyor Qualifications and Prohibition of Conflicts of Interest (§ 488.1115)

Section 1822(a)(4)(C) of the Act requires the Secretary to provide training for State and Federal surveyors, and any surveyor employed by an AO, including a training and testing program approved by the Secretary, no later than October 1, 2021. Further, no surveyor can conduct hospice program surveys until they complete training and testing. Currently, AOs are required by § 488.5(a)(8) to provide training to their surveyors. As the AO requirements outlined in § 488.5 also allow for standards and processes that exceed those of CMS, the AO's training may differ from what CMS provides to SA surveyors, thereby creating a potential disparity in overall survey performance. At § 488.1115, we proposed that all SA and AO hospice program surveyors would be required to take CMS-provided surveyor basic training currently available, and additional training as specified by CMS. As part of the AO application and reapplication process under § 488.5(a)(8), the AO is required to submit a description of the content and frequency of the organization's in-service training it provides to survey personnel. Under proposed § 488.1115, AO surveyors

would be required to complete the online CMS hospice program basic training. CMS proposed that until the rule is finalized, that it accepts the current AO training, that was previously reviewed and approved by CMS during the AO application process. State agency surveyors should already be in compliance with this requirement.

AOs already have voluntary access to our Quality, Safety & Education Portal (QSEP), which contains the CMS training. Currently, the trainings are available free of charge through the QSEP website at *https://qsep.cms.gov*, to providers and all entities conducting surveys, including AOs, and the public at large. QSEP training is accessible on an individual, self-paced basis.

The basic training online courses provide surveyors with the key knowledge and skills needed to survey the respective provider or supplier type for compliance with the Medicare conditions and assure an adequately trained, effective surveyor workforce. The online courses also help develop and refine surveying skills, promote critical thinking skills, and enhance surveyors' overall ability to conduct and document surveys. Users may access the online courses at any time. This allows surveyors to refresh knowledge regarding Medicare conditions and processes whenever necessary. The number of learners trained in online courses has steadily increased since the courses' inception.

We are updating the hospice program basic training and including enhanced guidance for surveyors. The updated training will emphasize the assessment of quality of care. Specifically, we would emphasize four ''core'' hospice program CoPs in revisions to the CMS State Operations Manual (SOM) (Pub. 100–07). The four core CoPs (identified in the preamble of the final rule, Medicare and Medicaid Programs; Hospice Conditions of Participation (73 FR 32088, June 5, 2008)) are § 418.52 Condition of Participation: Patient's rights; § 418.54 Condition of Participation: Initial and comprehensive assessment of the patient; § 418.56 Condition of Participation: Interdisciplinary group, care planning and coordination of care; and, § 418.58 Condition of Participation: Quality assessment and performance improvement. The revised training, which we expect to be implemented soon, emphasizes the requirements for establishing individualized written plans of care, which are integral to the delivery of high quality care, and regularly updating these plans with the full involvement of the interdisciplinary team, patients, and their families. Despite the emphasis placed on these core CoPs, hospice programs must comply with all CoPs to achieve successful certification.

We invite commenters to review the trainings by signing up for a free account on the homepage of the CMS website, or by choosing the ''Public Access'' button on the upper right–hand corner of the website homepage. We sought comments on the requirement for continued SA and AO surveyor training as CMS releases additional basic course updates.

In addition to training requirements for surveyors, we proposed to set out the circumstances that will disqualify a surveyor from surveying a particular hospice in accordance with section 1822(a)(4)(B) of the Act. While the statute specifically addresses SA surveyors, CMS takes prohibiting violations of public trust for those representing the Medicare program very seriously and therefore we proposed to include hospice AO surveyors under this requirement as well.

In 2012, as part of an effort to mitigate conflicts of interest in the HHA survey process, CMS established requirements at § 488.735(b) to outline circumstances that disqualify a surveyor from performing HHA surveys. For example, if the surveyor currently serves, or within the previous 2 years has served, on the staff of or as a consultant to the HHA undergoing the survey, they would be disqualified for a conflict of interest.

Chapter 4, Section 4008 of the SOM states, ''conflicts of interest may arise within the Medicare/Medicaid certification program when public employees utilize their position for private gain or to secure unfair advantages for outside associates. The gain involved may or may not be monetary. Abuses of privileged information, abuses of influence, and other abuses of trust are included, regardless of whether a monetary advantage is gained or sought.'' [103]

Individual health care professionals, such as physicians or nurses, commonly have concurrent employment relationships with more than one health care setting. Many health care professionals, such as physicians, physician assistants, and nurse practitioners have multi-setting practices or are employed at more than one health care facility. For example, an RN may work on staff at a hospital but also work at other hospitals through a medical staffing agency. In addition, as employees of a health care facility, these health care professionals could gain a financial interest in the health care facility through means such as being a contributor to the construction costs of a new wing of the facility or buying stock in the facility or its parent corporation. Management employees could be awarded stock or stock options for the facility or its parent corporation as part of their compensation and benefits package.

SAs and AOs often hire surveyors that are also employed at one or more outside health care settings because the professional associations, expertise, knowledge, and skills held by these health care practitioners make them an asset as a surveyor. Longstanding CMS policy noted in section 4008 of the SOM describes examples of scenarios that would be conflicts of interest for SA surveyors of any provider or supplier type, including surveyors who have an outside relationship with a facility that is surveyed by the SA. However, the SOM generally applies only to SA surveyors, not AO surveyors. Therefore, we proposed to codify these long-standing policies for both SA and AO surveyors to ensure there is no conflict of interest between the organization and the surveyor.

We proposed that a surveyor would be prohibited from surveying a hospice program if the surveyor currently serves, or within the previous 2 years has served, on the staff of or as a consultant to the hospice program undergoing the survey. Specifically, the surveyor could not have been a direct employee, employment agency staff at the hospice program, or an officer, consultant, or agent for the surveyed hospice program regarding compliance with the CoPs. A surveyor would be prohibited from surveying a hospice program if he or she has a financial interest or an ownership interest in that hospice. The surveyor would also be disqualified if he or she has an immediate family member who has a financial interest or ownership interest with the hospice program to be surveyed or has an immediate family member who is a patient of the hospice program to be surveyed.

In regards to the definition of ''immediate family member'' in the previous statement, we would utilize the definition of ''immediate family member'' located at § 411.351, which was also used for the development of similar HHA regulations (see 77 FR 67140). This definition includes husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother–in–law, or sister-in-law; grandparent or grandchild;

[103] CMS State Operations Manual, Chapter 4 Medicare State Operations Manual (*cms.gov*) (Internet Only Manual, Pub. 100–07).

and spouse of a grandparent or grandchild.

(1) Surveyor Qualifications

Comment: While commenters notably agreed that requiring all surveyors (AOs, State, and CMS Location surveyors) to take the training offered by CMS provides greater consistency, several expressed concern that the timeline would have the effect of needing to pull surveyors without training from the field by October 1, 2021, contributing to further backlogs in surveys, already large due to COVID restrictions. They requested that CMS allow a period beyond October 1, 2021, the current date for implementation of this provision.

Response: We anticipate that the revised Hospice Basic Training will be available at the time of the implementation of this rule. Surveyors should take the training that is available when their individual need for training arises (that is, upon hiring, or if beginning to survey a provider they have not previously been trained to survey). CMS will post a training update of changes in the new version for surveyors who used the older version of the CMS training so that they will not have to take the new training in its entirety.

Comment: Commenters made several suggestions related to surveyor training. Additional training content areas were suggested such as addressing psychosocial, emotional, and spiritual components of hospice care, that surveyors be trained to cite based on evidence of trends rather than a single violation, and requiring a minimum number of surveys as well as ongoing eligibility via competency evaluation and continuing education.

Response: These comments are outside of the scope of this rule, which focuses on the universality of CMS training. We note that the training suggestions are already included in CMS' hospice training (for example. citing deficiencies based on severity and frequency, and not just a single occurrence, unless it is severe) and among the experiential requirements for surveyors (minimum number of monitored/supported surveys prior to surveying independently). Regarding ongoing training and competency, we rely on the managerial oversight of state agencies, with the assistance of state training coordinators to monitor surveyor abilities, and direct access to the many additional training opportunities available through the CMS Quality, Safety & Education Portal (*QSEP-https://qsep.cms.gov/*).

Comment: Some commenters suggested that surveyors should have ''real-world experience'' or have worked in hospice care to qualify to be hospice surveyors.

Response: We are confident that given the appropriate professional background as a licensed physician, RN, social worker, or chaplain, surveyors' professional training, along with CMS training, that surveyors are fully prepared to conduct accurate field assessments of compliance with the Medicare Conditions of Participation (CoPs). Additionally, surveys are reviewed at multiple levels—through validation surveys and managerial oversight—to corroborate the interpretation of findings and citing of deficiencies.

Comment: A commenter stated that we should include emergency preparedness (EP) in hospice training as well as address patient safety in the comprehensive assessment.

Response: Though not expressly addressed in the comprehensive assessment, safety is addressed throughout the CoPs. EP is addressed in hospice training and references the dedicated State Operations Manual appendix and training related to EP.

Final Decision: After consideration of the public comments we received, we are finalizing the surveyor qualification provisions as proposed.

(2) Prohibition of Conflicts of Interest

Comment: A few commenters expressed appreciation of CMS' proposals to implement conflict of interest provisions as they believe it is an important element of ensuring fairness in the survey process.

Response: We appreciate the support for our prohibition of conflicts of interest proposals.

Comment: A commenter suggested that CMS develop a code of ethics for surveyors instead of trying to list out every potential conflict of interest. Additionally, it was suggested the code of ethics be tied to online training where surveyors would take the training and then sign the code of ethics.

Response: We appreciate the suggestion. Addressing conflicts of interest can be challenging because it is not possible to list all situations which could be construed as potential conflicts. CMS takes the responsibility of public trust very seriously and as such has a long-standing policy in the State Operations Manual, Chapter 4, which outlines the process for abuses of influence, privileged information, or trust arising through conflicts of interest. We believe these provisions address the most common scenarios where conflicts arise nationally. While we believe a code of ethics for surveyors is valuable, we will consider this suggestion for future policy changes that would affect all surveyors and all programs as this is out of scope for the current hospice program rule. We also appreciate the idea of adding it to a CMS training course and will consider this in the future.

Comment: A commenter suggested that CMS consider requiring surveyors to professionally attest that they are aware and will comply with the prohibition on conflicts of interest. Furthermore, they expressed support for a provision requiring surveyors to attest that they intend to judge providers objectively, within the bounds of the CoPs, and refrain from relying on any personal convictions about what end-of-life care should be or ought to entail.

Response: Similar to the suggestion for CMS to consider developing a code of ethics for surveyors, we appreciate the idea of attestation and will consider this in future policy changes for surveyors of all programs.

Comment: A few commenters stated CMS should develop materials to help guide surveyors and survey entities regarding potential conflicts of interest.

Response: We agree that surveyors benefit from training materials related to conflicts of interest. Currently, CMS has training in the Quality Safety and Education Portal (QSEP) related to surveying for non-long term care (non-LTC) that aids learners in developing surveyor skills and proficiency by establishing a foundational understanding of the non-LTC survey process. This training addresses roles and responsibilities of surveyors, including conflicts of interest. CMS will review the existing training and will make updates as needed.

Comment: Multiple commenters suggested additional conflicts of interest for consideration including: Prohibiting anyone who has a family member using hospice services; surveyors with prior work history, including termination from, a hospice being surveyed; or work history with a hospice's competitor. Specifically, commenters expressed concern with conflicts of interest arising out of a work history that includes an employment arrangement with a hospice's competitor and a suggestion was made that CMS consider a 2-year ban on staff from competing hospices surveying each other. However, a few commenters acknowledged addressing such a conflict through regulation may be challenging as it would be difficult to determine how far such a prohibition could extend. Several commenters also noted that adding additional conflicts

could create challenges in small, rural communities but encouraged CMS to provide surveyors with the opportunity to recuse themselves if needed.

Response: We appreciate the additional considerations and concerns that commenters have raised. We are particularly interested in the comments raised regarding competition between hospices and the potential conflict of interest if surveyors work for one hospice and participate in survey activity of known competitors. CMS has considered this potential conflict of interest and agrees with commenters that it would be challenging to address through rulemaking as it could be said that all hospices in certain geographic locations are considered competitors. We also agree with the concerns raised regarding small, rural communities and limiting surveyor availability. CMS, SAs, and AOs are all responsible for evaluating the need for preventive measures to protect the integrity of the survey process. All relevant circumstances that may exist beyond the benchmarks given in regulations should be considered to ensure that the integrity of the survey process is preserved. As noted in the current CMS State Operations Manual policy, SA administrators should require employees to make a declaration of any such outside interests and update this declaration periodically. Therefore, we believe surveyors are responsible for disclosing and recusing themselves as needed.

Final Decision: After consideration of these comments, we are revising § 488.1115 to add a requirement that surveyors must disclose actual or perceived conflicts of interest prior to participating in a hospice program survey and be provided the opportunity to recuse themselves as necessary.

e. Survey Teams (§ 488.1120)

The CAA 2021, adding section 1822(a)(4)(A) of the Act, calls for the use of multidisciplinary survey teams when the survey team comprises more than one surveyor, with at least one person being a RN. Currently, the SOM, Appendix M—Guidance to Surveyors requires that each hospice program survey team include at least one RN, and, if the team is more than one surveyor, the additional surveyors should include other disciplines with the expertise to assess hospice program compliance with the conditions of participation. We proposed at § 488.1120 under a new subpart M to require that all survey entities—SA or AOs—include diverse professional backgrounds among their surveyors to reflect the professional disciplines responsible for providing care to persons who have elected hospice care. Such multidisciplinary teams should include professions included in hospice core services at 42 CFR 418.64—physicians, nurses, medical social workers, pastoral or other counselors—bereavement, nutritional, and spiritual. To fulfill CAA 2021 requirements, SAs and AOs might need time to reconstruct their workforce to accommodate the new requirements for hospice program surveys to utilize multidisciplinary teams. We recognize that SAs and AOs may incur additional costs, given the varying, and potentially higher rates of average pay for some disciplines. Surveying entities may need up to 1 year to hire and train surveyors from the needed disciplines, depending on the timing of the attrition of current staff and workforce availability of the appropriately experienced professionals. In addition, we seek to better understand the current professional makeup of survey entities' workforces. In order to track compliance with this provision, we proposed to establish a baseline knowledge by asking survey entities to tell us: (1) The extent to which their surveys are conducted by one professional, who by regulation must be an RN; (2) the professional makeup of their current workforce; and (3) estimate a timeframe in which they could effectuate multidisciplinary teams if not already in place. We would provide additional guidance with instruction for the survey entities regarding the submission of this information to CMS.

Our rules at § 418.56 require that hospice programs use interdisciplinary teams or groups to determine a holistic plan of care for the hospice program patient and family. The interdisciplinary group or IDG, must include, but not be limited to a physician, an RN, a medical social worker, and pastoral or other counselor. Therefore, we proposed that when the survey team comprises more than one surveyor, the additional slots would be filled by professionals from among these disciplines, and we sought comments on this approach. Similarly, section 1819(g)(2)(E) of the Act and 42 CFR 488.314 require that long-term care (LTC) facility surveys be conducted by a multidisciplinary team of professionals, at least one of whom must be a RN.

Our certification guidance in Chapter 2 of the SOM provides details as to how the survey agency might select the appropriate disciplines for a survey team. SOM, Chapter 2 states that various professional disciplines should represent the expertise needed to determine compliance with the CoPs, standards, or requirements for that provider/supplier group. In establishing multidisciplinary teams under new section 1822(a)(4)(A) of the Act, we would consider, as a model, our current CMS guidance for LTC facilities, which uses specialty surveyors with expertise not typically included in a survey team (for example, a pharmacist, physician, or registered dietitian), who may not be needed for the entire survey, but must be onsite at some time during the survey.

Comment: Several commenters provided feedback on the makeup of survey teams, in response to the proposed provision that survey teams should be multi-disciplinary. Commenters suggested that a licensed practical nurse should be included on the survey team.

Response: We proposed that the survey teams be multidisciplinary and that at least one member of the survey team must be an RN. These are statutory requirements, and they are consistent with the current guidance in the SOM, Appendix M. Because an RN will be on every survey team, to ensure that the survey team is multidisciplinary, if there is more than one surveyor, then the additional team members must be selected from other disciplines included in the interdisciplinary group.

Comment: Several commenters suggested that the survey team members be required to have prior experience in the hospice field.

Response: We do not require that surveyors have actual hospice experience, nor target particular types of hospice expertise (that is, former hospice administrators). It is at the discretion of the hiring state survey agencies to identify individuals whose background is suitable. All surveyors must successfully complete CMS-based training to ensure that they are capable of conducting accurate and complete surveys. CMS's training includes substantial detail in content and interactive learning in the hospice philosophy of care and all hospice regulatory requirements, as well as guidance in survey technique and procedures specific to the CoPs. With the appropriate professional background (that is, credentialing in one of the disciplines included in the IDG) and CMS's hospice-specific training, we believe surveyors will have the expertise needed to conduct surveys for compliance with Medicare's well-prescribed requirements.

Final Decision: After consideration of the public comments we received, the proposed policy is being finalized without modification.

f. Consistency of Survey Results (§ 488.1125)

New section 1822(a)(3) of the Act requires that each State and the Secretary implement programs to measure and reduce inconsistency in the application of hospice program survey results among surveyors. In addition to ensuring consistency of hospice survey results across SAs, we believe that this also applies to reducing discrepancies between SA and AO surveys of hospice providers. Survey consistency has been a longstanding concern for CMS at multiple levels—interstate and intrastate, as well as Federal to State. While there are multiple strategies currently in place, as described in this section, to directly address the matters presented in the CAA 2021, we proposed at § 488.1125 to enhance the requirements of the State Performance Standards System (SPSS) to direct States to implement processes to measure the degree or extent to which surveyors' findings and determinations are aligned with Federal regulatory compliance and with an SA supervisor's determinations. Given the variation among State agencies with respect to the number of surveyors deployed for a particular survey, or the distribution of surveyor professional backgrounds, in the proposed rule we noted that we expected to promulgate objective measures of survey accuracy, and sought public opinion on what measures would be feasible for States. We desired measures that are both specific and utilize currently collected data, if possible. Accuracy could include whether a survey finding aligns with the selected regulatory deficiency, as well as failing to cite such findings. When applied to survey findings, the measures should allow CMS to determine the need for corrective action or education for individual surveyors or for a group of surveyors. If systemic issues were found, CMS would be prepared to enhance its training to address systemic issues found as a result of interstate analysis.

CMS monitors the consistency of SA surveys through a review of an SA's Form CMS-2567s (the Statement of Deficiencies and Plan of Correction), which is conducted by its assigned CMS Survey Operations Group (SOG) Location, and consistency among AOs through validations surveys conducted by SAs. The SAs perform validation surveys on a sample of providers and suppliers (such as hospitals, CAHs, ASCs, Hospice Programs, and HHAs) accredited by the AOs. Validation surveys report disparate findings as the percentage of validation surveys that have conditions identified by the SA but missed by the AO survey team. This percentage is referred to as the ''disparity rate'' and is tracked by CMS as an indication of the quality of the surveys performed by the AO. This is reported annually in a report to Congress (QSO–19–17–AO/CLIA). The most recent report can be found at *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Administrative-Information-Memos-to-the-States-and-Regions-Items/AdminInfo-20-02-ALL*.

Using the disparity rate approach used with AOs, where surveys are reviewed for condition-level deficiencies the AO fails to identify, we proposed to analyze trends in the disparity rate among States, as well as among AOs. State surveys results would be reviewed to identify findings that were potentially worthy of condition-level citation but were not cited.

We believe that the disparate deficiency citations between AO surveyors and SA surveyors may, in part, be attributed to differences in surveyor training and education. This variation may be due to inconsistencies in AO training with the CMS-provided SA basic surveyor training. We believe that uniform surveyor training would increase the consistency between the results of the surveys performed by SAs and AOs, and have a positive impact on the high disparity rates. We also want to align our processes more closely to those CMS has found effective for other provider types. For instance, what we proposed for hospice programs is similar to what is done with nursing homes, where validation surveys are described at section 1819(g)(3)(A) of the Act as ''. . . a representative sample . . . in a sufficient number to allow inferences about the adequacies of each State's surveys. . .(B). . .each year concerning at least 5 percent of the number of skilled nursing facilities . . .'' Even though AOs are not currently included in the CMS SPSS, we expect that a similar methodology would be applied to all hospice surveying entities, including AOs with an approved hospice program. Just as CMS monitors disparate results across States in their adherence to Federal processes for determining deficiencies, investigating, and reporting complaints, it requires States to monitor the quality of its surveyors' survey activity and actions. Performance measures are applied to all surveying entities to assess consistency. If CMS finds that surveying entities—SAs and AOs—do not meet the performance standards, they must develop and implement a corrective action plan.

The SPSS, established annually, provides for oversight of SA performance when conducting surveys to ensure that Medicare and Medicaid certified providers and suppliers are compliant with Federal CoPs, to improve and protect the health and safety of Americans. This oversight allows CMS to determine that surveyors are thorough, accurate, and consistent when they determine if a hospice program provider is complying with the Medicare CoPs. Survey findings with respect to a hospice program can include: (1) Standard level deficiency—where the hospice program is not complying fully with CoPs, which need corrective action; (2) condition-level deficiencies—which require remediation and could lead to termination of the hospice program; or, (3) immediate jeopardy (IJ) level—where beneficiaries are present in situations where significant harm could occur and which need to be addressed without delay. SA supervisors are responsible to ensure that surveyors' findings (from observations, interviews, and document reviews) are consistent with their determination of IJ, and standard- or condition-level deficiency where a hospice program is not compliant with a condition of participation.

To reduce inconsistencies in survey results among surveyors, we proposed to require agencies that review other entities' survey findings for missed condition-level deficiency citations (disparities) (SAs for AOs, and CMS SOG locations for SAs) to notify each survey entity of its disparity rate annually and to require a formal corrective plan as part of the survey entity's (SA or AO) Quality Assurance program. A disparity rate above 10 percent in 2 consecutive cycles would trigger remedial activity such as implementing corrective action through education, mentoring, or other processes to align surveyors' actions, and determinations of deficiencies with regulatory requirements.

Comment: Commenters supported our plans to create more opportunities for consistency between survey entities as well as between surveyors within the same surveying entity. They noted CMS' plan to require universal use of CMS hospice training as a key element of this effort. A commenter suggested that in this effort, CMS should provide AO surveyors with access to QSEP at the same level as state surveyors, so that all content and not just Basic Training is available to the AO surveyors as a means of greater consistency across agencies.

Response: We will modify access to QSEP for AO surveyors on the same basis as for state surveyors, so that all appropriate content is available, though only Hospice Basic will be required by the AO surveyors.

Final Decision: After consideration of the public comments we received, the proposed policy is being finalized without modification.

g. Special Focus Program (SFP) (§ 488.1130)

Section 1822(b) of the Act requires the Secretary to conduct a Special Focus Program for hospice programs that the Secretary has identified as having substantially failed to meet applicable requirements of the Act. We proposed at § 488.1130 to develop a hospice Special Focus Program (SFP) to address issues that place hospice beneficiaries at risk for poor quality of care through increased oversight, and/or technical assistance. We proposed that specific criteria would be used to determine whether a hospice program participates in the SFP. The proposed criteria are as follows: A history of condition-level deficiencies on two consecutive standard surveys, two consecutive substantiated complaint surveys, or two or more condition-level deficiencies on a single validation survey (the validation survey with condition-level deficiencies would be in addition to a previous recertification or complaint survey with condition-level deficiencies). A subset of hospice programs that meet the proposed criteria would be selected to be in the SFP, and those hospice programs would be surveyed every 6 months, which may result in additional enforcement remedies and/or termination. CMS uses a similar program with LTC facilities and outlined the following protocol for a hospice SFP in the proposed rule:

- The SA and CMS SOG location would receive a list from CMS of all hospice programs that meet the established criteria at proposed § 488.1130(b) for placement in the SFP (Candidate List). The SA would work with the CMS SOG location to select hospice programs from the list provided by CMS that would be selected for the SFP based on State priorities. In the event that no hospice programs in a State meet the established criteria, then the State SA would not have a hospice program in the SFP at that time.
- While a hospice program is in the SFP, the SA would survey the facility at least once every 6 months, as required by the CAA 2021, and may include progressively stronger enforcement actions in the event of a hospice program's continued failure to meet the requirements for participation with the Medicare and Medicaid programs.
- Once an SFP hospice program has completed 2 consecutive 6-month SFP surveys with no condition-level deficiencies cited, the facility would graduate from the SFP. If the hospice program did not meet the requirements to graduate, it would be placed on a termination track.

We sought public comment regarding the SFP, specifically the following issues:

- Should CMS utilize a similar criteria, process, or framework for the SFP as outlined in the current Special Focus Facility Program used for LTC facilities? What if any differences should CMS consider to enhance the overall impact of the hospice SFP?
- Are there additional selection criteria that CMS should consider for the identification and participation in the SFP? This may include use of current or future data elements that could be incorporated into a more comprehensive algorithm.
- Should we utilize a Technical Expert Panel (TEP) to enhance the SFP in terms of selection, enforcement and technical assistance criteria while a hospice is in the program? A TEP may assist CMS by identifying contextual data and relevant information that would help the public in obtaining a more comprehensive understanding of the Form CMS–2567 survey data and the overall performance of a hospice provider, in addition to what data to include, how to make this information useful and meaningful on a CMS website.

Comment: Many commenters believe that CMS should not implement this provision until a comprehensive framework can be established that focuses on a targeted approach in the identification and enrollment of hospice programs to the SFP. Some commenters stated that the criteria outlined in the proposed rule are subjective and may lead to inconsistencies across State Agencies in hospice identification and enrollment in the SFP, without addressing the most non-compliant hospices for not delivering quality care and putting patients at risk. Given the complexities associated with this proposal, commenters agreed that CMS should use a TEP that includes a wide array of stakeholders to assist CMS in the development of a comprehensive algorithm that would include relevant findings from the Form CMS–2567 and other metrics related to hospice performance. Commenters also thought that CMS should include relevant tools and education to assist hospice providers that participate in the SFP to improve quality and compliance prior to termination.

Response: The CAA 2021 mandates that a SFP be established to identify poor-performing hospice programs and enhance the quality of care. CMS recognizes that to accomplish the intent of this provision elements, in addition to the Form CMS–2567, may be needed to develop a comprehensive structure and methodology for a targeted approach to identify, select, and remove a hospice program for inclusion in the SFP. Given the intent of this provision to identify the poorest performing hospice programs and the need to define a comprehensive structure and methodology for selection into the SFP, CMS intends to review the public comments received and collaborate with hospice stakeholders to further develop the SFP that was initially proposed.

Taking into account the comments that we have received on this proposal, we are not finalizing the proposed SFP requirements at proposed § 488.1130. We intend to work on a revised proposal and will seek additional collaboration with stakeholders to further develop the structure and methodology for implementing the SFP, which we hope to include in a proposal for FY 2024 rulemaking.

4. New Subpart N—Enforcement Remedies for Hospice Programs With Deficiencies

a. Statutory Basis (§ 488.1200)

We proposed to set out the statutory basis for the proposed new subpart at § 488.1200, which is new sections 1822(c)(1) through 1822(c)(5) of the Act. The requirements under this new subpart would expand the Secretary's options to impose additional enforcement remedies for hospice programs failing to meet Federal requirements. These additional enforcement remedies may be used to encourage poor-performing hospice programs to come into substantial compliance with CMS requirements before CMS is forced to terminate the hospice program's provider agreement. This process is currently afforded to HHAs at § 488.745.

Prior to the enactment of section 1822(c)(5)(A) of the Act, the only enforcement action available to CMS to address hospice programs that are determined to be out of compliance with Federal requirements was the termination of their Medicare provider agreement. In accordance with section 1866(b)(2) of the Act and § 489.53(a)(3), CMS may terminate a hospice program provider agreement if that hospice program is not in substantial

compliance with the Medicare requirements (that is, the failure to meet one or more CoPs is considered to be a lack of substantial compliance).

We did not receive comments on this proposal and therefore are finalizing this provision without modification.

b. Definitions (§ 488.1205)

We proposed to add § 488.1205 to define the terms ''directed plan of correction,'' ''immediate jeopardy,'' ''new admission,'' ''per instance,'' ''plan of correction,'' ''repeat deficiency,'' and ''temporary management.'' Although section 1891 of the Act uses the term ''intermediate sanctions,'' with respect to HHA enforcement, and other rules use ''alternative sanctions,'' we proposed to use ''remedies'' or ''enforcement remedies,'' which we consider to have the same meaning and are closer to the language in section 1822 of the Act.

We did not receive comments on this proposal and therefore are finalizing this provision without modification.

c. General Provisions (§ 488.1210)

We proposed at § 488.1210 general rules pertaining to enforcement actions against a hospice program that is not in substantial compliance with the CoPs. Under section 1822(c)(1) of the Act, if CMS determines that a hospice program is not in compliance with the Medicare hospice programs CoPs and the deficiencies involved may immediately jeopardize the health and safety of the individual(s) to whom the hospice program furnishes items and services, then we may terminate the hospice program's provider agreement, impose the one or more enforcement remedies described in section 1822(c)(5)(B) of the Act, or both. We proposed that our decision to impose one or more remedies, including termination, would be based on the degree of noncompliance with the hospice program Federal requirements. With the proposed provisions, CMS would be able to impose one or more remedies for each discrete condition-level deficiency constituting noncompliance.

As noted in the proposed rule, it is also important to note that hospice programs can acquire initial certification for participation in Medicare via an SA survey or via accreditation by a CMS-approved AO. Accreditation by a CMS-approved AO is voluntary and not necessary to participate in the Medicare program. If an AO finds deficiencies during an accreditation survey, it communicates any condition-level findings to the applicable CMS SOG location. Based on the survey findings, CMS makes any determinations regarding the imposition of Federal enforcement remedies. An AO cannot recommend or implement enforcement remedies. In accordance with SOM Chapter 2, section 2005B, CMS may temporarily remove deemed status of an accredited hospice program due to condition-level findings found by the SA or Federal survey team during a complaint or validation survey. If the deficiencies remain uncorrected, oversight of that hospice program is transferred to CMS, through the SA, until the hospice program either demonstrates substantial compliance or CMS terminates its Medicare participation. In such a case where ''deemed status'' is removed, CMS will follow the usual procedures for oversight, as indicated in sections 3254 and 5100 of the SOM. Once an enforcement remedy is imposed on a formerly accredited hospice program and deemed status is removed, oversight and enforcement of that hospice program will be performed by the SA until the hospice program achieves compliance and the condition(s) causing the noncompliance are removed or until the hospice program is terminated from the Medicare program.

At proposed § 488.1210(e), we proposed that a hospice program would be required to submit an acceptable POC to the SA or CMS within 10 calendar days from receipt of the statement of deficiencies. This plan is the hospice program's written response to survey findings detailing corrective actions to cited deficiencies and the date by which those deficiencies would be corrected. CMS would determine if the POC was acceptable based on the information presented.

At proposed § 488.1210(e), we proposed the notification requirements for enforcement remedies for hospice programs that will be issued by CMS. CMS would provide a notice of intent to the hospice program that would include the intent to impose a remedy, the statutory basis for the remedy, the nature of the noncompliance, the intent to impose a payment suspension and which payments would be suspended (if applicable), the intent to proposed a CMP and the amount being imposed (if applicable), the proposed effective date of the sanction, and appeal rights.

We proposed that for all remedies imposed, except for CMPs, when there is IJ the notice period is at least 2 calendar days before the effective date of the enforcement action and when there is no IJ, that the notice period is at least 15 calendar days before the effective date of the enforcement action. As discussed later in this section, we proposed to codify these proposals at §§ 488.1225(b) and 488.1230(b), respectively.

With respect to CMPs, we proposed that once the administrative determination to impose the CMP is final, CMS would send a final notice to the hospice program with the amount of the penalty assessed, the total number of days of noncompliance (for CMPs imposed per day), the total amount due, the due date of the penalty, and the rate of interest to be charged on unpaid balances. We proposed to codify these proposals at § 488.1245(e).

We proposed that the hospice program could appeal the determination of noncompliance leading to the imposition of a remedy under the provisions of 42 CFR part 498. A pending hearing would not delay the effective date of the remedy against the hospice program and remedies will be in effect regardless of any pending appeals proceedings. Civil money penalties would accrue during the pendency of an appeal, but would not be collected until the administrative determination is final, as we note in proposed § 488.1245(f).

Comment: Several commenters recommended the incorporation of the informal dispute resolution (IDR) process to also align with the process available for HHAs.

Response: We thank the commenters for their suggestion about incorporating an informal dispute resolution (IDR) process, but because the IDR process was not proposed in this rule, we are not including it at this time. We will consider the commenter's suggestions for future rulemaking.

Final Decision: After consideration of the public comments received, we are finalizing this provision with one modification based on changes to proposed § 488.1240, which are discussed in section VII.B.4.i of this final rule. Because payment suspensions will apply only to new patient admissions, there will be no ambiguity as to which payments are being suspended. Accordingly, we are removing the requirement at § 488.1210(e) that the notice to hospice providers identify which payments are being suspended.

d. Factors To Be Considered in Selecting Remedies (§ 488.1215)

Section 1822(c) of the Act provides that if a hospice program is found to be out of compliance with the requirements specified in section 1861(dd) of the Act, CMS may impose one or more specified enforcement remedies. In the proposed rule, we proposed to establish requirements for enforcement remedies that may be

imposed when hospice programs are out of compliance with Federal requirements. At CMS' discretion, these enforcement remedies can be imposed instead of, or in addition to, termination of the hospice program's participation in the Medicare program, for a period not to exceed 6 months. The choice of any enforcement remedy or termination would reflect the impact on patient care and the seriousness of the hospice program's patterns of noncompliance and would be based on the factors proposed in § 488.1215. CMS may impose termination of the provider agreement (that is, begin termination proceedings that would become effective at a future date, but no later than 6 months from the determination of noncompliance), and impose one or more remedies for hospice programs with the most egregious deficiencies, on a hospice program that was unwilling or unable to achieve compliance within the maximum timeframe of 6 months, whether or not the violations constituted an immediate jeopardy (IJ) situation. We proposed at § 488.1215, consistent with section 1822(5)(B)(i) of the Act, to establish procedures for selecting the appropriate enforcement remedy, including the amount of any CMP and the severity of each remedy, which have been designed to minimize the time between the identification of deficiencies and the final imposition of remedies, as required under section 1822(c)(5)(A)(ii) of the Act. To determine which remedy or remedies to apply, we proposed to consider the following factors that are consistent with the factors for HHA alternative sanctions:

- The extent to which the deficiencies pose IJ to patient health and safety.
- The nature, incidence, manner, degree, and duration of the deficiencies or noncompliance.
- The presence of repeat deficiencies (defined as condition-level), the hospice program's compliance history in general, and specifically concerning the cited deficiencies, and any history of repeat deficiencies at any of the hospice program's additional locations.
- The extent to which the deficiencies are directly related to a failure to provide quality patient care.
- The extent to which the hospice program is part of a larger organization with documented performance problems.
- Whether the deficiencies indicate a system-wide failure of providing quality care.

Comment: Several commenters requested that CMS provide staff in the CMS locations (formerly CMS Regional Offices) training in the factors to be used in making determinations on when remedies should be applied and develop processes to ensure these remedies are consistently applied. A commenter stated that this guidance and training should also be made available to hospice providers.

Response: We will develop associated guidance and provide training to CMS location and SA staff, as appropriate, that will address the concerns raised by the commenters regarding the procedures that will be followed to apply and implement the enforcement remedies while also allowing for surveyor judgment. Developed guidance and training will be made publicly available.

Comment: A few commenters recommended a step-wise approach to enforcement remedies for hospice programs that consider the seriousness and prevalence of the deficiency beginning with more targeted education remedies (for example, directed plan of correction and directed in-service training) to more stringent remedies for more severe deficiencies.

Response: We have set forth the factors upon which we will base our choice of remedy or remedies. Those factors include the extent to which the deficiencies are directly related to a failure to provide quality care and pose an immediate threat to patient health and safety, as well as the nature, incidence, manner, degree, and duration of the deficiencies or noncompliance.

Final Decision: After consideration of the public comments we received, we are finalizing this section as proposed.

e. Available Remedies (§ 488.1220)

Section 1822(c)(5)(A)(ii) of the Act provides that we ''shall develop and implement specific procedures for the conditions under which each of the remedies developed under clause (i) is to be applied, including the amount of any fines and the severity of each of these remedies.'' Section 1822(c)(5)(B) of the Act explicitly provides for the following enforcement remedies to be included in the range of remedies: (1) CMPs in an amount not to exceed $10,000 for each day of noncompliance by a hospice program with the requirements specified in section 1861(dd) of the Act; (2) suspension of all or part of payments, , on or after the date on which the Secretary determines that remedies should be imposed; and (3) appointment of temporary management to oversee the operation of the hospice program and to protect and assure the health and safety of the individuals under the care of the program while improvements are made to bring the program into compliance with all such requirements. In addition to those specified in the statute, we proposed to add a directed POC and directed in-service training as additional enforcement remedies at § 488.1220.

We did not receive comments on this proposal and therefore are finalizing this provision without modification.

f. Action When Deficiencies Pose Immediate Jeopardy (§ 488.1225) and Termination (§ 489.53)

For situations involving IJ, if we determine based on a standard survey or otherwise that a hospice program's deficiencies involve IJ to the health and safety of the individuals to whom the program furnishes items and services, it shall take immediate action to ensure the removal of the IJ and to correct the deficiencies or terminate the certification of the program. We proposed at § 488.1225(a) to implement the statutory requirement of 1822(c)(1) of the Act by specifying that if the IJ situation is not addressed and resolved within 23 days from the last day of the survey because the hospice program is unable or unwilling to correct the deficiencies, we will terminate the hospice program's provider agreement. In addition, we could impose one or more enforcement remedies including a CMP, temporary management, and/or suspension of Medicare payments before the effective date of termination.

We proposed § 488.1225(b), that for a deficiency or deficiencies that pose IJ, we would provide the hospice program with at least 2 days advance notice of any proposed remedies, except CMPs (discussed at proposed § 488.1245). The requirements for a notice of intent are set forth at proposed § 488.1210(e). Under our existing survey process, providers are informed of any IJ findings upon discovery of the IJ situation during the survey or as part of the exit conference at the end of the survey. This would give a hospice program time to remove the IJ and correct the deficiencies that gave rise to the IJ finding. To assure a hospice program achieves prompt compliance, we expect that we will give hospice programs written notice of an impending enforcement actions against them as quickly as possible following the completion of a survey of any kind.

For terminations, we proposed that we would give notice of the termination within 2 days before the effective date of the termination, to hospice programs consistent with the requirement for HHAs. We also proposed to amend § 489.53(a)(17) to indicate that we would terminate a hospice program's (as well as an HHA's) provider agreement if

the hospice program failed to correct a deficiency or deficiencies within the required time frame.

Finally, at proposed § 488.1225(c), we proposed to require a hospice program whose provider agreement is terminated to appropriately and safely transfer its patients to another local hospice program within 30 days of termination, unless a patient or caregiver chooses to remain with the hospice program as a self-pay or with another form of insurance (for example, private insurance). In addition, the hospice program would be responsible for providing information, assistance, and any arrangements necessary for the safe and orderly transfer of its patients.

Comment: Several commenters recommended that CMS clarify the notice period in calendar days for action imposed when deficiencies pose immediate jeopardy or are at the condition-level but do not pose immediate jeopardy.

Response: We appreciate the comments and in this final rule added ''calendar'' days for the notice period in the titles at §§ 488.1225(b) and 488.1230(b). Additionally, we are making a technical correction in § 488.1225(b) to reflect the notice requirements are outlined in § 488.1210(e), not § 488.1225(e).

Comment: Several commenters recommended that CMS consider the method that will be used to deliver the notices and whether 2 days is reasonable. Commenters stated situations where the statement of deficiencies has exceeded the 10-business day delivery requirement to the provider and they are concerned that delays will occur when enforcement remedies are applied. Commenters recommended that for delays in the statement of deficiencies that the hospice provider should be granted an extension for the plan of correction submission equivalent to the number of delinquent days, and commenters also believed that in situations where enforcement remedies are applied, the implementation date of the remedy should be delayed for the same number of days that the notice is delinquent. One commenter recommended that CMS investigate the reasons for these delays and implement processes to remedy the situation.

Response: The 2-day calendar notice is to inform the hospice program of the immediate jeopardy situation and that the hospice program will be terminated in 23 days unless the immediate jeopardy is corrected and for all imposed remedies, except for CMPs. This policy is consistent with the current HHA requirements and has been used in immediate jeopardy situations for other providers. The written notice will be delivered in hard copy by mail or in an electronic format, such as email. The 2-day calendar notice of termination with an immediate jeopardy finding is prudent considering the short 23-day time frame to attain compliance and also given the serious risk to patient health and safety. For remedies imposed when there is immediate jeopardy, the notice will be given at least 2 calendar days before the effective date of the enforcement action. The notice will include the requirements finalized in § 488.1210(e) that includes the proposed effective date of the remedy. The recommendation for us to investigate delays in notices and implement processes to remedy the situation is beyond the scope of this rule.

Final Decision: After consideration of the public comments we received, we are adding the word ''calendar'' to the 2-day notice at § 488.1225(b) and fixing a technical error in that same paragraph, in the reference to notice requirements, to accurately reflect § 488.1210(e).

g. Action When Deficiencies Are at the Condition-Level But Do Not Pose Immediate Jeopardy (§ 488.1230)

In section 1822(c)(2) of the Act, if the Secretary determines based on a survey or otherwise that a hospice program is no longer in compliance with the requirements specified in section 1861(dd) of the Act and determines that the deficiencies involved do not immediately jeopardize the health and safety of the individuals to whom the program furnishes items and services, the Secretary may (for a period not to exceed 6 months) impose remedies developed under section 1822(c)(5)(A) of the Act, in lieu of terminating the hospice program's participation in the Medicare program. If, after such a period of remedies, the program is still not in compliance with all requirements, the Secretary shall terminate the hospice program's participation in the Medicare program.

In the proposed rule, we specified that enforcement remedies, such as those proposed in § 488.1220, would be imposed before the termination becomes effective, but cannot continue for a period that exceeded 6 months. In addition, to protect the health and safety of individuals receiving services from the hospice program, enforcement remedies would continue in effect until the hospice program achieves compliance or has its Medicare participation terminated, whichever occurs earlier. For example, the suspension of payment remedy would end when the hospice program corrects all condition-level deficiencies or is terminated from the Medicare program.

We proposed at § 488.1230, that for a deficiency or deficiencies that do not pose IJ, we would provide the hospice program at least 15 days advance notice of any proposed remedies, except for CMPs (discussed at proposed § 488.1245). Such remedies would remain in effect until the effective date of an impending termination (at 6 months) or until the hospice program achieves compliance with CoPs, whichever is earlier. This 15-day period is consistent with the general rule for providers and suppliers in § 489.53(d)(1).

Comment: Several commenters recommended that for enforcement remedies at the condition level that do not pose immediate jeopardy, CMS clarify that the notice period is in calendar days.

Response: We appreciate the comments and in this final rule we have included ''calendar'' in the title at § 488.1230(b).

Final Decision: After consideration of the public comments we received, we are adding the word ''calendar'' to the 15-day notice at § 488.1230(b).

h. Temporary Management (§ 488.1235)

Section 1822(c)(5)(B)(iii) of the Act specifies the use of appointment of temporary management as an enforcement remedy to oversee the operation of the hospice program and to protect and assure the health and safety of the individuals under the care of the program while improvements are made in order to bring the program into compliance with all such requirements. As we proposed at § 488.1205, ''temporary management'' means the temporary appointment by us or an authorized agent, of a substitute manager or administrator, who would be under the direction of the hospice program's governing body and who would have authority to hire, terminate or reassign staff, obligate hospice program funds, alter hospice program procedures, and manage the hospice program to correct deficiencies identified in the hospice program's operation. The substitute manager or administrator would be appointed based on qualifications described in §§ 418.100 and 418.114 and would be under the direction of the hospice program's governing body.

We proposed at § 488.1235 to set out the circumstances under which we would utilize our authority under section 1822(c)(5)(C)(iii) of the Act to place a hospice program under temporary management. We proposed to specify the duration and effect of this

enforcement remedy, and the payment procedures for temporary managers' salaries and other additional costs. We would provide the hospice program with written notice of our intent to impose a temporary management remedy in accordance with proposed § 488.1210(e).

At § 488.1235(a), we proposed that temporary management would be imposed when a hospice program is determined to have condition-level deficiencies and that the deficiencies or the management limitations of the hospice program are likely to impair the hospice program's ability to correct the deficiencies and return the hospice program to compliance with all of the CoPs within the required timeframe. We proposed at § 488.1235(c) to impose temporary management to bring a hospice program into compliance with program requirements within 6 months of the date of the survey identifying noncompliance.

We proposed at § 488.1235(b) if the hospice program refuses to relinquish authority and control to the temporary manager, we would terminate the hospice program's provider agreement. If a temporary manager was appointed, but the hospice program failed to correct the condition-level deficiencies within 6 months from the last day of the survey, the hospice program's Medicare participation would be terminated. Additionally, if the hospice program resumes management control without CMS's approval, we would impose termination and could impose additional enforcement remedies. The appointment of a temporary manager would not relieve the hospice program of its responsibility to achieve and maintain compliance with the participation requirements. We proposed at § 488.1235 that temporary management would end when—

- We determine that the hospice program has achieved substantial compliance and has the management capability to remain in compliance;
- The hospice program provider agreement is terminated; or
- The hospice program resumes management control without CMS approval.
- Temporary management would not exceed a period of 6 months from the date of the survey identifying noncompliance.

At § 488.1235, we proposed that temporary management would be required to be provided at the hospice program's expense. Before the temporary manager was installed, the hospice program would have to agree to pay his/her salary directly for the duration of the appointment. We believe that the responsibility for the hospice program to pay the expenses of the temporary manager is an inherent management responsibility of the hospice agency for which Medicare regularly reimburses the hospice program and through such temporary outside management might be necessary in some cases to bring the hospice program back into compliance with the CoPs. We proposed that the salary for the temporary manager would not be less than the amount equivalent to the prevailing salary paid by providers in the geographic area for positions of this type, based on the Bureau of Labor Statistics, National Occupational Employment and Wage Estimates. In addition, the hospice program would have to pay for any additional costs that the hospice program may have incurred if such person had been in an employment relationship, and any other costs incurred by such a person in furnishing services under such an arrangement or as otherwise set by the State. We would consider a hospice program's failure to pay the salary of the temporary manager to be a failure to relinquish authority and control to temporary management.

Comment: Several commenters stated that when the temporary management enforcement remedy is imposed, the individual acting as the temporary manager should complete the basic CMS hospice surveyor training before beginning their assignment.

Response: Although not an explicit requirement, we encourage the temporary manager to complete the basic CMS hospice surveyor training. The training is available free of charge on the QSEP website at *https://qsep.cms.gov,* to providers and all entities conducting surveys, and the public at large. QSEP training is accessible on an individual, self-paced basis. The basic training courses provide surveyors with the key knowledge and skills needed to survey the respective provider or supplier type for compliance with the Medicare CoPs and assure an adequately trained, effective surveyor workforce.

Comment: Several commenters recommended that we clarify whether a temporary manager is required to be external to the hospice organization.

Response: The temporary manager must have the experience and education that qualifies the individual to oversee the hospice program. The temporary manager can be either internal or external to the hospice program, and will be appointed by CMS or the SA based on qualifications described in §§ 418.100 and 418.114. Additionally, the temporary manager would be under the direction of the hospice program's governing body.

Final Decision: After consideration of the public comments we received, we are finalizing this section as proposed.

i. Suspension of Payment for All New Patient Admissions (§ 488.1240)

We proposed in § 488.1240 provisions describing when and how we would apply a suspension of payment for all new patient admissions on or after the date on which the Secretary determines that remedies should be imposed under § 488.1225 or § 488.1230. We proposed that if a hospice program has a condition-level deficiency or deficiencies (regardless of whether or not an IJ exists), we may suspend payments for all or part of the payments to which a hospice program would otherwise be entitled for items and services furnished by a hospice program on or after the effective date of the enforcement remedy. We proposed to determine whether to impose a suspension of all or part of the payments on or after the effective date of the enforcement remedy. We proposed to determine whether to impose a suspension of payment based on the factors outlined in proposed § 488.1215 that are considered when selecting remedies. The suspension of payment was proposed at § 488.1240 to be for a period not to exceed 6 months and would end when the hospice program either achieved substantial compliance or was terminated. We proposed to provide the hospice program with written notice of our intent to impose a payment suspension remedy at least 2 calendar days before the effective date of the remedy in IJ situations, per proposed § 488.1225(b), or 15 calendar days before the effective date of the remedy in non-IJ situations, per proposed § 488.1230(b). The proposed notice of intent for all remedies, described at § 488.1210(e), would be used to notify a hospice program of a suspension of all or part of the payments to which the hospice program would otherwise be entitled.

Additionally, section 1822(c)(5)(C)(ii) of the Act provides that a suspension of payment remedy shall terminate when we find that the hospice program is in substantial compliance with the requirements specified in, or developed in accordance with, section 1861(dd) of the Act. That is, the suspension of payment remedy would end when the hospice program is determined to have corrected all condition-level deficiencies, or upon termination, whichever is earlier. We proposed to codify that duration of the remedy at § 488.1240(c).

Comment: Several commenters expressed concerns and requested that CMS consider limiting the suspension of all or part of payments to new hospice admissions only. The commenters stated that a suspension of payment not limited to new hospice admissions would result in a disproportionate financial burden on hospice providers and would affect access to care. Commenters also stated that limiting the suspension of all or part of payments to new hospice admissions only would be consistent with existing HHA enforcement sanctions, Congressional intent, and OIG recommendations. A commenter recommended we consider suspension of all or part of payments to new hospice admissions only in the case of an immediate jeopardy situation.

Response: We have considered the commenters' suggestions and agree that limiting the payment suspension to all new patient admissions would help avoid disproportionate financial burdens on hospice programs. In addition, for poor performing hospice programs, CMS continues to have the option to terminate.

Final Decision: After consideration of the public comments we received, we are finalizing this provision with modifications to limit the suspension of payments to all new patient admissions. As noted elsewhere, we have made conforming edits to §§ 488.1210(e), 488.1220(b), and 488.1260(a)(1)(i).

j. CMPs (§ 488.1245)

We proposed at § 488.1245 requirements for the imposition of CMPs. Section 1822(c)(5)(C) of the Act outlines the requirements for CMP procedures. Additionally, section 1822(c)(5)(C)(i)(I) of the Act requires that the CMP provisions under section 1128A (other than subsections (a) and (b)) of the Act shall be applied to the hospice CMPs, which also must be considered when establishing the amount. We proposed to impose a CMP against a hospice program that is determined to be out of compliance with one or more CoPs, regardless of whether the hospice program's deficiencies pose IJ to patient health and safety. We could also impose a CMP for the number of days of IJ. Under section 1822(c)(5)(B)(i) of the Act, the CMP amount cannot exceed $10,000 for each day of noncompliance. Our proposals align with the imposition of CMPs authorized by section 1891(f) of the Act as set out for HHAs at § 488.845, which we may impose against an HHA that is determined to be out of compliance with one or more CoPs, regardless of whether the HHA's deficiencies pose IJ to patient health and safety.

In this section, we proposed both ''per day'' and ''per instance'' CMPs at § 488.1245(a). The per day CMPs would be imposed for each day of noncompliance with the CoPs. Additionally, should a survey identify a particular instance or instances of noncompliance during a survey, we proposed to impose a CMP for that instance or those individual instances of noncompliance. We proposed to define ''per instance'' in § 488.1205 as a single event of noncompliance identified and corrected during a survey, for which the statute authorizes that we impose a remedy.

While there may be a single event that leads to noncompliance, there can also be more than one instance of noncompliance identified and more than one CMP imposed during a survey. For penalties imposed per instance of noncompliance, we proposed penalties from $1,000 to $10,000 per instance. Such penalties would be assessed for one or more singular events of condition-level noncompliance that were identified at the survey and where the noncompliance was corrected during the onsite survey.

Since the range of possible deficiencies is great and depends upon the specific circumstances at a particular time, it would be impossible to assign a specific monetary amount for each type of noncompliance that could be found. Thus, we believe that each deficiency would fit into a range of CMP amounts.

We proposed that, in addition to those factors that we would consider when choosing a type of remedy proposed in § 488.1215, we would consider the following factors when determining a CMP amount:

- The size of the hospice program and its resources.
- Evidence that the hospice program has a built-in, self-regulating quality assessment and performance improvement system to provide proper care, prevent poor outcomes, control patient injury, enhance quality, promote safety, and avoid risks to patients on a sustainable basis that indicates the ability to meet the CoPs and to ensure patient health and safety. When several instances of noncompliance would be identified at a survey, more than one per-day or per instance CMP could be imposed as long as the total CMP did not exceed $10,000 per day. In addition, a per-day and a per-instance CMP would not be imposed simultaneously for the same deficiency in conjunction with a survey.

At proposed § 488.1245, we would have the discretion to increase or reduce the amount of the CMP during the period of noncompliance, depending on whether the level of noncompliance had changed at the time of a revisit survey. However, section 1822(c)(5)(B)(i) of the Act specifies that the remedies shall include a CMP in an amount not to exceed $10,000 for each day of noncompliance. Therefore, we proposed at § 488.1245(b)(2)(iii) that no CMP assessment could exceed $10,000 per day of noncompliance. To comply with sections 1822(c)(5)(B)(i) and 1822(c)(5)(C)(i) of the Act, we proposed to establish a three-tier system with subcategories that would establish the amount of a CMP.

In proposed § 488.1245(b)(3), (4), and (5), we proposed ranges of CMP amounts based on three levels of seriousness—upper, middle, and lower:

- Upper range—For a deficiency that poses IJ to patient health and safety, we would assess a penalty within the range of $8,500 to $10,000 per day of condition-level noncompliance.
- Middle range—For repeat and/or a condition-level deficiency that did not pose IJ, but is directly related to poor quality patient care outcomes, we would assess a penalty within the range of $1,500 up to $8,500 per day of noncompliance with the CoPs.
- Lower range—For repeated and/or condition-level deficiencies that did not constitute IJ and were deficiencies in structures or processes that did not directly relate to poor quality patient care, we would assess a penalty within the range of $500 to $4,000 per day of noncompliance.

The proposed CMP amounts would be subject to annual adjustments for inflation in accordance with the Federal Civil Monetary Penalty Inflation Adjustment Act of 1990 (Pub. L. 101–140), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (section 701 of Pub. L. 114–74). Annually adjusted amounts are published at 45 CFR part 102.

Under the proposed provisions, if we imposed a CMP, we would send the hospice program written notification of the intent to impose it, including the amount of the CMP being imposed and the proposed effective date of the sanction, under proposed §§ 488.1210(e) and 488.1245(c). Once the administrative determination is final, we proposed to send a final notice to the hospice program with the amount of the penalty that was assessed; the total number of days of noncompliance (for per day CMPs); the total amount due; the due date of the penalty; and the rate

of interest to be charged on unpaid balances.

Whether per instance or per day CMPs are imposed, once the hospice program has received the notice of intent to impose the CMP, it would have 60 calendar days from the receipt of the written notice of intent to either request an administrative hearing in accordance with § 498.40 or to provide notice to CMS of its intent to waive its right to an administrative hearing, in accordance to the procedures specified in proposed § 488.1245(c)(2), to receive a 35 percent reduction in the CMP amount. The CMP would be due within 15 calendar days of hospice programs' written request for waiver. If the hospice program did not respond to the notice of intent to impose a CMP within 60 calendar days of receipt, it would waive its right to a hearing. In such cases, the CMP would not be reduced by 35 percent because a hospice program must follow the procedures specified at proposed § 488.1245(c)(2) to receive the reduction.

A per-day CMP would begin to accrue as early as the beginning of the last day of the survey that determines that the hospice program was out of compliance and would end on the date of correction of all deficiencies, or the date of termination. We proposed at § 488.1245(d) that in IJ cases, if the IJ is not removed, the CMP would continue to accrue until we terminated the provider agreement (within 23 calendar days after the last day of the survey which first identified the IJ). Under proposed § 488.1245(d)(4), if IJ did not exist, the CMP would continue to accrue until the hospice program achieved substantial compliance or until we terminated the provider agreement.

As noted elsewhere, in no instance would a period of noncompliance be allowed to extend beyond 6 months from the last day of the survey that initially determined noncompliance. If the hospice program has not achieved compliance with the CoPs within those 6 months, we would terminate the hospice program. The accrual of per-day CMPs would stop on the day the hospice program provider agreement was terminated or the hospice program achieved substantial compliance, whichever was earlier. The total CMP amounts would be computed and collected after an administrative determination is final and a final notice sent to the hospice program as described in § 488.1245(e).

We also proposed that for a hospice program being involuntarily terminated and for which a civil money penalty had been imposed and was still due, we would include the final notice, also known as a due and payable notice, as part of the termination notice. In other words, the information in a final notice, as described in § 488.1245(e), would be included in the termination notice.

At proposed § 488.1245(f), a CMP would become due and payable 15 calendar days from—

- The time to appeal had expired without the hospice program appealing its initial determination;
- We received a request from the hospice program waiving its right to appeal the initial determination;
- A final decision of an Administrative Law Judge or Appellate Board of the Departmental Appeals Board upheld CMS's determinations; or
- The hospice program was terminated from the program and no appeal request was received.

A request for a hearing would not delay the imposition of the CMP, but would only affect the collection of any final amounts due to us.

Comment: Commenters recommended CMS develop specifications for penalties collected at the national and/or state level for hospice program improvements.

Response: Determinations on whether to impose an enforcement remedy and the specific remedy to be imposed will not be left to the sole discretion of the hospice surveyor. All final decisions regarding whether or not to impose a remedy and what type of remedy to be imposed will be made by the applicable CMS Location. Any funds collected as a result of CMPs imposed upon a hospice are distributed to the State Medicaid Agency and to the US Treasury under section 1128A(f) of the Act. Additionally, the CAA 2021 included a provision at section 1822(c)(5)(C) that allows the Secretary to use a portion of the CMPs collected to support activities that benefit individuals receiving hospice care, including education and training programs to ensure hospice program compliance. We will consider using this authority to support improvement activities in hospices in the future and will consider developing interpretive guidance for clarification as needed.

Comment: Many commenters recommended that CMS consider a hospice provider-initiated improvement plan to achieve positive outcomes and sustained compliance over a ''look back'' period in determining whether to impose the CMP remedy for previous noncompliance.

Response: We disagree that a hospice provider-initiated improvement plan should be a determination on whether to impose the CMP remedy for previous noncompliance. The hospice program is expected to be in continuous compliance with the health and safety CoPs. When we determine the amount of the CMP penalty, one factor that is considered is evidence that the hospice program has an internal quality assessment and performance improvement system to ensure patient health and safety and compliance with the CoPs. We are finalizing as proposed the requirement at § 488.1245(b)(1)(iii) that CMS take into account that the hospice program has evidence of a self-regulating quality assessment and improvement plan when determining the amount of the penalty. We can also decrease the CMP penalty amount from the upper range to the middle or lower range if a condition-level deficiency exists and the hospice program shows an earnest effort to correct systemic causes of the deficiencies and sustain improvement. We are finalizing as proposed the requirement at § 488.1245(b)(7) to allow CMS to shift the CMP amount imposed per day from the upper range to the middle or lower range.

Comment: Commenters recommended that CMS use a scaled approach to CMPs based on deficiency scope and severity and a commenter noted that CMS proposes criteria that also include factors that account for the size of the hospice program and its resources in order to provide some relief for small hospice programs.

Response: We will factor in the size of the hospice program and its resources when considering the amount of the CMP as proposed in § 488.1245(b)(1)(ii). CMPs may be adjusted based on revisit survey findings and after a review of the provider's attempted correction of deficiencies as proposed in § 488.1245(b)(2). Additionally, CMS may impose a more severe amount of penalties for repeated noncompliance with the same condition-level deficiency or uncorrected deficiencies from a prior survey as proposed in § 488.1245(b)(8)(iii).

Comment: Commenters encouraged CMS to provide a standardized, transparent process regarding the calculation of CMPs.

Response: The proposed CMP regulations at § 488.1245 provide a transparent process regarding CMP application, penalty amounts and adjustments, and appeal procedures consistent with requirements standardized for HHAs. CMS will also consider developing interpretive guidance for clarification as needed.

Final Decision: After consideration of the public comments we received, we are finalizing this section as proposed.

k. Directed Plan of Correction (§ 488.1250)

We proposed at § 488.1250 to include a directed plan of correction as an available remedy. This remedy is a part of the current HHA and nursing home alternative sanction procedures and has been an effective tool to encourage the correction of deficient practices. Specifically, we proposed that we may impose a directed POC on a hospice program that is out of compliance with the CoPs. A directed POC remedy would require the hospice program to take specific actions to bring the hospice program back into compliance and correct the deficient practice(s). As indicated in § 488.1250(b)(2) a hospice program's directed POC would be developed by us or by the temporary manager, with CMS approval. The directed POC would set forth the outcomes to be achieved, the corrective action necessary to achieve these outcomes, and the specific date the hospice program would be expected to achieve such outcomes. The hospice program would be responsible for achieving compliance. If the hospice program failed to achieve compliance within the timeframes specified in the directed POC, we could impose one or more additional enforcement remedies until the hospice program achieved compliance or was terminated from the Medicare program. Before imposing this remedy, we would provide appropriate notice to the hospice program under § 488.1210(e).

Comment: Commenters were in support of the proposed directed POC and directed in-service training enforcement remedies that align with the available home health alternative sanctions. A commenter recommended that the directed POC be developed by CMS or by the temporary manager, with CMS approval. The commenter also recommended that the directed POC include follow-up reports to CMS or the SA and/or a resurvey to ensure continued progress and compliance with the directed POC. Additionally, the commenter recommended that directed POCs ultimately be publicly reported and delineate between and among deficiencies, especially regarding the scope and severity of such deficiencies.

Response: We appreciate the support for the proposed directed POC and directed in-service training enforcement remedies that align with the available home health alternative sanctions. Similar to HHAs, a directed POC can be guided by CMS, the SA, or a temporary manager (with CMS/SA approval) to ensure that the underlying cause of the cited deficiency or deficiencies does not recur. Follow-up reports to the directed POC and/or a resurvey to ensure compliance with the directed POC will be at the discretion of CMS or the SA. The public reporting of directed POCs and delineation of deficiencies is beyond the scope of this rule.

Final Decision: After consideration of the public comments we received, we are finalizing this section as proposed.

l. Directed In-Service Training (§ 488.1255)

We proposed at § 488.1255, to outline the requirements for conducting directed in-service training for hospice programs with condition-level deficiencies. At proposed § 488.1255(a), directed in-service training would be required where staff performance resulted in noncompliance and it was determined that a directed in-service training program would correct this deficient practice through retraining the staff in the use of clinically and professionally sound methods to produce quality outcomes.

At § 488.1255(a)(3), we proposed that hospice programs use in-service programs conducted by instructors with an in-depth knowledge of the area(s) that would require specific training so that positive changes would be achieved and maintained. Hospice programs would be required to participate in programs developed by well-established education and training services. These programs would include, but not be limited to, schools of medicine or nursing, area health education centers, and centers for aging. We would only recommend possible training locations to a hospice program and not require that the hospice program utilize a specific school/center/provider. In circumstances where the hospice is subject to the SFP, additional technical assistance and/or resources could be made available. The hospice program would be responsible for payment for the directed in-service training for its staff. At proposed § 488.1255(b), if the hospice program did not achieve substantial compliance after such training, we could impose one or more additional remedies. Before imposing this remedy, we would provide appropriate notice to the hospice program under proposed § 488.1210(e).

Comment: Commenters were in support of the proposed directed plan of correction and directed in-service training enforcement remedies that align with the available home health alternative sanctions.

Response: We appreciate the support for the proposed directed plan of correction and directed in-service training enforcement remedies that align with the available home health alternative sanctions.

Final Decision: After consideration of the public comments we received, we are finalizing this section as proposed.

m. Continuation of Payments to a Hospice Program With Deficiencies (§ 488.1260)

We proposed at § 488.1260, the continuation of Medicare payments to hospice programs not in compliance with the requirements specified in section 1861(dd) of the Act over a period of no longer than 6 months in accordance with section 1822(c)(4) of the Act. The continuation of Medicare payments would continue for 6 months if—

- An enforcement remedy or remedies (with the exception of suspension of all payments) have been imposed on the hospice program and termination has not been imposed;
- The hospice program has submitted a POC which has been approved by CMS; and
- The hospice program agrees to repay the Federal Government the payments received under this arrangement should the hospice program fail to take the corrective action as outlined in its approved POC in accordance with the approved plan and timetable for corrective action.

We proposed these three criteria at § 488.1260(a). If any of these three requirements outlined in the Act were not met, a hospice program would not receive any Federal payments from the time that deficiencies were initially identified. We would also terminate the agreement before the end of the 6-month correction period, which begins on the last day of the survey, in accordance with § 488.1265 if the requirements at § 488.1260(a)(1) were not met. If any remedies were also imposed, they would stop accruing or end when the hospice program achieved compliance with all requirements, or when the hospice program's provider agreement was terminated, whichever was earlier.

Finally, if a hospice program provided an acceptable POC but could not achieve compliance with the CoPs upon resurvey within 6 months of the last day of the survey, we proposed at § 488.1230(d) that we would terminate the provider agreement.

Comment: A commenter recommended that CMS modify the proposed regulatory text at § 488.1260(a) by replacing ''may'' with ''will'' to ensure continuity of the continuation of payments to a hospice program with deficiencies.

Response: We respectfully disagree with the commenter's suggested change

of ''may'' to ''will'' at § 488.1260(a). The language for continued payments is consistent with the language in the HHA regulation at § 488.860. Therefore, the language at § 488.1260(a) for continued payments will read ''CMS *may* continue payments to a hospice program with condition-level deficiencies that do not constitute immediate jeopardy for up to 6 months from the last day of the survey if the criteria in paragraph (a)(1) of this section are met.''

Final Decision: After consideration of the public comments we received, we are finalizing this section with one modification. Because we are finalizing § 488.1240 to apply only to payments for all new patient admissions, we are removing the parenthetical in proposed § 488.1260(a)(1)(i) that excepted the suspension of all payment.

n. Termination of Provider Agreement (§ 488.1265)

At § 488.1265(a), we proposed to address the termination of a hospice program's Medicare provider agreement, as well as the effect of such termination. Termination of the provider agreement would end all payments to the hospice program, including any payments that were continued at the proposed § 488.1260. Termination would also end enforcement remedies imposed against the hospice program, regardless of any proposed timeframes for the remedies originally specified. At proposed § 488.1265(b), we would terminate the provider agreement if—(1) the hospice program failed to correct condition-level deficiencies within 6 months unless the deficiencies constitute IJ; (2) the hospice program failed to submit an acceptable POC; (3) the hospice program failed to relinquish control of the temporary manager (if that remedy is imposed); or (4) the hospice program failed to meet the eligibility criteria for continuation of payments. At § 488.1265(d) we proposed using the procedures for terminating a hospice program at § 489.53 and providing appeal rights in accordance with 42 CFR part 489. Additionally, we proposed using the procedures for payments 30 days post termination for hospice programs at § 489.55. Payment is available for up to 30 days after the effective date of termination for hospice care furnished under a plan established before the effective date of termination (§ 489.55(a)(2)).

We did not receive comments on this proposal and therefore are finalizing this provision without modification.

VIII. Requests for Information

A. Fast Healthcare Interoperability Resources (FHIR) in Support of Digital Quality Measurement in Post-Acute Care Quality Reporting Programs—Request for Information

In the proposed rule, we sought input on the following steps that would enable transformation of our quality measurement enterprise to be fully digital (86 FR 19765):

1. What EHR/IT systems do you use and do you participate in a health information exchange (HIE)?
2. How do you currently share information with other providers and are there specific industry best practices for integrating SDOH screening into EHR's?
3. What ways could we incentivize or reward innovative uses of health information technology (IT) that could reduce burden for post-acute care settings, including but not limited to HHAs?
4. What additional resources or tools would post-acute care settings, including but not limited to HHAs and health IT vendors, find helpful to support testing, implementation, collection, and reporting of all measures using FHIR standards via secure APIs to reinforce the sharing of patient health information between care settings?
5. Would vendors, including those that service post-acute care settings, including but not limited to HHAs, be interested in or willing to participate in pilots or models of alternative approaches to quality measurement that would align standards for quality measure data collection across care settings to improve care coordination, such as sharing patient data via secure FHIR API as the basis for calculating and reporting digital measures?
6. What could be the potential use of FHIR dQMs that could be adopted across all QRPs?

Most commenters supported the use and adoption of Fast Healthcare Interoperative Resources (FHIR) Application Programming Interfaces (APIs). Many commenters stressed the need for further work in standardizing data that are part of clinical documents to exchange information based on high-value use. Another requirement suggested by commenters is to specify the defined set of FHIR–APIs and HL7 messages that each health IT vendor must support to meet interoperability standards of practice or both. Many commenters shared that we need to consider providing incentives to working with EHR vendors that promote practices that support interoperability. Commenters supported the meaningful use framework and how it relates to promoting dQMs. They note that HHAs and other PAC providers were not included in the HITECH Act and therefore did not have the incentives as other provider communities that are needed to support providers and vendors. A commenter suggested that incentives need not be financial and that they could be in the form of points via a value-based purchasing program. Other incentives suggested included training and technical assistance for providers with the lowest adoption of technology infrastructure. Commenters requested there be a robust trial period before any dQM adoption nationally. Ideally, commenters would prefer 6 months to 1 year from whenever final specifications around dQMs are made before implementation. A commenter noted that family or caregivers play an important role in older patients care and need to be included and supported in any transition to more digital records as they support patients. Some commenters also provided responses to questions about their EHR systems and capabilities. We appreciate commenters' input on this very important work.

While we are not responding to comments in response to this Request for Information, we intend to use this input to inform future policy related to Fast Healthcare Interoperability Resources (FHIR) in Support of Digital Quality Measurement in Quality Programs.

B. Closing the Health Equity Gap in Post-Acute Care Quality Reporting Programs—Request for Information

In the proposed rule, we sought public comment on the following:

- As finalized in the HH PPS final rule (84 FR 60597 through 60608), HHAs will be required to report Standardized Patient Assessment Data Elements on certain SDOH, includingrace, ethnicity, preferred language, interpreter services, health literacy, transportation and social isolation.[104] We sought guidance on any additional Standardized Patient Assessment Data Elements that could be used to assess health equity in the care of HHA patients, for use in the HH QRP.
- Recommendations for how we can promote health equity in outcomes among HHA patients. We are also interested in feedback regarding whether including HHA-level quality measure results stratified by social risk

[104] In response to the COVID–19 PHE, CMS released a May 8, 2020 interim final rule with comment period (85 FR 27595 through 27597) which delayed the compliance date for the collection and reporting of the SDOH for at least 2 full fiscal years after the end of the PHE.

factors and social determinants of health (for example, dual eligibility for Medicare and Medicaid, race) in confidential feedback reports could allow HHAs to identify gaps in the quality of care they provide (for example, methods similar or analogous to the *CMS Disparity Methods* [105] which provide hospital-level confidential results stratified by dual eligibility for condition-specific readmission measures currently included in the Hospital Readmission Reduction Program (84 FR 42496 through 42500).

- Methods that commenters or their organizations use in employing data to reduce disparities and improve patient outcomes, including the source(s) of data used, as appropriate.
- Given the importance of structured data and health IT standards for the capture, use, and exchange of relevant health data for improving health equity, the existing challenges HHAs encounter for effective capture, use, and exchange of health information include data on ethnicity and other social determinants of health to support care delivery and decision-making.

Commenters consistently supported our focus on closing health equity gaps in post-acute care, including under the HH QRP. Many commenters shared that relevant data collection and appropriate stratification are very important in addressing any health equity gaps. Stratification of health outcomes would be very helpful to organizations and some commenters supported providing home health agencies with confidential reports that report quality measures stratified by social risk factors. Many commenters shared their strategies for addressing health disparities, noting that this was an important commitment for many health provider organizations. Some commenters who worked for HHAs note that they collect SDOH elements to develop comprehensive and individualized care plans. Commenters also shared that HHAs currently use OASIS data on payer information, race/ethnicity, zip code, and age.

Commenters had recommendations for additional SDOH elements that could strengthen data collection efforts. Many commenters suggest capturing information related to food insecurity, income, education, transportation, and housing. Other commenters suggested the data collection and measurement of demographic characteristics such as sexual orientation and gender identity (SOGI), language preference, tribal membership, and disability status. Numerous commenters suggested that for any data elements introduced, we need to ensure the format align with other Federal agency best practices, such as indicators used by the U.S. Census Bureau. Commenters also suggested that we need to consider adopting the use of Z codes for SDOH on home health claims. Some commenters emphasized balancing the need to have targeted new data elements that capture necessary information on non-clinical patient characteristics without introducing undue burden with too many new, untested items. Some commenters proposed working with existing efforts in the public and private sector that promote health equity by addressing social determinants of health. A commenter cautioned we from the inclusion of social risk factors without careful methodological considerations into risk adjustment models. They note inclusion of some social risk factors could perpetuate low performance expectations. Commenters noted that the COVID–19 PHE promoted use of more digital health tools and that this expansion need to be made permanent to help support the reduction in the equity gap. Some also highlighted how the PHE underscores the need for better data collection and analysis of demographic data to aid in addressing disparities in outcome and care. Some commenters are against indirect estimation methods and suggest that we need to work on a timeline for introducing any SDOH data elements needed and to focus on direct estimation. A commenter shared that it is important to consider the needs of American Indian/Alaska Natives in any data collection strategy.

While we are not responding to specific comments submitted in response to this Health Equity request for information (RFI) in this final rule, we appreciate all of the comments and interest in this topic. We will continue to take all concerns, comments, and suggestions into account as we continue work to address and develop policies on this important topic. It is our hope to provide additional stratified information to HHAs related to race and ethnicity if feasible. The provision of stratified measure results will allow HHAs to understand how they are performing with respect to certain patient risk groups, to support these providers in their efforts to ensure equity for all of their patients, and to identify opportunities for improvements in health outcomes.

[105] *https://qualitynet.cms.gov/inpatient/measures/disparity-methods/methodology.*

IX. Revised Compliance Date for Certain Reporting Requirements Adopted for Inpatient Rehabilitation Facility (IRF) Quality Reporting Program (QRP) and Long-Term Care Hospital (LTCH) QRP

A. Revised Compliance Date for Certain Inpatient Rehabilitation Facility (IRF) QRP Reporting Requirements

1. Background

In IFC–2 (85 FR 27550), we delayed the compliance date for certain reporting requirements under the IRF QRP (85 FR 27595 through 27596). Specifically, we delayed the requirement for IRFs to begin reporting the Transfer of Health (TOH) Information to Provider-PAC and the TOH Information to Patient-PAC measures and the requirement for IRFs to begin reporting certain Standardized Patient Assessment Data Elements from October 1, 2020, to October 1st of the year that is at least 1 full fiscal year after the end of the COVID–19 PHE. We also delayed the adoption of the updated version of the IRF Patient Assessment Instrument (PAI) V4.0 with which IRFs would have used to report the TOH measures and certain Standardized Patient Assessment Data Elements.

Under IFC–2, IRFs must use the IRF–PAI V4.0 to begin collecting data on the two TOH Information measures beginning with discharges on October 1st of the year that is at least 1 full fiscal year after the end of the COVID–19 PHE. IRFs must also begin collecting data on certain Standardized Patient Assessment Data Elements on the IRF–PAI V4.0, beginning with admissions and discharges (except for the hearing, vision, race, and ethnicity Standardized Patient Assessment Data Elements, which would be collected at admission only) on October 1st of the year that is at least 1 full fiscal year after the end of the COVID–19 PHE. The delay to begin collecting data for these measures was intended to provide relief to IRFs from the added burden of implementing an updated instrument during the COVID–19 PHE. We wanted to provide maximum flexibilities for IRFs to respond to the public health threats posed by the COVID–19 PHE, and to reduce the burden in administrative efforts associated with attending trainings, training their staff, and working with their vendors to incorporate the updated assessment instruments into their operations.

At the time we finalized the policy in the IFC–2, we believed that the delay in collection of the TOH Information measures and Standardized Patient Assessment Data Elements would not

have a significant impact on the IRF QRP. However, the COVID–19 PHE showed the important need for theses TOH Information measures and Standardized Patient Assessment Data Elements under the HH QRP. The PHE's disproportionate impact demonstrates the importance of analyzing this impact and the needs for these populations in order to improve quality of care within IRFs especially during a public health emergency.

2. Current Assessment of IRFs

To accommodate the COVID–19 PHE, we provided additional guidance and flexibilities, and as a result IRFs have had the opportunity to adopt new processes and modify existing processes to accommodate the significant health crisis presented by the COVID–19 PHE. For example, we held regular ''Office Hours'' conference calls to provide IRFs regular updates on the availability of supplies, as well as answer questions about delivery of care, reporting and billing. We also supported PAC providers, including IRFs, by providing flexibilities in the delivery of care in response to the PHE, such as modifying the required face-to-face visits in IRF to be completed by telehealth (42 CFR 412.622(a)(3)(iv) and 412.29(e)) during the PHE for COVID–19, and waiving the post-admission physician evaluation requirement at § 412.622(a)(4)(ii). In the FY 2021 IRF PPS final rule (85 FR 48445 through 48447),[106] we removed the post-admission physician evaluation requirement permanently beginning October 1, 2021. In addition, as of June 9, 2021, 63.8 percent of the adult population has received at least one vaccination, and COVID–19 cases and deaths have steadily declined over the last 30 days.[107] We also believe that much more is known about COVID–19 than we did at the time IFC–2 was finalized.[108] [109] [110] [111]

Based upon other flexibilities such as the previous examples, the increase in knowledge IRF providers have about treating patients with COVID–19 [112] since finalizing IFC–2, and the trending data on COVID–19, IRFs are in a better position to accommodate reporting of the TOH measures and certain (Social Determination of Health) Standardized Patient Assessment Data Elements. Also, recent reports (that were not available at the time the IFC–2 was finalized) suggest that IRFs have the capacity to begin reporting the TOH measures and certain Social Determinant of Health (SDOH) Standardized Patient Assessment Data Elements.[113]

After evaluating the impact of the revised compliance date under IFC–2, feasibility around data collection by IRFs, and support needs of providers during the COVID–19 PHE, we have determined that IRFs now have the administrative capacity to attend training, train their staff, and work with their vendors to incorporate the updated assessment instruments, the IRF–PAI V4.0 into their operations.

We now believe that based upon the advancement of information available about COVID–19 vaccination and treatments described previously, and the importance of the data in the IRF QRP, it would be appropriate to modify the compliance date finalized in IFC–2. This may support future activities under Executive Order 13985, entitled ''Advancing Racial Equity and Support for Underserved Communities Throughout the Federal Government,'' issued January 20, 2021 (*https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government*).

3. Collection of the Transfer of Health Information to Provider-PAC Measure, the Transfer of Health Information to Patient-PAC Measure, and Certain Standardized Patient Assessment Data Elements Beginning October 1, 2022

We proposed to revise the compliance date from IFC–2 to October 1, 2022. This revised date would begin the collection of data on the Transfer of Health Information to Provider-PAC measure and Transfer of Health Information to Patient-PAC measure, and certain Standardized Patient Assessment Data Elements on the updated version of the IRF–PAI assessment instrument referred to as IRF–PAI V4.0. This revised date of October 1, 2022, which is a 2-year delay from the original compliance date finalized in the FY 2020 IRF PPS final rule (84 FR 39054 through 39173), balances the support that IRFs needed during much of the COVID–19 PHE as we provided flexibilities to support IRFs along with the need to collect this important data.

The need for the Standardized Patient Assessment Data Elements and TOH Information measures have been shown to be even more pressing with issues of inequities the COVID–19 PHE laid bare. This data that includes addressing SDOH provides information expected to improve quality of care for all. Consequently, we proposed to revise the compliance date to reflect this balance and assure that data collection begins on October 1, 2022.

As stated in the FY 2020 IRF PPS final rule, we will provide the training and education for IRFs to be prepared for this implementation (84 FR 39119 through 39147). In addition, if we adopt an October 1, 2022 compliance date, we would release a draft of the updated version of the IRF–PAI, IRF–PAI V4.0, in early 2022.

Based upon our evaluation, we proposed that IRFs collect the Transfer of Health Information to Provider-PAC measure, the TOH Information to the Patient-PAC measure, and certain Standardized Patient Assessment Data Elements beginning October 1, 2022. Accordingly, we proposed that IRFs begin collecting data on the two TOH measures beginning with discharges on October 1, 2022. We also proposed that IRFs begin collecting data on the six categories of Standardized Patient Assessment Data Elements on the IRF–PAI V4.0, beginning with admissions and discharges (except for the hearing, vision, race, and ethnicity Standardized Patient Assessment Data Elements, which would be collected at admission only) on October 1, 2022.

We invited public comment on these proposals.

Comment: Many commenters raised concerns with revising the compliance date from October 1st of the year that is at least 1 full fiscal year after the end of the PHE to October 1, 2022, given the current increase in the number of COVID–19 cases across the nation. Several commenters also stated CMS was too optimistic about the COVID–19 data and IRFs' readiness to train staff on

[106] In the FY 2022 HH proposed rule (86 FR 35874), CMS provided an incorrect citation and is correcting that error here and throughout this final rule.

[107] CDC COVID Data Tracker. Retrieved from: *https://covid.cdc.gov/covid-data-tracker/#datatracker-home.*

[108] Here's Exactly Where We are with Vaccine and Treatments for COVID–19. Healthline. May 11, 2021. Retrieved from: *https://www.healthline.com/health-news/heres-exactly-where-were-at-with-vaccines-and-treatments-for-covid-19.*

[109] COVID research: A year of scientific milestones. Nature. May 5, 2021. Retrieved from: *https://www.nature.com/articles/d41586-020-00502-w.*

[110] Clinical trial of therapeutics for severely ill hospitalized COVID–19 patients begins. National Institutes of Health News Releases. April 22, 2021. Retrieved from: *https://www.nih.gov/news-events/news-releases/clinical-trial-therapeutics-severely-ill-hospitalized-covid-19-patients-begins.*

[111] COVID–19 Treatment Guidelines. National Institutes of Health. Updated April 21, 2021. Retrieved from: *https://www.covid19treatmentguidelines.nih.gov/whats-new/.*

[112] Ehsanian R, Workman J, Jones D, et al. Free-standing acute inpatient rehabilitation hospital enhanced practices and policies in response to the COVID–19 outbreak. Future Sci OA. 2021 Fe; 7(2): FSO667. Retrieved from: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7745654/.*

[113] *https://www.healthaffairs.org/do/10.1377/hblog20201214.543463/full/.*

the IRF–PAI V4.0. They point to the CDC's Daily Tracker which shows a 7-day average of new COVID–19 cases having increased by >100,000 since the CY 2022 HH PPS proposed rule (86 FR 35874) was published on July 7, 2021.

Response: As stated in section IX.A. 2 of the CY 2022 HH PPS proposed rule (86 FR 35983 through 35984), CMS has provided IRFs a number of flexibilities to accommodate the COVID–19 PHE, including delaying the adoption of the updated version of the IRF Patient Assessment Instrument (PAI) V4.0 with which IRFs would have used to report the TOH measures and Standardized Patient Assessment Data Elements (85 FR 27595 through 27596). We also waived the IRF QRP reporting requirements for Q1 (January 1, 2020 through March 31, 2020) and Q2 (April 1, 2020 through June 30, 2020) and modified the required face-to-face visits in IRF such that they could be completed by telehealth (42 CFR 412.622(a)(3)(iv) and 412.29(e)) during the PHE for COVID–19. Additionally, we also made the waiver on the post-admission physician evaluation requirement permanent beginning October 1, 2021, in the FY 2021 IRF PPS final rule (85 FR 48445 through 48447). We believe we have provided a number of flexibilities to provide relief to IRFs throughout the PHE. We have also previously provided IRFs with the necessary tools they would need to implement the new IRF PAI 4.0, including release of the item set in 2019 and draft data specifications in early 2020. If this proposal is finalized, we will continue to provide IRFs with the tools they need well in advance of the implementation of the IRF PAI V4.0.

Despite the COVID–19 PHE, we must maintain its commitment to the quality of care for all patients, and we continue to believe that the collection of the Standardized Patient Assessment Data Elements and TOH Information measures will contribute to this effort. That includes staying committed to achieving health equity by improving data collection to better measure and analyze disparities across programs and policies [114] [115] [116] [117] [118] [119] and improving the quality of care in IRFs through a reduction in preventable adverse events. 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.[120] [121] [122] [123] [124] [125] Poor communication and coordination across health care settings contributes to patient complications, hospital readmissions, emergency department visits and medication errors.[126] [127] [128] [129] [130] [131] [132] [133] [134] [135] While we understand that there are concerns related to the timeline proposed, we do not believe that further delaying the data collection is an actionable solution to these concerns.

Comment: A commenter stated that CMS' original postponement from IFC–2 would likely have called for full adoption by October 1, 2023 and they believe this is still an appropriate adoption date.

Response: We interpret the commenter's reference to ''full adoption'' to refer to the adoption of the IRF–PAI V4.0, which includes the items for the TOH-Patient measure, the TOH-Provider measure, and the Standardized Patient Assessment Data Elements. We believe that as the healthcare community continues to learn about the enormous impact that social determinants of health (SDOH) and social risk factors (SRFs) have on patient health and health outcomes,[136] it becomes more critical to collect this in order to better understand the impact of the PHE on our healthcare system, as well as how to improve the inequities that the PHE has made so visible. We believe it will help IRFs, physicians, and other practitioners caring for patients in IRFs better prepare for the complex and resource-intensive care needs of patients with COVID–19, which will be particularly important during continued surges of this virus or new and emerging viruses. If finalized, this proposal would effectively grant a 2-year delay to the originally planned release of the IRF–PAI V4.0, a delay we granted due to the PHE. We believe that there has been a sufficient timeframe for

[114] Centers for Medicare & Medicaid Services. CMS Quality Strategy. 2016. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[115] Report to Congress: Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 Strategic Plan for Accessing Race and Ethnicity Data. January 5, 2017. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Research-Reports-2017-Report-to-Congress-IMPACT-ACT-of-2014.pdf.*

[116] Rural Health Research Gateway. Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. November 2018.

[117] *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.*

[118] *www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm.*

[119] Poteat TC, Reisner SL, Miller M, Wirtz AL. COVID–19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. Preprint. *medRxiv.* 2020;2020.07.21.20159327. Published 2020 Jul 24. doi:10.1101/2020.07.21.20159327.

[120] 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.

[121] Boockvar, K.S., Blum, S., Kugler, A., Livote, E., Mergenhagen, K.A., Nebeker, J.R., & Yeh, J., ''Effect of admission medication reconciliation on adverse drug events from admission medication changes,'' *Archives of Internal Medicine,* 2011, Vol. 171(9), pp. 860–861.

[122] 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.

[123] 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.

[124] 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.

[125] Boling, P.A., ''Care transitions and home health care,'' *Clinical Geriatric Medicine,* 2009, Vol. 25(1), pp. 135–48.

[126] Barnsteiner, J.H., ''Medication Reconciliation: Transfer of medication information across settings—keeping it free from error,''

[127] Arbaje, A.I., Kansagara, D.L., Salanitro, A.H., Englander, H.L., Kripalani, S., Jencks, S.F., & Lindquist, L.A., ''Regardless of age: incorporating principles from geriatric medicine to improve care transitions for patients with complex needs,'' *Journal of General Internal Medicine,* 2014, Vol. 29(6), pp. 932–939.

[128] Jencks, S.F., Williams, M.V., & Coleman, E.A., ''Rehospitalizations among patients in the Medicare fee-for-service program,'' *New England Journal of Medicine,* 2009, Vol. 360(14), pp. 1418–1428.

[129] 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.*

[130] 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 app roach,'' *BMC Health Services Research,* 2013, Vol. 13(1), pp. 1–10.

[131] 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.

[132] 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.*

[133] 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 app roach,'' *BMC Health Services Research,* 2013, Vol. 13(1), pp. 1–10.

[134] Forster, A.J., Murff, H.J., Peterson, J.F., Gandhi, T.K., & Bates, D.W., ''The incidence and severity of adverse events affecting patients after discharge from the hospital.'' *Annals of Internal Medicine,* 2003,138(3), pp. 161–167.

[135] King, B.J., Gilmore-Bykovsky, A.L., Roiland, R.A., Polnaszek, B.E., Bowers, B.J., & Kind, A.J. ''The consequences of poor communication during transitions from hospital to skilled nursing facility: a qualitative study,'' *Journal of the American Geriatrics Society,* 2013, Vol. 61(7), 1095–1102.

[136] Hood CM, Gennuso KP, Swain GR, Catlin BB. County Health Rankings: Relationships Between Determinant Factors and Health Outcomes. *Am J Prev Med.* 2016 Feb;50(2):129–35. Available at: *https://pubmed.ncbi.nlm.nih.gov/26526164/.* Accessed 9/1/21.

IRFs to adjust to the change in care patterns associated with the PHE.

Comment: A commenter stated that the Delta variant, and the potential for other variants, has undermined the knowledge and experience gained by IRFs earlier in the pandemic. Commenters stated a continued delay would provide IRFs the necessary capacity to accommodate additional surges.

Response: We understand the conditions under which IRFs are working to address the number of new COVID–19 cases resulting from the Delta variant. We disagree with the commenter, however, that the knowledge and experience IRFs have gained since the beginning of the pandemic has been undermined by the Delta variant. The Delta variant is a mutation of the original SARS–CoV–2 strain, rather than a novel virus as COVID–19 was when it emerged in January of 2020. While the CDC has described the Delta variant as more transmissible than the Alpha COVID–19 virus,[137] many of the symptoms are similar.[138] The methods of reducing transmission of the Delta variant are also similar, that is indoor masking, social distancing, and vaccination.[139] Currently, there are multiple treatments [140] [141] for COVID–19 and vaccines that are either authorized under a Food and Drug Administration's (FDA) Emergency Use Authorization [142] [143] or have approval from FDA.[144]

Comment: A commenter stated that if the PHE was a valid reason to delay implementation of the TOH measures and certain Standardized Patient Assessment Data Elements a year ago, the recent surge is a valid reason to maintain the delay.

Response: We disagree with the commenter. As described in section XI.A.1 of the CY 2022 HH PPS proposed rule (86 FR 35983 through 35984), at the time we finalized the policy in the IFC–2 (85 FR 27550), we were in the initial months of the COVID–19 PHE and very little was known about the COVID–19 virus. We believed the delay in collection of the TOH Information measures and Standardized Patient Assessment Data Elements was necessary in order to allow IRFs to focus on patient care and staff safety during a time when very little was known about COVID–19. However, the COVID–19 PHE has illustrated the important need for these TOH Information measures and Standardized Patient Assessment Data Elements under the IRF QRP. The PHE's disproportionate impact among black, Latino, and American Indian and Alaska Native (AI/AN) persons [145] [146] demonstrates the importance of analyzing this impact in order to improve quality of care within IRFs especially during a crisis. As stated in section VII.F of the FY 2022 IRF PPS proposed rule (86 FR 19110 through 19112), one important strategy for addressing these important inequities is by improving data collection to allow for better measurement and reporting on equity across post-acute care programs and policies, and the data collected will support future activities under Executive Order 13985, entitled ''Advancing Racial Equity and Support for Underserved Communities Throughout the Federal Government,'' issued January 20, 2021 (*https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government*).

Currently, there are multiple treatments [147] [148] for COVID–19, and vaccines that are either authorized under FDA's Emergency Use Authorization [149] [150] or have approval from FDA.[151] As of August 13, 2021, 82.2% of the population 65 years of age or older and 64.4% of the population 18 years of age or older have been fully vaccinated.[152]

Comment: Several commenters stated implementing the IRF–PAI V4.0 would divert critical patient care resources at a time when IRFs are struggling to keep up with current documentation requirements. They raised concerns that having to train nursing staff to collect and report these data would divert their attention away from direct patient care. A commenter stated that hospitals are still requiring social distancing and limiting large group gatherings, so the logistics of training would be challenging. A commenter stated that implementing the new assessment tool at this time may increase the risk for patient-care errors, while another commenter stated they would have no means to dedicate staff to the task of training which would defeat the purpose of collecting the information.

Response: As described in section IX.A.2. of this final rule, we granted IRF providers several waivers related to documentation in order to ease burden during the PHE, and many of these are still in effect. We are very mindful of burden that may occur from the collection and reporting of data. Both the TOH-Patient measure and TOH-Provider measure are comprised of one item, and further, the activities associated with the measure align with existing requirements related to transferring information at the time of discharge to safeguard patients (84 FR 51882 and § 482.43). Additionally, TEP feedback and pilot testing of the items

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[137] Delta Variant: What We Know about the Science. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html* Accessed 9/1/2021.

[138] What Are the Symptoms of the COVID–19 Delta Variant? Available at: *https://www.emedicinehealth.com/what_are_the_symptoms_of_covid19_delta_variant/article_em.htm.* Accessed 9/1/2021.

[139] Things to Know About the Delta Variant. Available at: *https://www.yalemedicine.org/news/5-things-to-know-delta-variant-covid.* Accessed 9/1/2021.

[140] National Institutes of Health COVID–19 Treatment Guidelines. Available at: *https://www.covid19treatmentguidelines.nih.gov/.* Accessed 9/9/2021.

[141] FDA Approves First Treatment for COVID–19. October 22, 2020. Available at: *https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-covid-19.* Accessed 9/9/2021.

[142] U.S. Food and Drug Administration (2021). Janssen Biotech, Inc. COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/146303/download.* Accessed 9/9/2021.

[143] U.S. Food and Drug Administration. (2021). ModernaTX, Inc. COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/144636/download.* Accessed 9/9/2021.

[144] FDA Approves First COVID–19 Vaccine | FDA, *available at https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine.* Accessed 9/03/21. The Pfizer-BioNTech vaccine also continues to be available under EUA. U.S. Food and Drug Administration (2021). Comirnaty and Pfizer-BioNTech COVID–19 Vaccine. Accessed 9/28/2021.

[145] *https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-fact-sheet.pdf.*

[146] Ochieng N, Cubanski J, Neuman T, Artiga S, and Damico A. Racial and Ethnic Health Inequities and Medicare. Kaiser Family Foundation. February 2021. Available at: *https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/.*

[147] National Institutes of Health COVID–19 Treatment Guidelines. Available at: *https://www.covid19treatmentguidelines.nih.gov/.* Accessed 9/9/2021.

[148] FDA Approves First Treatment for COVID–19. October 22, 2020. Available at: *https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-covid-19.* Accessed 9/9/2021.

[149] U.S. Food and Drug Administration (2021). Janssen Biotech, Inc. COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/146303/download.* Accessed 9/9/2021.

[150] U.S. Food and Drug Administration. (2021). ModernaTX, Inc. COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/144636/download.* Accessed 9/9/2021.

[151] FDA Approves First COVID–19 Vaccine. FDA. Available at: *https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine.* Accessed 9/03/21. The Pfizer-BioNTech vaccine also continues to be available under EUA. U.S. Food and Drug Administration (2021). Comirnaty and Pfizer-BioNTech COVID–19 Vaccine. Accessed 9/28/2021.

[152] COVID–19 Vaccinations in the United States. Available at: *https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total.* Accessed 9/9/2021.

did not find the burden of reporting to be significant.[153]

The new Standardized Patient Assessment Data Element items in the IRF–PAI 4.0 are also reflective of patient characteristic that providers are likely already gathering in order to meet hospital conditions of participation, such as patient's preferred language, race, ethnicity, hearing, vision, health literacy, pain, high-risk drug classes and cognitive function.

We also understand provider's concerns with developing training materials for the TOH-Patient measure and TOH-Provider measure items and the Standardized Patient Assessment Data Elements. We plan to provide multiple training resources and opportunities for IRFs to take advantage of, reducing the burden to IRFs in creating their own training resources. These training resources may include online learning modules, tip sheets, questions and answers documents, and/or recorded webinars and videos, and would be available to providers in early 2022, allowing IRFs several months to ensure their staff take advantage of the learning opportunities. Having the materials online and on-demand would also eliminate the need for large group gatherings, a concern raised by some commenters. The IRF QRP Helpdesk would also be available for providers to submit their follow up questions by email, further enhancing the educational resources.

Comment: We received a comment stating that implementing the IRF–PAI 4.0 would require additional staffing, specifically nursing staff, at a time when there is a pandemic-induced nursing staff shortage, which in some areas is so critical that IRF beds have been reduced. A commenter noted that although there are multiple positions open at their IRF, they have had no applicants. This same commenter reported they have had to reinstitute COVID emergency staffing registered nurse (RN)-to-patient ratios, and without a foreseeable end in the surge in cases, staff leadership cannot turn their resources and attention to the task of training. They suggested that not finalizing the proposal would minimize administrative and reporting requirements and provide an opportunity to recover from the pandemic's effects on the workforce.

Response: We interpret the commenter's concern to be associating the nursing shortage with the COVID–19 pandemic. According to the Centers for Disease Control and Prevention's (CDC) COVID Data Tracker Weekly review on October 1, 2021,[154] the current 7-day moving average of daily cases has decreased 13.3% compared to the previous 7-day moving average. Additionally, COVID–19 cases have been steadily declining since January 2021. Despite an uptick in weekly reported cases in September, the height of new cases at that time was still 36% less than the numbers reported in January 2021.[155] According to the CDC's forecast modeling, new cases are estimated to continue to decline another 30% in the next four weeks. The impacts of the COVID–19 PHE on the healthcare system, including staffing shortages, make it especially important now to monitor quality of care.[156] Still, we are mindful of burden that may occur from the collection and reporting of our measures. We emphasize, however, that that TOH Information Provider-PAC and TOH Information Patient-PAC measures consist of one item each, and further, the activities associated with the measures align with the existing requirements related to transferring information at the time of discharge to safeguard patients. Additionally, as stated in the FY 2020 IRF PPS final rule (84 FR 39054 through 39173), we convened a Technical Expert Panel (TEP) [157] and conducted a pilot test.[158] Both the TEP feedback and the pilot participants found the burden of reporting not to be significant.

We have strived to balance the scope and level of detail of the data elements against the potential burden placed on IRFs. We plan to provide multiple training resources and opportunities for IRFs to take advantage of, which will reduce the burden to IRFs. We plan to make these training resources available to IRFs in early 2022.

Comment: Several commenters pointed out the lack of Information Systems (IT) personnel as a barrier to being able to implement the IRF–PAI V4.0 on October 1, 2022. They state that implementing the IRF–PAI V4.0 would require new flowsheets, interfaces, and reports to inform the new version of the assessment instrument, and they are limited in their resources. They state that IT systems and personnel had to quickly pivot to developing virtual platforms for care during the PHE, and/or develop platforms and reports to implement mandatory and time-sensitive COVID–19-related tracking requirements. A commenter noted that there are also 2020 ''maintenance releases'' that have been delayed due to the PHE and staffing shortages. As a result, these commenters do not believe they have the operational resources to dedicate to the investment of retooling their electronic health record for the IRF–PAI V4.0.

Response: While we acknowledge there will be some updates required of IT vendors and systems, we believe a significant portion of the work has already been completed. For example, we posted a change table in November 2019 illustrating the changes that would occur to the IRF–PAI with the transition from the IRF–PAI 3.0 to 4.0. In March 2020, we posted the IRF–PAI Draft Technical Data Submission Specifications. The IRF–PAI 4.0 was not postponed due to the PHE until June 17, 2020, fewer than 4 months before it was to be implemented October 1, 2020. Therefore, we believe that most IRFs would have already made the necessary enhancements to their electronic medical records and flowsheets in preparation for the transition. We plan to provide the final draft specifications and release that to providers and vendors in late 2021 or when technically feasible, which would give providers just under 1 year to build their necessary IT programs.

Comment: Several commenters stated that if CMS finalized the October 1, 2022, date for the collection of the TOH Information to the Patient-PAC measure, the TOH Information to the Patient-Provider measure, and the Standardized Patient Assessment Data Elements, they would have to divert resources away from the tasks associated with patient care and instead put the resources in training nursing staff to complete the new assessment. A commenter stated they believe the benefit to CMS of having this information to study is significantly outweighed by the burden imposed on IRFs.

[153] Transfer of Health Information TEP Meeting 4—June 2018. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Transfer-of-Health-Information-TEP-Meeting-4-June2018.pdf.* Accessed 9/9/2021.

[154] *https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html.*

[155] Centers for Disease Control and Prevention. COVID–19 Forecasts: Cases. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/science/forecasting/forecasts-cases.html.* Accessed September 27, 2021.

[156] Nursing and Patient Safety. Agency for Healthcare Research and Quality. April 21, 2021. Available at: *https://psnet.ahrq.gov/primer/nursing-and-patient-safety.* Accessed 10/4/2021.

[157] Transfer of Health Information TEP Meeting 4—June 2018. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Transfer-of-Health-Information-TEP-Meeting-4-June2018.pdf.* Accessed 9/1/2021.

[158] Transfer of Health Information 2018 Pilot Test Summary Report. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Transfer-of-Health-Information-Pilot-Test-Summary-Report_Final_Feb2018.pdf.* Accessed 9/1/2021.

Response: We would like to clarify that CMS proposed to begin collecting the TOH Information to the Patient-PAC measure, the TOH Information to the Patient-Provider measure and the Standardized Patient Assessment Data Elements to support our responsibility to monitor and ensure quality of care for patients. Additionally, this information will provide actionable data on which IRFs can improve health care outcomes.

We disagree that the benefit of having this information is outweighed by the burden. As stated earlier, we plan to provide multiple training resources and opportunities for IRFs to take advantage of, which will reduce the burden to IRFs. We plan to make these training resources available to IRFs in early 2022, allowing IRFs several months to ensure their staff take advantage of the learning opportunities, and to allow IRFs to spread the cost of training out over several quarters.

Comment: A commenter stated that proposing the implementation of the IRF–PAI V4.0 so soon after CMS' request for information (RFI) on creating new standardized data collection elements across the continuum of care (not just post-acute care) in the IRF PPS proposed rule (86 FR 19110 through 19112) created confusion for providers. They believe it would create confusion and unnecessary administrative burden for CMS to add data elements to the IRF–PAI V4 because they are available, only to replace them with more reliable elements based on the feedback received to the FY 2022 IRF RFI.

Response: To clarify, the Standardized Patient Assessment Data Elements that would be collected in the IRF–PAI V4.0 were finalized in the FY 2020 IRF PPS final rule (84 FR 4 FR 39109 through 39161). The request for information published in section VII.F. of the FY 2022 IRF PPS proposed rule (86 FR 19110 through 19112) requested public comment on recommendations for quality measures or measurement domains that address health equity as well as additional items that could be used to assess health equity in the care of IRF patients, which may or may not include Standardized Patient Assessment Data Elements. Therefore, we do not anticipate unnecessary administrative burden as a result of the feedback received to the FY 2022 IRF RFI.

Comment: A commenter noted it was unclear if CMS' proposal intended to implement the full scope of the IRF–PAI version 4.0, or only those Standardized Patient Assessment Data Elements and the two new TOH measures discussed in the proposal. They reference the original change table CMS provided back in 2019. For example, the data elements for IRF–PAI V.4.0 in section O starting on page 26 of the change table are not addressed by CMS's proposed scope of adoption. The commenter asked CMS to clarify what data elements would be adopted to support their proposal.

Response: We believe the commenter is referencing the document titled, ''Change Table for Final IRF–PAI Version 4.0—Effective date: October 1, 2020'', that was posted to the CMS QRP website on November 21, 2019.[159] This change table reflects the reporting requirements under the IRF QRP that were finalized in the FY 2020 IRF PPS Final Rule. Our proposal is consistent with the reporting requirements finalized in the FY 2020 IRF PPS Rule; specifically, IRFs would begin using the IRF Patient Assessment Instrument (PAI) V4.0 to report the TOH Information to Provider-PAC and the TOH Information to Patient—PAC measures and certain Standardized Patient Assessment Data Elements. If finalized, we would release an updated draft of the IRF–PAI V.4.0 and accompanying IRF–PAI V.4.0 manual in early 2022.

Comment: A commenter acknowledged that CMS has the authority to issue proposals through a variety of avenues, but requested CMS include proposals impacting IRF payment or the Quality Reporting Program (QRP) in the annual IRF Prospective Payment System (PPS) rulemaking in order to avoid confusion for stakeholders.

Response: We thank the commenter for the suggestion and will take it under consideration. We note, however, that an announcement was posted to the IRF QRP Spotlights and Announcements [160] webpage on June 28, 2021, an announcement was sent from the PAC listserv.

Final Decision: After careful consideration of the comments received, we are finalizing our proposal that IRFs begin collecting the TOH Information to Provider-PAC measure, the TOH Information to the Patient-PAC measure, and on the six categories of Standardized Patient Assessment Data Elements on the IRF–PAI V4.0, beginning with admissions and discharges (except for the hearing, vision, race, and ethnicity Standardized Patient Assessment Data Elements, which would be collected at admission only) on October 1, 2022.

B. Proposed Revised Compliance Date for Certain Long-Term Care Hospital (LTCH) QRP Reporting Requirements

1. Background

In IFC–2 (85 FR 27550), we delayed the compliance date for certain reporting requirements under the LTCH QRP (85 FR 27595 through 27596). Specifically, we delayed the requirement for LTCHs to begin reporting the TOH Information to Provider-PAC measure and the TOH Information to Patient-PAC measure and the requirement for LTCHs to begin reporting certain Standardized Patient Assessment Data Elements from October 1, 2020, to October 1st of the year that is at least 1 full fiscal year after the end of the COVID–19 PHE. We also delayed the adoption of the updated version of the LTCH Continuity Assessment and Record of Evaluation (CARE) Data Set (LCDS) V5.0 with which LTCHs would have used to report the TOH measures and certain Standardized Patient Assessment Data Elements.

Under IFC–2, LTCHs must use the LCDS V5.0 to begin collecting data on the two TOH Information measures beginning with discharges on October 1st of the year that is at least 1 full fiscal year after the end of the COVID–19 PHE. LTCHs must also begin collecting data on certain Standardized Patient Assessment Data Elements on the LCDS V5.0, beginning with admissions and discharges (except for the hearing, vision, race, and ethnicity Standardized Patient Assessment Data Elements, which would be collected at admission only) on October 1st of the year that is at least 1 full fiscal year after the end of the COVID–19 PHE. The delay to begin collecting data for these measures was intended to provide relief to LTCHs from the associated burden of implementing an updated instrument during the COVID–19 PHE. We wanted to provide maximum flexibilities for LTCHs to respond to the public health threats posed by the COVID–19 PHE, and to reduce the burden in administrative efforts associated with attending trainings, training their staff, and working with their vendors to incorporate the updated assessment instruments into their operations.

At the time we finalized the policy in the IFC–2, we believed that the delay in collection of the TOH Information measures, and Standardized Patient Assessment Data Elements would not

[159] File available here: *https://www.cms.gov/files/document/final-irf-pai-version-40-change-table-1.pdf* and on the IRF–PAI and IRF–PAI Manual webpage in the Downloads section at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-PAI-and-IRF-PAI-Manual.*

[160] Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Spotlights-Announcements.* Accessed 10/4/2021.

have a significant impact on the LTCH QRP. However, the COVID–19 PHE showed the important need for theses TOH Information measures and Standardized Patient Assessment Data Elements under the LTCH QRP. The PHE's disproportionate impact on minority populations demonstrates the importance of analyzing this impact and the needs for these populations in order to improve quality of care within LTCHs especially during a public health emergency.

2. Current Assessment of LTCHs

To accommodate the COVID–19 PHE, we have provided additional guidance and flexibilities, and as a result LTCHs have had the opportunity to adopt new processes and modify existing processes to accommodate the significant health crisis presented by the COVID–19 PHE. For example, we held regular ''Office Hours'' conference calls to provide LTCHs regular updates on the availability of supplies, as well as answer questions about delivery of care, reporting and billing. We also supported PAC providers, including LTCHs, by providing flexibilities in the delivery of care in response to the PHE, such as waiving requirement at 42 CFR 482.43(a)(8), 482.61(e), and 485.642(a)(8) to provide detailed information regarding discharge planning. To address workforce concerns related to COVID–19, we waived requirements under 42 CFR 482.22(a)(1) through (4) to allow for physicians whose privileges would expire to continue practicing at the hospital and for new physicians to be able to practice before full medical staff/governing body review and approval. In addition, as of June 9, 2021, 63.8 percent of all the adult population has received at least one vaccination, and COVID–19 cases and deaths have steadily declined over the last 60 days.[161] We also believe that much more is known about COVID–19 than at the time we finalized IFC–2.[162] [163] [164] [165]

Based upon other flexibilities such as the previous examples, the increase in knowledge LTCH providers have about treating patients with COVID–19 [166] since finalizing IFC–2, and the trending data on COVID–19, LTCHs are now in a better position to accommodate reporting of the TOH measures and certain Standardized Patient Assessment Data Elements.[167]

After evaluating the impact of the revised compliance date under IFC–2, feasibility around data collection in LTCHs, and support needs of providers during the COVID–19 PHE, we have determined that LTCHs now have the administrative capacity to attend trainings, train their staff, and work with their vendors to incorporate the updated assessment instrument, the LCDS V5.0 into their operations.

We now believe that based upon the advancement of information available about COVID–19 vaccination and treatments described previously, and the importance of the data to the LTCH QRP it would be appropriate to modify the compliance date finalized in IFC–2. This may support future activities under Executive Order 13985, entitled ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,'' issued January 20, 2021 (*https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government*).

3. Collection of the Transfer of Health Information to Provider-PAC Measure, the Transfer of Health Information to Patient-PAC Measure, and Certain Standardized Patient Assessment Data Elements Beginning October 1, 2022

We proposed to revise the compliance date from IFC–2 to October 1, 2022. This revised date would begin the collection of data on the Transfer of Health Information to Provider-PAC measure, Transfer of Health Information to Patient-PAC measure, and certain Standardized Patient Assessment Data Elements on the updated version of the LCDS V5.0. This revised date of October 1, 2022, which is a 2-year delay from this original compliance date finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42044 through 42701), balances the support that LTCHs needed during much of the COVID–19 PHE as we provided flexibilities to support LTCHs along with the need to collect this important data.

The need for the Standardized Patient Assessment Data Elements and TOH Information measures have been shown to be even more pressing with issues of inequities the COVID–19 PHE laid bare. This data that includes addressing SDOH provides information expected to improve quality of care for all. Consequently, we proposed to revise the compliance date to reflect this balance and assure that data reporting begins on October 1, 2022.

As stated in the FY 2020 IPPS/LTCH PPS final rule, we will provide the training and education for LTCHs to be prepared for this implementation (84 FR 42540 through 42560). In addition, if we adopt an October 1, 2022, compliance date, we stated that we would release a draft of the updated version of the LCDS, LCDS V5.0, in early 2022.

Based upon our evaluation, we proposed that LTCHs collect the Transfer of Health Information to Provider-PAC measure, the Transfer of Health Information to the Patient-PAC measure, and certain Standardized Patient Assessment Data Elements, beginning on October 1, 2022. We proposed that accordingly, LTCHs begin collecting data on the two TOH measures beginning with discharges on October 1, 2022. We also proposed that LTCHs begin collecting data on the six categories of Standardized Patient Assessment Data Elements on the LCDS V5.0, beginning with admissions and discharges (except for the hearing, vision, race, and ethnicity Standardized Patient Assessment Data Elements, which would be collected at admission only) on October 1, 2022.

We invited public comment on these proposals.

Comment: Several commenters raised concerns with revising the compliance date from October 1st of the year that is at least 1 full year after the end of the PHE to October 1, 2022, given the current increase in the number of COVID–19 cases across the nation. Commenters also stated CMS was too optimistic about the COVID–19 data and LTCHs' readiness to train staff on the LCDS V5.0. They point to the CDC's Daily Tracker which shows a 7-day average of new COVID–19 cases having increased by >100,000 since the CY 2022 HH PPS proposed rule (86 FR 35874) was published on July 7, 2021.

[161] CDC COVID Data Tracker. Retrieved from: *https://covid.cdc.gov/covid-data-tracker/#datatracker-home.*

[162] Here's Exactly Where We are with Vaccine and Treatments for COVID–19. Healthline. May 11, 2021. Retrieved from: *https://www.healthline.com/health-news/heres-exactly-where-were-at-with-vaccines-and-treatments-for-covid-19.*

[163] COVID research: a year of scientific milestones. Nature. May 5, 2021. Retrieved from: *https://www.nature.com/articles/d41586-020-00502-w.*

[164] Clinical trial of therapeutics for severely ill hospitalized COVID–19 patients begins. National Institutes of Health News Releases. April 22, 2021. Retrieved from: *https://www.nih.gov/news-events/news-releases/clinical-trial-therapeutics-severely-ill-hospitalized-covid-19-patients-begins.*

[165] COVID–19 Treatment Guidelines. National Institutes of Health. Updated April 21, 2021. Retrieved from: *https://www.covid19treatmentguidelines.nih.gov/whats-new/.*

[166] Ehsanian R, Workman J, Jones D, et al. Free-standing acute inpatient rehabilitation hospital enhanced practices and policies in response to the COVID–19 outbreak. Future Sci OA. 2021 Fe; 7(2): FSO667. Retrieved from: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7745654/.*

[167] *https://www.healthaffairs.org/do/10.1377/hblog20201214.543463/full/.*

Response: As stated in section IX.B. 2 of the CY 2022 HH PPS proposed rule (86 FR 35984 through 35985), we have provided LTCHs a number of flexibilities to accommodate the COVID–19 PHE. In addition to delaying the adoption of the updated version of the LCDSV5.0 with which LTCHs would have used to report the TOH measures and certain Standardized Patient Assessment Data Elements (85 FR 27595 through 27596), we also waived the LTCH QRP reporting requirements for Q1 (January 1, 2020 through March 31, 2020) and Q2 (April 1, 2020 through June 30, 2020). Additionally, we waived the requirement at 42 CFR 482.43(a)(8), 482.61(e), and 485.642(a)(8) to provide detailed information regarding discharge planning, and waived the requirements under 42 CFR 482.22(a)(1) through (4) to allow for physicians whose privileges would expire to continue practicing at the hospital and for new physicians to be able to practice before full medical staff/governing body review and approval. Both of these waivers, as well as others, remain in place today. We believe we have provided a number of flexibilities to provide relief to LTCHs throughout the PHE. We have also previously provided LTCHs with the necessary tools they would need to implement the new LTCH V5.0, including release of the item set in 2019 and draft data specifications in early 2020. If this proposal is finalized, we will continue to provide LTCHs with the tools they need well in advance of the implementation of the LTCH V5.0.

Despite the ongoing COVID–19 PHE, we must maintain commitment to the quality of care for all patients, and we continue to believe that the collection of the Standardized Patient Assessment Data Elements and TOH Information measures will contribute to this effort. That includes staying committed to achieving health equity by improving data collection to better measure and analyze disparities across programs and policies[168] [169] [170] [171] [172] [173] and improving the quality of care in LTCHs through a reduction in preventable adverse events. 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.[174] [175] [176] [177] [178] [179] Poor communication and coordination across health care settings contributes to patient complications, hospital readmissions, emergency department visits and medication errors.[180] [181] [182] [183] [184] [185] [186] [187] [188] [189]

While we understand that there are concerns related to the timeline proposed, we do not believe that further delaying the data collection is an appropriate response to these concerns. As the healthcare community continues to learn about the enormous impact that social determinants of health (SDOH) and social risk factors (SRFs) have on patient health and health outcomes,[190] it becomes more critical for Medicare to collect this information. The information is extremely important to understanding the impact of the PHE on our healthcare system, and how to improve the inequities the PHE has made so visible, and we believe it will help LTCHs better prepare for the complex and resource-intensive care needs of patients with COVID–19, which will be particularly important during continued surges of this virus or new and emerging viruses. If finalized, this proposal would effectively grant a 2-year delay to the originally planned release of the LCDS V5.0, a delay we granted due to the PHE. We believe that there has been a sufficient timeframe for LTCHs to adjust to the change in care patterns associated with the PHE.

Comment: Another commenter stated that if the PHE was a valid reason to delay implementation of the TOH measures and certain Standardized Patient Assessment Data Elements a year ago, the recent surge is a valid reason to maintain the delay.

Response: We disagree with the commenter. As described in section XI.A.1 of the CY 2022 HH PPS proposed rule (86 FR 35983 through 35984), at the time we finalized the policy in the IFC–2 (85 FR 27550), we were in the initial months of the COVID–19 PHE and very little was known about the COVID–19 virus. We believed the delay in

[168] Centers for Medicare & Medicaid Services. CMS Quality Strategy. 2016. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[169] Report to Congress: Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 Strategic Plan for Accessing Race and Ethnicity Data. January 5, 2017. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Research-Reports-2017-Report-to-Congress-IMPACT–ACT-of-2014.pdf.*

[170] Rural Health Research Gateway. Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. November 2018.

[171] *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.*

[172] *www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm.*

[173] Poteat TC, Reisner SL, Miller M, Wirtz AL. COVID–19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. Preprint. *medRxiv.* 2020;2020.07.21.20159327. Published 2020 Jul 24. doi:10.1101/2020.07.21.20159327.

[174] 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.

[175] Boockvar, K. S., Blum, S., Kugler, A., Livote, E., Mergenhagen, K. A., Nebeker, J. R., & Yeh, J., ''Effect of admission medication reconciliation on adverse drug events from admission medication changes,'' *Archives of Internal Medicine,* 2011, Vol. 171(9), pp. 860–861.

[176] 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.

[177] 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.

[178] 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.

[179] Boling, P. A., ''Care transitions and home health care,'' *Clinical Geriatric Medicine,* 2009, Vol. 25(1), pp. 135–48.

[180] Barnsteiner, J. H., ''Medication Reconciliation: Transfer of medication information across settings—keeping it free from error,''

[181] Arbaje, A. I., Kansagara, D. L., Salanitro, A. H., Englander, H. L., Kripalani, S., Jencks, S. F., & Lindquist, L. A., ''Regardless of age: incorporating principles from geriatric medicine to improve care transitions for patients with complex needs,'' *Journal of General Internal Medicine,* 2014, Vol. 29(6), pp. 932–939.

[182] Jencks, S. F., Williams, M. V., & Coleman, E. A., ''Rehospitalizations among patients in the Medicare fee-for-service program,'' *New England Journal of Medicine,* 2009, Vol. 360(14), pp. 1418–1428.

[183] 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.*

[184] 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 app roach,'' *BMC Health Services Research,* 2013, Vol. 13(1), pp. 1–10.

[185] 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.

[186] 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.*

[187] 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 app roach,'' *BMC Health Services Research,* 2013, Vol. 13(1), pp. 1–10.

[188] Forster, A. J., Murff, H. J., Peterson, J. F., Gandhi, T. K., & Bates, D. W., ''The incidence and severity of adverse events affecting patients after discharge from the hospital.'' *Annals of Internal Medicine,* 2003,138(3), pp. 161–167.

[189] King, B. J., Gilmore- Bykovsky, A. L., Roiland, R. A., Polnaszek, B. E., Bowers, B. J., & Kind, A. J. ''The consequences of poor communication during transitions from hospital to skilled nursing facility: a qualitative study,'' *Journal of the American Geriatrics Society,* 2013, Vol. 61(7), 1095–1102.

[190] Hood CM, Gennuso KP, Swain GR, Catlin BB. County Health Rankings: Relationships Between Determinant Factors and Health Outcomes. *Am J Prev Med.* 2016 Feb;50(2):129–35. Available at: *https://pubmed.ncbi.nlm.nih.gov/26526164/.* Accessed 9/1/21.

collection of the TOH Information measures and Standardized Patient Assessment Data Elements was necessary in order to allow LTCHs to focus on patient care and staff safety during a time when very little was known about COVID–19. However, the COVID–19 PHE has illustrated the important need for these TOH Information measures and Standardized Patient Assessment Data Elements under the LTCH QRP. The PHE's disproportionate impact among black, Latino, and American Indian and Alaska Native (AI/AN) persons [191] [192] demonstrates the importance of analyzing this impact in order to improve quality of care within LTCHs especially during a crisis. As stated in section IX.E.7 of the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25616 through 25618) one important strategy for addressing these important inequities is by improving data collection to allow for better measurement and reporting on equity across post-acute care programs and policies, and the data collected will support future activities under Executive Order 13985, entitled ''Advancing Racial Equity and Support for Underserved Communities Throughout the Federal Government,'' issued January 20, 2021 (*https://www.federalregister.gov/documents/2021/01/25/2021–01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government*).

Currently, there are multiple treatments[193] [194] for COVID–19, and vaccines that are either authorized through FDA's Emergency Use Authorization [195] [196] or have approval from FDA.[197] As of August 13, 2021, 82.2% of the population 65 years of age or older and 64.4% of the population 18 years of age or older have been fully vaccinated.[198]

Comment: A commenter stated that the Delta variant of COVID–19, and the potential for other variants, has undermined the knowledge and experience gained by LTCHs earlier in the pandemic. Commenters stated a continued delay would provide LTCHs the necessary capacity to accommodate additional surges.

Response: We understand the conditions under which LTCHs are working to address the number of new COVID–19 cases resulting from the COVID–19 Delta variant. We disagree with the commenter, however, that the knowledge and experience LTCHs have gained since the beginning of the PHE has been undermined by the Delta variant. The Delta variant is a mutation of the original SARS–CoV–2 strain, rather than a novel virus as COVID–19 was when it emerged in January of 2020. While the CDC has described Delta as more transmissible than the Alpha COVID–19 virus,[199] many of the symptoms are similar.[200] The methods of reducing transmission of the Delta variant are also similar, that is indoor masking, social distancing, and vaccination.[201] Currently, there are multiple treatments[202] [203] for COVID–19, and vaccines that are either authorized through FDA's Emergency Use Authorization [204] [205] or have approval from FDA.[206]

Comment: Several commenters stated implementing the LCDS V5.0 would divert critical patient care resources at a time when LTCHs are struggling to keep up with current documentation requirements. They raised concerns that having to train nursing staff to collect and report these data would divert their attention away from direct patient care.

Response: As described in section IX.B.2. of this final rule, we have granted LTCH providers several waivers related to documentation in order to ease burden during the PHE, and many of these are still in effect. We are very mindful of burden that may occur from the collection and reporting of data. Both the TOH Information to the Patient—PAC measure and TOH Information to the Provider—PAC measure are comprised of one item, and further, the activities associated with the measure align with existing requirements related to transferring information at the time of discharge to safeguard patients (84 FR 51882 and § 482.43). Additionally, TEP feedback and pilot testing of the items did not find the burden of reporting to be significant.[207]

The new Standardized Patient Assessment Data Element items in the LCDS V5.0 are also reflective of patient characteristic that providers are likely already gathering in order to meet hospital conditions of participation, such as patient's preferred language, race, ethnicity, hearing, vision, health literacy, pain, high-risk drug classes and cognitive function.

We also understand provider's concerns with developing training materials for the TOH Information to the Patient—PAC measure and TOH Information to the Provider—PAC measure items and the Standardized Patient Assessment Data Elements. We plan to provide multiple training resources and opportunities for LTCHs

[191] *https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-fact-sheet.pdf.*

[192] Ochieng N, Cubanski J, Neuman T, Artiga S, and Damico A. Racial and Ethnic Health Inequities and Medicare. Kaiser Family Foundation. February 2021. Available at: *https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/.*

[193] National Institutes of Health COVID–19 Treatment Guidelines. Available at: *https://www.covid19treatmentguidelines.nih.gov/.* Accessed 9/9/2021.

[194] FDA Approves First Treatment for COVID–19. October 22, 2020. Available at: *https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-covid-19.* Accessed 9/9/2021.

[195] U.S. Food and Drug Administration (2021). Janssen Biotech, Inc. COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/146303/download.* Accessed 9/9/2021.

[196] U.S. Food and Drug Administration. (2021). ModernaTX, Inc. COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/144636/download.* Accessed 9/9/2021.

[197] FDA Approves First COVID–19 Vaccine | FDA. Accessed 9/03/21. The Pfizer-BioNTech vaccine also continues to be available under EUA. U.S. Food and Drug Administration (2021). Comirnaty and Pfizer-BioNTech COVID–19 Vaccine. Accessed 9/28/2021.

[198] COVID–19 Vaccinations in the United States. Available at: *https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total.* Accessed 9/9/2021.

[199] Delta Variant: What We Know about the Science. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html.* Accessed 9/1/2021.

[200] What Are the Symptoms of the COVID–19 Delta Variant? Available at: *https://www.emedicinehealth.com/what_are_the_symptoms_of_covid19_delta_variant/article_em.htm.* Accessed 9/1/2021.

[201] 5 Things to Know About the Delta Variant. Available at: *https://www.yalemedicine.org/news/5-things-to-know-delta-variant-covid.* Accessed 9/1/2021.

[202] National Institutes of Health COVID–19 Treatment Guidelines. Available at: *https://www.covid19treatmentguidelines.nih.gov/.* Accessed 9/9/2021.

[203] FDA Approves First Treatment for COVID–19. October 22, 2020. Available at: *https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-covid-19.* Accessed 9/9/2021.

[204] U.S. Food and Drug Administration (2021). Janssen Biotech, Inc. COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/146303/download.* Accessed 9/9/2021.

[205] U.S. Food and Drug Administration. (2021). ModernaTX, Inc. COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/144636/download.* Accessed 9/9/2021.

[206] FDA Approves First COVID–19 Vaccine | FDA. Accessed 9/03/21. The Pfizer-BioNTech vaccine also continues to be available under EUA. U.S. Food and Drug Administration (2021). Comirnaty and Pfizer-BioNTech COVID–19 Vaccine. Accessed 9/28/2021.

[207] Transfer of Health Information TEP Meeting 4—June 2018. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Transfer-of-Health-Information-TEP-Meeting-4-June2018.pdf.* Accessed 9/9/2021.

to take advantage of, reducing the burden to LTCHs in creating their own training resources. These training resources may include online learning modules, tip sheets, questions and answers documents, and/or recorded webinars and videos, and would be available to LTCHs in early 2022, allowing LTCHs several months to ensure their staff take advantage of the learning opportunities. Having the materials online and on-demand would also eliminate the need for large group gatherings, a concern raised by some commenters. The LTCH QRP Helpdesk would also be available for providers to submit their follow up questions by email, further enhancing the educational resources.

Comment: We received comment stating that implementing the LCDS V5.0 would require additional staffing, specifically nursing staff, at a time when there is a pandemic-induced nursing staff shortage, which in some areas is so critical that LTCH beds have been reduced.

Response: We interpret the commenter's concern regarding the nursing shortage with the COVID–19 pandemic. According to the Centers for Disease Control and Prevention's (CDC) COVID Data Tracker Weekly review on October 1, 2021,[208] the current 7-day moving average of daily cases has decreased 13.3% compared to the previous 7-day moving average. Additionally, COVID–19 cases have been steadily declining since January 2021. Despite an uptick in weekly reported cases in September, the height of new cases at that time was still 36% less than the numbers reported in January 2021.[209] According to the CDC's forecast modeling, new cases are estimated to continue to decline another 30% in the next four weeks. The impacts of the COVID–19 PHE on the healthcare system, including staffing shortages, make it especially important now to monitor quality of care.[210] Still, we are mindful of burden that may occur from the collection and reporting of our measures. We emphasize, however, that that TOH Information Provider—PAC and TOH Information Patient—PAC measures consist of one item each, and further, the activities associated with the measures align with the existing requirements related to transferring information at the time of discharge to safeguard patients. Additionally, as stated in the FY 2020 IPPS/LTCH PPS Final Rule (84 FR 42535 through 42588), we convened a Technical Expert Panel (TEP) [211] and conducted a pilot test.[212] Both the TEP feedback and the pilot participants found the burden of reporting not to be significant.

We have strived to balance the scope and level of detail of the data elements against the potential burden placed on LTCHs. We plan to provide multiple training resources and opportunities for LTCHs to take advantage of, which will reduce the burden to LTCHs. We plan to make these training resources available to LTCHs in early 2022.

Comment: Several commenters pointed out the lack of Information Systems (IT) personnel as a barrier to being able to implement the LCDS V5.0 on October 1, 2022. They state that implementing the LCDS V5.0 would require new flowsheets, interfaces, and reports to inform the new version of the assessment instrument, and they are limited in their resources. They state that IT systems and personnel had to quickly pivot to developing virtual platforms for care during the PHE, and/or develop platforms and reports to implement mandatory and time-sensitive COVID–19-related tracking requirements. A commenter noted that there are also 2020 ''maintenance releases'' that have been delayed due to the PHE and staffing shortages. As a result, these commenters do not believe they have the operational resources to dedicate to the investment of retooling their electronic health record for the LCDS V5.0.

Response: While we acknowledge there will be some updates required of IT vendors and systems, we believe a significant portion of the work has already been completed. For example, we posted a change table in November 2019 illustrating the changes that would occur to the LCDS with the transition from the LCDS V4.0 to V5.0.[213] In March 2020, we posted the LCDS V5.0 Draft Technical Data Submission Specifications.[214] The LCDS V5.0 was not postponed due to the PHE until June 17, 2020, fewer than 4 months before it was to be implemented October 1, 2020. Therefore, we believe that most LTCHs would have already made the necessary enhancements to their electronic medical records and flowsheets in preparation for the transition. We plan to provide the final draft specifications and release that to providers and vendors in late 2021 or when technically feasible, which would give providers just under 1 year to build their necessary IT programs.

Comment: A commenter stated they believe the benefit to CMS of having this information to study is significantly outweighed by the burden imposed on LTCHs.

Response: We would like to clarify that CMS proposed to begin collecting the TOH Information to the Patient—PAC measure, the TOH Information to the Patient-Provider measure, and the Standardized Patient Assessment Data Elements to support our responsibility to monitor and ensure quality of care for patients. Additionally, this information will provide actionable data on which LTCHs can improve health care outcomes.

Final Decision: After careful consideration of the comments received, we are finalizing our proposal that LTCHs begin collecting the TOH Information to Provider-PAC measure, the TOH Information to the Patient-PAC measure, and on the six categories of Standardized Patient Assessment Data Elements on the LCDS V5.0, beginning with admissions and discharges (except for the hearing, vision, race, and ethnicity Standardized Patient Assessment Data Elements, which would be collected at admission only) on October 1, 2022.

X. COVID–19 Reporting Requirements for Long Term Care Facilities

A. Background

The United States is responding to the COVID–19 Public Health Emergency (PHE) caused by the coronavirus which has been detected in more than 190 countries internationally, and all 50

[208] *https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html.*

[209] Centers for Disease Control and Prevention. COVID–19 Forecasts: Cases. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/science/forecasting/forecasts-cases.html.* Accessed September 27, 2021.

[210] Nursing and Patient Safety. Agency for Healthcare Research and Quality. April 21, 2021. Available at: *https://psnet.ahrq.gov/primer/nursing-and-patient-safety.* Accessed 10/4/2021.

[211] Transfer of Health Information TEP Meeting 4—June 2018. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Transfer-of-Health-Information-TEP-Meeting-4-June2018.pdf.* Accessed 9/1/2021.

[212] Transfer of Health Information 2018 Pilot Test Summary Report. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Transfer-of-Health-Information-Pilot-Test-Summary-Report_Final_Feb2018.pdf.* Accessed 9/1/2021.

[213] File available here: *https://www.cms.gov/files/zip/ltch-care-data-set-v50-effective-october-1–2020-zip.zip* and on the LTCH LCDS and LTCH QRP Manual webpage in the Downloads section at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH–CARE-Data-Set-and-LTCH–QRP-Manual.*

[214] File available here: *https://www.cms.gov/files/zip/ltch-data-specs-v4000-draft-03–05–2020zip.zip* and on the LTCH QRP Technical Information webpage at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Technical-Information.*

States and the District of Columbia. In an effort to respond to the COVID–19 PHE and protect the health and safety of LTC facility residents, CMS published three interim final rules with comment period (IFCs) directly affecting LTC facilities. The May 8, 2020 IFC titled, ''Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program'' (85 FR 27550) revised the infection prevention and control requirements for LTC facilities to more effectively respond to the specific challenges posed by the COVID–19 pandemic. Specifically, this IFC added provisions to require facilities to electronically report information related to confirmed or suspected COVID–19 cases in a standardized format and frequency specified by the Secretary and required facilities to inform residents and their representatives of confirmed or suspected COVID–19 cases in the facility among residents and staff.

The September 2, 2020 IFC, entitled ''Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act, Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' (85 FR 54820, 54873) set out provisions regarding testing for COVID–19 in long-term care facilities, including documentation requirements and protocols specifying actions to be taken if a resident or staff member tests positive. The May 13, 2021 IFC, titled ''Medicare and Medicaid Programs; COVID–19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) Residents, Clients, and Staff'' (86 FR 26306) revised the infection control requirements that LTC facilities and intermediate care facilities for individuals with intellectual disabilities (ICFs-IID) must meet to participate in the Medicare and Medicaid programs. This IFC aimed to reduce the spread of SARS–CoV–2 infections, the virus that causes COVID–19 by requiring education about COVID–19 vaccines for LTC facility residents, ICF–IID clients, and staff serving both populations, and by requiring that such vaccines, when available, be offered to all residents, clients, and staff. It also required LTC facilities to report COVID–19 vaccination status of residents and staff to the Centers for Disease Control and Prevention (CDC). Additional information and data regarding SARS–CoV–2, and populations at greatest risk were presented in these IFCs (85 FR 27550 and 86 FR 26306).

This final rule focuses on the LTC facility COVID-related reporting requirements established in these three IFCs and codifies these requirements in order to extend them beyond the PHE. While COVID–19 cases for both staff and residents had been consistently declining from April to July 2021, there has been a recent increase in confirmed cases for staff and residents of LTC facilities.[215] In addition, the Delta variant is currently the predominant variant of the virus in the United States. It is more infectious and has led to increased transmissibility when compared to other variants, even in some vaccinated individuals. Specifically, the Delta variant is more than 2x contagious than previous variants. Preliminary data also suggest that the Delta variant may cause more severe illness than previous variants in unvaccinated people. Available data continue to suggest that breakthrough infections are relatively rare, and the majority of new cases are attributable to unvaccinated persons. The greatest risk of transmission is among unvaccinated people who are more likely to become infected, and therefore transmit the virus.[216] Furthermore, while resident vaccination rates are high in LTC facilities, standing at about 84 percent, it is not reasonable to anticipate complete vaccination coverage, leaving all facilities at risk for a COVID–19 outbreak after the official PHE declaration has ended. It is also important to note that only 64 percent of current nationwide LTC facility staff have been vaccinated.[217] The nature of LTC facilities make outbreaks of COVID–19 difficult to control, especially as many staff and potentially residents may be asymptomatic. Asymptomatic people with SARS–CoV–2 may move in and out of the LTC facility and the community, putting residents and staff at risk of infection. The CDC is continuing to assess data on whether fully vaccinated individuals with asymptomatic breakthrough infections can transmit the virus.[218] Routine testing of LTC residents and staff, along with visitation restrictions, personal protective equipment (PPE) usage, social distancing, and vaccination for residents and staff are the best defense against COVID–19.

The rate of staff vaccination, coupled with the continued threat of numerous variants, including the highly transmissible Delta variant, the congregate living nature of LTC facilities that make them more susceptible to COVID–19 outbreaks, and breakthrough cases, creates an ongoing risk of outbreaks, with significant risks of morbidity and mortality, in this higher risk population. This final rule maintains the current COVID–19 reporting requirements while modifying the reporting frequency of these requirements to no more than weekly, which may be reduced at the discretion of the Secretary, and adds a sunset date of December 31, 2024 for most of the reporting requirements, in order to ensure patient safety and health while informing future pandemic and emergency response.

B. Statutory Authority and Regulatory Background

Under sections 1866 and 1902 of the Act, providers of services seeking to participate in the Medicare or Medicaid program, or both, must enter into an agreement with the Secretary or the State Medicaid agency, as appropriate. Long-term care (LTC) facilities seeking to be Medicare and Medicaid providers of services must be certified as meeting Federal participation requirements. LTC facilities include SNFs for Medicare and NFs for Medicaid. The Federal participation requirements for SNFs, NFs, and dually certified facilities, are set forth in sections 1819 and 1919 of the Act and codified in the implementing regulations at 42 CFR part 483, subpart B.

Sections 1819(d)(3) and 1919(d)(3) of the Act explicitly require that LTC facilities develop and maintain an infection control program that is designed, constructed, equipped, and maintained in a manner to protect the health and safety of residents, personnel, and the general public. In addition, sections 1819(d)(4)(B) and 1919(d)(4)(B) of the Act explicitly authorize the Secretary to issue any regulations he deems necessary to protect the health and safety of

[215] *Data.CMS.gov, COVID–19 Nursing Home Data, https://data.cms.gov/covid-19/covid-19-nursing-home-data.*

[216] Centers for Disease Control and Prevention, *Delta Variant: What We Know About the Science https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html.*

[217] *Data.CMS.gov, COVID–19 Nursing Home Data, https://data.cms.gov/covid-19/covid-19-nursing-home-data.*

[218] Centers for Disease Control and Prevention, *Delta Variant: What We Know About the Science https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html?s_cid=11512:covid%20delta:sem.ga:p:RG:GM:gen:PTN:FY21.*

residents. Infection prevention and control is a primary goal of initiatives taking place in LTC facilities during the COVID–19 PHE. Under the explicit instructions of Congress, existing regulations at § 483.80 require facilities to, among other things, establish and maintain an infection prevention and control program (IPCP) designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of communicable diseases and infections.

C. Summary of the Provisions and Responses to Public Comments

In response to the three IFCs that were published on May 8, 2020, September 2, 2020, and May 13, 2021, we received 537 total comments. Commenters included individuals, health care professionals and corporations, national associations and coalitions, patient advocacy organizations, and individual facilities that will be impacted by the rule.

In this final rule, we are finalizing provisions from two of the three IFCs that made amendments to § 483.80. We provide a summary of our proposed provisions, a summary of the public comments received and our responses to them, and the policies we are finalizing for LTC facilities. We have organized our proposed provisions and responses to the comments as follows: COVID–19 Reporting and Vaccine Reporting. Comments related to the collection of information requirements and impact analysis sections are addressed in sections XI and XII, ''Collection of Information Requirements'' and ''Regulatory Impact Analysis'' of this final rule.

1. Requirement for Facilities To Report Nursing Home Residents and Staff Infections, Potential Infections, and Deaths Related to COVID–19 (§ 483.80(g)(1) Through (3))

In the IFC, ''Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program'' (85 FR 27550), we finalized a requirement at § 483.80 (g)(1), that LTC facilities electronically report information about COVID–19 in a standardized format specified by the secretary. This report must include suspected and confirmed COVID–19 infections among residents and staff, including residents previously treated for COVID–19; total deaths and COVID–19 deaths among residents and staff; personal protective equipment and hand hygiene supplies in the facility; ventilator capacity and supplies in the facility; resident beds and census; access to COVID–9 testing while the resident is in the facility; and staffing shortages.

In addition, § 483.80(g)(2) requires that the information specified in § 483.80(g)(1) be provided at a frequency specified by the Secretary, but no less than weekly to the CDC's National Healthcare Safety Network (NHSN). Finally, § 483.80(g)(3) requires that residents, their representatives, and their families be informed of the occurrence of either a single or confirmed infection of COVID–19, or three or more residents or staff with new-onset of respiratory symptoms occurring within 72 hours of each other. This information must be reported to the residents, their representatives, and their families by 5:00 PM the next calendar day.

In response to the May 8, 2020 IFC, we received 297 public comments. While a significant number of commenters indicated that they supported increased reporting requirements, the majority of the comments expressed concerns about the burden of the reporting requirements.

Comment: A significant number of commenters indicated that the reporting requirements were too burdensome, time consuming, duplicative, and create a heightened sense of alarm.

Response: We understand the burden concerns expressed by commenters. However, due to the unpredictable nature of the virus and the new variants that are arising, we believe that it is vital that this information be collected and recorded. Retaining the data reporting requirements after the end of the PHE is an important element of maintaining effective surveillance of this novel virus. While COVID–19 cases for both staff and residents were consistently declining for several weeks, there has been an increase in confirmed cases for staff and residents of LTC facilities. Specifically, national case rates have continued to climb precipitously, reaching levels not seen since early February 2021. As of October 1, 2021, the current 7-day moving average of daily new cases was 106,395. As of September 25, 2021, the overall rate of COVID–19 hospitalizations per 100,000 was 6.4 hospitalizations.[219] Collectively, this information highlights the gravity of the delta variant.

The rate of staff vaccinations, coupled with the presence of multiple variants, specifically the highly contagious Delta variant, and breakthrough infections, creates an ongoing risk of outbreaks, with significant risks of morbidity and mortality, in this higher risk population. Timely and actionable surveillance will enable CMS to continue to respond to facilities in need of additional technical support and oversight, should they experience new COVID–19 infections.

In addition, agencies across HHS have released data and guidance that should have addressed and alleviated some of the confusion that commenters are referring to. As such, we will be maintaining the current reporting requirements, which require LTC facilities to report weekly, unless the Secretary specifies a lesser frequency, and the potential to modify the number of data elements reported in the future, contingent upon the state of the pandemic. In an effort to further address concerns regarding burden, we are also finalizing a sunset date of December 31, 2024 for the reporting requirements, with the exception of the staff and resident vaccination reporting requirements in § 483.80(g)(1)(viii). We believe that the need to collect data will likely extend past the end of the PHE. We therefore are granting ourselves and other government authorities the continued ability to monitor LTC facilities, given that this population has been most vulnerable to the virus. This provision will automatically expire on December 31, 2024 unless it is determined that further regulations must be established.

Comment: Several commenters questioned the need to report COVID related deaths for individuals with multiple comorbidities, as many LTC residents have pre-existing and chronic conditions, and they believe that COVID was not the primary or sole cause of death.

Response: Many individuals that succumb to COVID–19 have multiple co-morbidities, none of which negate a person's COVID–19 infection status. COVID–19 related deaths need to be reported to provide CMS with information that enables us to protect these vulnerable populations and ensure that the appropriate care is being provided. Therefore, we are retaining the requirement that facilities must report nursing home resident and staff infections, potential infections, and deaths related to COVID–19.

In an effort to support surveillance of COVID–19 cases, we are maintaining the requirements to establish explicit reporting requirements for confirmed or suspected cases with the possibility for reduced frequency of reporting and minimizing the number of required data

[219] COVID–NET, Laboratory-Confirmed COVID–19-Associated Hospitalizations *https://gis.cdc.gov/grasp/covidnet/covid19_3.html.*

elements in the future at the discretion of the Secretary. Specifically, we are finalizing our requirements by maintaining the provision at § 483.80(g)(1)(i) through (ix), to require facilities to electronically report information about COVID–19 in a standardized format specified by the Secretary. The report includes, but is not limited to, information on: Suspected and confirmed COVID–19 infections among residents and staff, including residents previously treated for COVID–19; total deaths and COVID–19 deaths among residents and staff; personal protective equipment and hand hygiene supplies in the facility; ventilator capacity and supplies available in the facility; resident beds and census; access to COVID–19 testing while the resident is in the facility; staffing shortages; and other information specified by the Secretary. In the future, the number of data elements required to be reported may be reduced to allow for greater flexibility and mitigate burden concerns. This information will be used to monitor trends in infection rates, and inform future public health and emergency preparedness policies.

Comment: A commenter stated that the rationale for additional reporting to Federal authorities is unclear, since LTC facilities must already report to State and local authorities and that a universal reporting system should be used instead.

Response: Federal reporting requirements are used by State and local authorities to inform their operations and pandemic response for their particular population. We understand the burden concerns expressed by commenters and have therefore revised the frequency of reporting information specified in paragraph (g)(1) to weekly, unless the Secretary specifies a lesser frequency, and a reduced number of data elements in the future, at the discretion of the Secretary, when the COVID–19 virus is less prevalent and we may no longer need all of this data as frequently. Due to the variation in mandates across States and localities, we will continue to require surveillance efforts at the Federal level and maintain current reporting requirements.

In addition, at § 483.80(g)(2), we are revising the current requirements to require that LTC facilities provide the information noted previously weekly, unless the Secretary specifies a lesser frequency, to the Center for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN) with the possibility for reduced frequency of reporting in the future, contingent on the state of the PHE. Furthermore, we note that the information reported will be shared with us and we will retain and publicly report this information to support protecting the health and safety of residents, in accordance with sections 1819(d)(4)(B) and 1919(d)(4) of the Act, as well as facility personnel, and the general public. These requirements will support our efforts to proactively and transparently inform interested parties and ensure that the most complete information on COVID–19 cases is available. The existing reporting requirements at § 483.80(g)(1) and (2) do not relieve LTC facilities of the obligation to continue to comply with § 483.80(a)(2)(ii), which requires facilities to report possible incidents of communicable disease and infections. This includes complying with State and local reporting requirements for COVID–19.

Comment: Many commenters indicated that the reporting requirements are not stringent or detailed enough, resulting from lack of oversight and the vague definitions/terminology set out in the IFCs. A significant portion of commenters requested further clarification and more detailed regulations to ensure that programs achieved better quality and lower costs.

Commenters also recommended additional reporting requirements including but not limited to retroactive reporting and the collection of additional demographic information (race, ethnicity, sex, age, disability status, primary language, sexual orientation, gender identity, socio-economic status, and location (urban/rural)). The commenters noted that retroactive reporting dating back to January 1, 2020, is necessary in order to gain a better understanding of the trajectory of SARS–CoV–2 and the rapidly evolving situation. A few commenters also expressed their desire for disability status to be collected as well, as these individuals are often predisposed to disease and are more likely to experience medical complications and succumb to the virus.

The majority of commenters also recommended additional reporting requirements regarding the number of staff and residents who were hospitalized and who recovered from COVID–19. They stated that additional reporting requirements related to testing should include the number of residents and staff who have been tested, the percent of residents and staff who have been tested, the frequency of resident and staff testing, and the number of tests available.

Response: The reporting requirements were written in a manner that would allow for maximum flexibility by covering a broad array of services and entities. While we agree that additional data, including demographic information, could be useful to inform the pandemic response, especially since underserved populations including racial and ethnic minorities have been disproportionately impacted by COVID–19, we also understand that additional requirements could be more burdensome for providers that are caring for residents during the pandemic at this time. However, we are committed to advancing health equity and reducing disparities for those in underserved populations that have been disproportionately impacted by COVID–19 and we believe that these data reporting requirements are an essential first steps in helping us better understand the impacts of COVID–19 on underserved populations that reside in LTC facilities. Information gained from this reported data will be assessed and used to determine if additional policy changes, especially those affecting underserved populations, should be made in the future. Additionally, the NHSN system already collects this type of information and, therefore, we are not adding additional categories in order to avoid duplicative efforts and further confusion. In an effort to mitigate potential concern about the burdensome nature of the requirements, we will not be adding additional reporting requirements and data elements at this time, but we have modified our regulations to include the flexibility to change the data elements that are required to be reported to NHSN in the future, as appropriate.

Comment: Many commenters noted that the current reporting requirements do not accomplish the goal of ensuring that residents are informed participants in the care that they receive.

Response: We disagree with the commenters. The collection of this data allows for residents and their caregivers to be informed participants in their care, as it allows them to understand the current state of the environment that they reside in. Resident health and safety are of the utmost importance, and therefore, we are continuing all of our current reporting requirements.

Specifically, at § 483.80(g)(3), we are maintaining the provision to require facilities to inform residents, their representatives, and families of those residing in facilities of confirmed or suspected COVID–19 cases in the facility among residents and staff. This reporting requirement supports the overall health and safety of residents by ensuring they are informed participants in the care that they receive as well as providing assurances of the mitigating

steps the facility is taking to prevent and control the spread of COVID–19. Facilities must inform residents, their representatives, and families by 5 p.m. the next calendar day following the occurrence of either: A single confirmed infection of COVID–19; or three or more residents or staff with new-onset of respiratory symptoms that occur within 72 hours of each other. Also, cumulative updates to residents, their representatives, and families must be provided at least weekly by 5 p.m. the next calendar day following the subsequent occurrence of either: (1) Each time a confirmed infection of COVID–19 is identified; or (2) whenever three or more residents or staff with new onset of respiratory symptoms occur within 72 hours of each other. This information must be reported in accordance with existing privacy regulations and statute and must not include Personally Identifiable Information (PII). Facilities must include information on mitigating actions implemented to prevent or reduce the risk of transmission, including if normal operations in the nursing home will be altered such as restrictions or limitations to visitation or group activities. For purposes of this reporting requirement and to mitigate the concerns regarding burden that have been expressed in public comments, facilities are not expected to make individual telephone calls. Instead, facilities can utilize communication mechanisms that make this information easily available to all residents, their representatives, and families, such as paper notification, listservs, website postings, or recorded telephone messages.

These reporting requirements, along with public reporting of the data, support our responsibility to protect and ensure the health and safety of residents by enforcing the standards required to help each resident attain or maintain their highest level of well-being. In addition, sections 1819(d)(3)(B) and 1919(d)(3) of the Act requires that a facility must establish an infection control program that is designed, constructed, equipped, and maintained in a manner to protect the health and safety of residents, personnel, and the general public. We believe that the reporting requirements comply with these statutory requirements. We also note that they are necessary for us to monitor whether individual nursing homes are appropriately tracking, responding, and mitigating the spread and impact of COVID–19 on our most vulnerable citizens, personnel who care for them, and the general public. The information provided may be used to inform residents, families, and communities of the status of COVID–19 infections in their area. We believe that this action strengthens our response to the PHE for the COVID–19 pandemic and reaffirms our commitment to transparency and protecting the health and safety of nursing home residents.

2. COVID–19 Vaccine Reporting for Residents and Staff (§ 483.80(g)(1)(viii))

In the May 2021 IFC, ''Medicare and Medicaid Programs; COVID–19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs–IID) Residents, Clients, and Staff'', we finalized a requirement, at § 483.80(g)(1)(viii), that LTC facilities report on the COVID–19 vaccine status of residents and staff, including total numbers of residents and staff, numbers of residents and staff vaccinated, numbers of each dose of COVID–19 vaccine received, and COVID–19 vaccination adverse events. We are also finalizing the requirement at § 483.80(g)(1)(ix) to require the reporting of therapeutics administered to residents for treatment of COVID–19. We received 71 comments in response to this IFC, with no comments discussing the requirement to report information about therapeutics administered to residents for treatment of COVID–19. A significant number of commenters indicated that they supported increased reporting requirements, however, the majority of the comments expressed concerns about the burdensome nature of the requirements.

Comment: Several commenters supported our staff and resident vaccination reporting requirements and cited statistics about the higher rate of contracting COVID–19 and succumbing to the virus compared to the general population. Additionally, they note, continued collection of data and surveillance will allow CDC and other Federal agencies to identify facilities that need additional support. This will also enable current and prospective residents and families to make informed decisions regarding their options for care.

Response: We thank commenters for their support and their ability to recognize the gravity of the situation. Due to the evolving nature of the virus and the continued threat of the delta and other new variants, it is vital that surveillance be maintained. On August 18, CMS announced the development of an emergency regulation requiring staff vaccinations within the nation's more than 15,000 Medicare and Medicaid-participating nursing homes. Subsequently, on September 9, CMS announced the expansion of the August 18 announcement requiring staff vaccinations in nursing homes to add additional Medicare and Medicaid-certified health care providers and suppliers certified by CMS, including, but not limited to, hospitals, dialysis facilities, ambulatory surgical centers, and home health agencies. We believe maintaining these vaccination reporting requirements aligns with the President's recent announcements [220] regarding staff vaccination.

Comment: Most commenters indicated that this vaccine reporting requirement is challenging to comply with due to staffing shortages, difficulty hiring and retaining a qualified workforce, and paying competitive wages. Many commenters expressed concern about the time it takes to complete the reporting due to short staffing and the requirement to report to multiple entities. Commenters also questioned if this requirement is the best use of resources, and argue that this time would be better utilized providing personal care. A few commenters noted that smaller LTC facilities do not have the same kind of infrastructure and resources that larger agencies and other institutional providers have access to, and that this should be considered when determining compliance and expectations of the rule.

The majority of commenters were concerned that these vaccine reporting requirements were duplicative of other currently existing requirements and systems used for reporting this data. Some of these commenters noted that the requirements are duplicative of requirements to report this data to State and local health departments. Additionally, a few commenters were unclear on where to report vaccination metrics and how to document compliance efforts. A commenter expressed concern that this type of reporting is only beneficial for data analysts, not the residents of the facility.

Commenters believed that reporting should be more user friendly and less time consuming. Most commenters were in favor of using systems that are already in place and that they use often (Minimum Data Set [MDS], Payroll Based Journal [PBJ]) in order to improve these processes and comply with the requirements. Commenters recommended creating an item for

[220] The White House, *Remarks by President Biden on Fighting the COVID–19 Pandemic https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/09/09/remarks-by-president-biden-on-fighting-the-covid-19-pandemic-3/.*

COVID–19 vaccinations in the MDS for residents and pulling data from there. Multiple commenters also proposed adding an item on PBJ data submissions for staff requirements. PBJ and MDS are already required, the commenters stated, and they explained that it would take less time to complete these reporting requirements through these platforms instead of NHSN. Additionally, a small number of commenters shared some privacy concerns and implications of tracking and documenting staff vaccination status through NHSN.

Finally, a commenter indicated that they could use MDS to submit this information as they do for pneumonia and influenza; this would combine processes that are already in place. Another commenter also suggested REDCap as an alternative, as it is used for the Federal Partnership Vaccine Program.

Response: We acknowledge the burdensome nature of some of these requirements and thank the staff for their hard work in complying with these requirements while providing care to their residents. Since this IFC was initially published, CMS and other agencies across HHS have released additional guidance in an effort to address some of these questions and concerns about how to comply to these requirements. Additionally, CMS has standing calls with several key stakeholders in an effort to address some of these questions and concerns. We recognize that some facilities have stronger infrastructures and more resources available to work with. However, while some of this reporting may seem duplicative of other State and local reporting requirements, it has been instrumental in developing a tailored pandemic response and allows authorities to understand where most resources need to be directed.

Consistent vaccination reporting by LTC facilities via the NHSN will help to identify LTC facilities that have potential issues with vaccine confidence or slow uptake among either residents or staff or both. The NHSN is the nation's most widely used health care-associated infection (HAI) tracking system. It furnishes States, facilities, regions, and the government with data regarding problem areas and measures of progress. CDC and CMS use information from NHSN to support COVID–19 vaccination programs by focusing on groups or locations that would benefit from additional resources and strategies that promote vaccine uptake. CMS surveyors and State agency surveyors will use the vaccination data in conjunction with the reported data that includes COVID–19 cases, resident deaths, staff shortages, PPE supplies and testing. This combination of reported data is used by surveyors to determine individual facilities that need to have focused infection control surveys as well as technical assistance in expanding vaccine delivery and uptake. Facilities having difficulty with vaccine acceptance can be identified through examining trends in NHSN data; and the Quality Improvement Organizations (QIOs), groups of health quality experts, clinicians, and consumers organized to improve the quality of care delivered to people with Medicare, can provide assistance to increase vaccine acceptance. Specifically, QIOs may provide assistance to LTC facilities by targeting small, low performing, and rural nursing homes most in need of assistance, and those that have low COVID–19 vaccination rates; disseminating accurate information related to access to COVID–19 vaccines to facilities; educating residents and staff on the benefits of COVID–19 vaccination; understanding nursing home leadership perspectives and assist them in developing a plan to increase COVID–19 vaccination rates among residents and staff; and assisting providers with reporting vaccinations accurately.

We believe direct submission of data by LTC facilities through NHSN will show actions and trends that can be addressed more efficiently on a national level. All State health departments and many local health departments already have direct access through NHSN to LTC facilities' COVID–19 data and are using the data for their own local response efforts. Thus, reporting in NHSN will, in many cases, serve the needs of State and local health departments.

Therefore, we are modifying the requirements at § 483.80(g)(1)(viii) to require that LTC facilities report to NHSN, on a weekly basis, unless the Secretary specifies a lesser frequency, the COVID–19 vaccination status and related data elements of all residents and staff. The data to be reported each week will be cumulative, that is, data on all residents and staff, including total numbers and those who have received the vaccine, as well as additional data elements. In this way, the vaccination status of every LTC facility will be known on a weekly basis. Data on vaccine uptake will be important to understanding the impact of vaccination on SARS–CoV–2 infections and transmission in nursing homes. This understanding, in turn, will help CDC make changes to guidance to better protect residents and staff in LTC facilities. In addition, LTC facilities must also report any COVID–19 therapeutics administered to residents. CDC has currently defined ''therapeutics'' for the purposes of the NHSN as a ''treatment, therapy, or drug'' and stated that monoclonal antibodies are examples of anti-SARS–CoV–2 antibody-based therapeutics used to help the immune system recognize and respond more effectively to the SARS–CoV–2 virus.

Our intent in mandating reporting of COVID–19 vaccines and therapeutics to NHSN is in part to monitor broader community vaccine uptake, but also to allow CDC to identify and alert CMS to facilities that may need additional support in regards to vaccine education and administration. The information reported to CDC in accordance with § 483.80(g) will be shared with CMS and we will retain and publicly report this information to support protecting the health and safety of residents, staff, and the general public, in accordance with sections 1819(d)(3)(B) and 1919(d)(3) of the Act.

Comment: A significant proportion of commenters recommended that CMS expand these vaccination reporting requirements to other facilities where Medicare beneficiaries receive care ([psychiatric] residential treatment facilities, psychiatric hospitals, adult foster care homes, group homes, and assisted living facilities) as these communities are at the highest risk for infection and severe illness. Another commenter stated that this requirement should also be expanded to include prisons, homeless shelters, forensic hospitals, supervised apartments, and inpatient hospice facilities. Several commenters also emphasized the importance of this due to the emergence of new variants and continued mitigation efforts.

Some commenters highlighted the disproportionate impact that COVID–19 has had on minority groups and individuals with disabilities. Because of this, commenters recommended that CMS arrange and collect vaccination reporting data by race and ethnicity. They stated that the data should be de-aggregated to examine the disparate outcomes for individuals based on sex, age, race, and ethnicity. Another commenter believes that in addition to data on race and ethnicity, data on sexual orientation, gender identity, preferred language, urban/rural environment, and service setting should be collected. The commenters stated that for people with intellectual and developmental disabilities, as well as other disability groups, the pandemic has revealed the need for public health

surveillance systems to include disability status as a basic demographic characteristic.

Response: We agree that additional data collection could be useful in informing emergency preparedness and future pandemic response and we reaffirm our commitment to addressing disparities in healthcare that have disproportionately affected underserved populations. However, in an effort to mitigate some of the burden concerns expressed by commenters, we will not be adding additional data elements or reporting requirements. Instead, we will maintain the current reporting requirements for the reporting of staff and resident vaccinations. The May 2021 IFC sought information regarding the potential application of these requirements in other congregate living settings and suggested ICFs–IID report vaccine administration. However, in light of the commenters overall concerns regarding the burden of these reporting requirements, we do not believe that it is appropriate to mandate these requirements for other congregate living settings at this time. Additionally, CMS does not have the authority to extend these reporting requirements to some of the settings that commenters discuss, including prisons, assisted living facilities, supervised apartments, or homeless shelters. We appreciate this feedback and will consider it for future rulemaking.

We believe that all LTC facility residents and the staff who care for them, should be provided with ongoing access to vaccination against COVID–19. The accountable entities responsible for the care of residents and clients of LTC facilities must proactively pursue access to COVID–19 vaccination due to a unique set of challenges that generally prevent these residents and clients from independently accessing the vaccine. These challenges create potential disparities in vaccine access for those residing in LTC facilities. It is CMS's understanding that very few individuals who are residents of LTC facilities are likely able to independently schedule or travel to public offsite vaccination opportunities. People reside in LTC facilities because they need ongoing support for medical, cognitive, behavioral, and/or functional reasons. Because of these issues, they may be less capable of self-care, including arranging for preventive health care. Independent scheduling and traveling off-site may be especially challenging for people with low health literacy, intellectual and developmental disabilities, dementia including Alzheimer's disease, visual or hearing impairments, or severe physical disability. To support national efforts to control the spread of COVID–19, we are finalizing the LTC facility infection control regulations related to reporting COVID–19 data at § 483.80(g)(1)(viii) so that they will continue in effect. We have not finalized a sunset date for these requirements in order to allow for continued monitoring and surveillance of vaccine delivery and uptake.

Comment: Several commenters shared their stance on vaccination and indicated that vaccines should not be required and that this should be a decision between an individual and their provider. A commenter expressed feeling being ''discriminated'' against because of the commenter's decision to not receive the COVID vaccination.

Response: The IFCs did not finalize a vaccination mandate for LTC staff or residents; therefore, these comments outside the scope of this rule. We are maintaining the requirement at § 483.80(g)(1)(viii) for the reporting of staff and resident vaccinations.

Final Decision: After consideration of the public comments we received on the COVID–19 reporting requirements, we are finalizing the requirements at § 483.80(g)(1) through (3) with the following modifications: (1) Reporting frequency of the information specified in § 483.80(g)(1) is modified to weekly, unless the Secretary specifies a lesser frequency; (2) Reporting data elements are unchanged, but may be reduced, contingent on the state of the pandemic and at the discretion of the Secretary; and (3) with a sunset date of December 31, 2024 for all reporting requirements, with the exclusion of the requirements at § 483.80(g)(1)(viii).

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TABLE 37 IFC CROSSWALK OF COVID-19 REPORTING REQUIREMENTS AND PROVISIONS OF THE FINAL RULE

IFC Provisions	Final Requirements	End Date
Provisions Finalized in CMS-5531-IFC (May 8, 2020)		
The facility must—	Until December 31, 2024, with the exception of requirements regarding COVID-19 vaccine status of residents and staff, the facility must do all of the following:	N/A
1. Electronically report information about COVID-19 in a standardized format specified by the Secretary. This report must include but is not limited to—	1. Electronically report information about COVID-19 in a standardized format specified by the Secretary. To the extent as required by the Secretary, this report must include the following:	N/A
a. Suspected and confirmed COVID-19 infections among residents and staff, including residents previously treated for COVID-19;	a. Suspected and confirmed COVID-19 infections among residents and staff, including residents previously treated for COVID-19.	December 31, 2024
b. Total deaths and COVID-19 deaths among residents and staff;	b. Total deaths and COVID-19 deaths among residents and staff.	December 31, 2024
c. Personal protective equipment and hand hygiene supplies in the facility;	c. Personal protective equipment and hand hygiene supplies in the facility.	December 31, 2024
d. Ventilator capacity and supplies in the facility.	d. Ventilator capacity and supplies in the facility.	December 31, 2024
e. Resident beds and census;	e. Resident beds and census.	December 31, 2024
f. Access to COVID-19 testing while the resident is in the facility;	f. Access to COVID-19 testing while the resident is in the facility.	December 31, 2024
g. Staffing shortages; and	g. Staffing shortages.	December 31, 2024
2. Provide the information specified in item 1. at a frequency specified by the Secretary, but no less than weekly to the Centers for Disease Control and Prevention's National Healthcare Safety Network. This information will be posted publicly by CMS to support protecting the health and safety of residents, personnel, and the general public.	2. Provide the information specified in item 1. weekly, unless the Secretary specifies a lesser frequency, to the Centers for Disease Control and Prevention's National Healthcare Safety Network. This information will be posted publicly by CMS to support protecting the health and safety of residents, personnel, and the general public.	N/A
3. Inform residents, their representatives, and families of those residing in facilities by 5 p.m. the next calendar day following the occurrence of either a single confirmed infection of COVID-19, or three or more residents or staff with new-onset of respiratory symptoms occurring within 72 hours of each other. This information must—	3. Inform residents, their representatives, and families of those residing in facilities by 5 p.m. the next calendar day following the occurrence of either a single confirmed infection of COVID-19, or three or more residents or staff with new-onset of respiratory symptoms occurring within 72 hours of each other. This information must do all of the following:	N/A
a. Not include personally identifiable information;	a. Not include personally identifiable information.	N/A
b. Include information on mitigating actions implemented to prevent or reduce the risk of transmission, including if normal operations of the facility will be altered; and	b. Include information on mitigating actions implemented to prevent or reduce the risk of transmission, including if normal operations of the facility will be altered.	N/A
c. Include any cumulative updates for residents, their representatives, and families at least weekly or by 5 p.m. the next calendar day following the subsequent occurrence of either: Each time a confirmed infection of COVID-19 is identified, or whenever three or more residents or staff with new onset of respiratory symptoms occur within 72 hours of each other.	c. Include any cumulative updates for residents, their representatives, and families at least weekly or by 5 p.m. the next calendar day following the subsequent occurrence of either: Each time a confirmed infection of COVID-19 is identified, or whenever three or more residents or staff with new onset of respiratory symptoms occur within 72 hours of each other.	N/A
Provisions Finalized in CMS-3414-IFC (May 21, 2021)		
1. The COVID-19 vaccine status of residents and staff, including total numbers of residents and staff, numbers of residents and staff vaccinated, numbers of each dose of COVID-19 vaccine received, and COVID-19 vaccination adverse events; and	1. The COVID-19 vaccine status of residents and staff, including total numbers of residents and staff, numbers of residents and staff vaccinated, numbers of each dose of COVID-19 vaccine received, and COVID-19 vaccination adverse events; and	None
2. Therapeutics administered to residents for treatment of COVID-19.	2. Therapeutics administered to residents for treatment of COVID-19.	December 31, 2024

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XI. Collection of Information Requirements and Waiver of Proposed Rulemaking

A. Statutory Requirement for Solicitation of Comments

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 the CY 2022 HH PPS proposed rule, we solicited public comment on each of these issues for the following sections of this document that contain information collection requirements.

B. Collection of Information Requirements

1. HH QRP

In section IV.C. of the proposed rule, we proposed changes and updates to the HH QRP. We believe that the burden associated with the HH QRP proposals is the time and effort associated with data quality and reporting. As of March 1, 2021, there are approximately 11,400 HHAs reporting data to CMS under the HH QRP. For purposes of calculating the costs associated with the information collection requirements, we obtained mean hourly wages for these from the U.S. Bureau of Labor Statistics' May 2020 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 38.

TABLE 38: U.S. BUREAU OF LABOR STATISTICS' MAY 2020 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	$38.47	$38.47	$76.94
Physical therapists HHAs	29-1123	$44.08	$44.08	$88.16
Speech-Language Pathologists (SLP)	29-1127	$40.02	$40.02	$80.04
Occupational Therapists (OT)	29-1122	$42.06	$42.06	$84.12
Medical Dosimetrists, Medical Records Specialists, and Health Technologists and Technicians	29-2098	$23.21	$23.21	$46.42

In section IV.C.4.a. of the final rule, we are finalizing our proposal to remove the Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care measure under removal factor 1, measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made. Further, we are finalizing our proposal to remove OASIS item M2016 used to calculate this measure. This item removal results in a decrease in overall burden.

In sections IV.C.4.b. of this final rule, we are finalizing our proposal to adopt the Home Health Within Stay Potentially Preventable Hospitalization measure which is claims-based. We are replacing the Acute Care Hospitalization During the First 60 Days of HH (NQF #0171) measure and the Emergency Department Use without Hospitalization During the First 60 Days of HH (NQF #0173) measure with the Within Stay Potentially Hospitalization measure beginning with the CY 2023 HH QRP under our measure removal factor 6: A measure that is more strongly associated with desired patient outcomes for the particular topic is available. Because the measures are claims-based, their replacement or removal does not impact our collection of information.

Therefore, the result of our final policies is a net reduction of 1 data element at the Discharge from Agency time point and 1 data element at the Transfer of Care time point associated with OASIS item (M2016) collection as a result of the measure removal. We assumed that each data element requires 0.3 minutes of clinician time to complete. Therefore, we estimated that there would be a reduction in clinician burden per OASIS assessment of 0.3 minutes at Discharge from Agency and 0.3 minutes at Transfer of Care.

The OASIS is completed by RNs or PTs, or very occasionally by occupational therapists (OTs) or speech language pathologists (SLT/SP). Data from 2020 show that the OASIS is completed by RNs (approximately 76.5 percent of the time), PTs (approximately 20.78 percent the time) and other therapists including OTs and SLP/STs (approximately 2.72 percent of the time). Based on this analysis, we estimated a weighted estimated clinician average hourly wage of $79.41, inclusive of fringe benefits using the wage data from Table 38 Individual providers determine the staffing necessary.

Table 39 shows the total number of assessments submitted in CY 2020 and estimated costs at each time point.

TABLE 39: CY 2020 OASIS SUBMISSIONS AND ESTIMATED COSTS, BY TIME POINT

Time Point	CY 2020 Assessments Completed	Estimated Cost ($)
Transfer of Care	1,788,100	$4,259,791
Discharge from agency	5,168,903	$228,832,891
TOTAL	**6,957,003**	**$233,092,681**

* Estimated Burden ($) at each Time-Point = (# CY 2020 Assessments Completed) x (clinician burden [min]/60) x ($79.41 [weighted clinician average hourly wage]). Excluding M2016, there are 1.8 minutes to complete 6 transfer of care data elements and 33.45 minutes to complete 123 data elements at discharge.

Based on the data in Tables 38 and 39 for the 11,400 active Medicare-certified HHAs, we estimated the total decrease in costs associated with the changes in the HH QRP at approximately $242 per HHA annually or $2,762,277 for all HHAs as derived in the RIA section. This corresponds to an estimated decrease in clinician burden associated with the changes to the HH QRP of approximately 3.1 hours per HHA or approximately 34,785 hours for all HHAs. This decrease in burden will be accounted for in the information collection under OMB control number 0938–1279 (Expiration date: 12/31/2021).

In section IV.C. of this final rule, we are finalizing our proposal to revise the compliance date for certain reporting requirements adopted for the HH QRP. The burden for the proposed revision to the HH QRP requirements as adopted in the CY 2020 HH PPS final rule (84 FR 60632 through 60642) has been accounted for in OMB control number 0938–1279. Therefore, this proposal would not affect the information collection burden already established.

We did not receive any comments on this proposal and therefore are finalizing this provision without modification.

2. ICRs Regarding Revised Compliance Dates for Certain Reporting Requirements

a. IRF QRP Requirements

In section VIII.A. of the proposed rule, we proposed to revise the compliance date for certain reporting requirements adopted for the IRF QRP. We believe that the burden associated with the IRF QRP proposed provision is the time and effort associated with reporting data. As of April 4, 2021, there are approximately 1,109 IRFs reporting IRF QRP data to CMS. The burden for the proposed revision to the IRF QRP requirements as adopted in the FY 2020 IRF PPS final rule (84 FR 39165 through 39172) has been accounted for in OMB control number 0938–0842 (Expiration date: 12/31/2022). Therefore, this proposed provision would not affect the information collection burden for the IRF QRP.

We did not receive any comments on this proposal and therefore are finalizing this provision without modification.

b. LTCH QRP Requirements

In section VIII.B. of the proposed rule, we proposed a revised compliance date for certain reporting requirements adopted for the LTCH QRP. We believe that the burden associated with the LTCH QRP proposal is the time and effort associated with reporting data. As of April 21, 2021, there are approximately 363 LTCHs reporting LTCH QRP data to CMS. The burden for the proposed revision to the LTCH QRP requirements as adopted in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42602 through 42656) has been accounted for in OMB control number 0938–1163 (Expiration date: 12/31/2022). Therefore, this proposal would not affect the information collection burden for the LTCH QRP.

We did not receive any comments on this proposal and therefore are finalizing this provision without modification.

3. ICRs Related to the Changes in the Home Health CoPs

a. ICRs Related to the Virtual Supervision of HHA Aides

In section IV.D. of the final rule, we revised § 484.80(h)(1) to specify that if a patient is receiving skilled care (patient who is receiving skilled nursing, physical or occupational therapy, or speech language pathology services), the home health aide supervisor (RN or therapist) must complete a supervisory assessment of the aide services being provided, either onsite (that is, an in person visit) or using interactive telecommunications systems no less frequently than every 14 days. The home health aide would not have to be present during the supervisory assessment. The use of interactive telecommunications systems for the aide supervisory assessment must not exceed 2 times per HHA in a 60–day period. We finalized § 484.80(h)(2) to specify that, if a patient is not receiving skilled care, the RN must make an in–person supervisory visit to the location where the patient is receiving care, once every 60 days to assess the quality of care and services provided by the home health aide and to ensure that services met the patient's needs. The home health aide would not need to be present during this visit. We are also finalizing with modification that the RN would make a semi-annual on-site (in-person) visit to the location where a patient is receiving care in order to observe and assess each home health aide while he or she is performing care for each of their assigned patients. This semi-annual supervisory visit of the aide performing care would replace the current every 60–day requirement of direct supervision of the aide performing care. In addition, we are finalizing § 484.80(h)(3), which includes retraining and competency evaluations related to both the skills verified as deficient and any related skills. We believe that this would not add any information collection burden and would enhance the provisions of safe, quality home health services. In accordance with the implementing regulation of the PRA at 5 CFR 1320.3(b)(2), we believe that both the existing requirements and the proposed revisions to the requirements at 484.80(h) are exempt from the PRA. We believe competency evaluations are a usual and customary business practice and we state as such in the information collection request associated with the Home Health CoPs and approved under OMB control number: 0938–1299 (Expiration date: 06/30/2024). Therefore, we did not propose to seek

PRA approval for any information collection or recordkeeping activities that may be conducted in connection with the proposed revisions to § 484.80(h), but we requested public comment on our determination that the time and effort necessary to comply with these evaluation requirements is usual and customary, and would be incurred by home health staff even absent this regulatory requirement.

We did not receive comments on his section of the collection of information proposed and therefore are finalizing this provision without modification.

b. ICRs Related To Permitting Occupational Therapist To Complete the Initial and Comprehensive Assessments for Home Health Agencies

In section IV.D. of the final rule, we are implementing Division CC, section 115 of CAA 2021 by finalizing conforming regulations text changes at § 484.55(a)(2) and (b)(3) permitting the occupational therapist to complete the initial and comprehensive assessments for Medicare patients when ordered with another rehabilitation therapy service (speech language pathology or physical therapy) that establishes program eligibility, in the case where skilled nursing services are not initially on the home health plan of care. These changes, which permit occupational therapists to complete these assessments even though the need for occupational therapy would not establish the patient's eligibility for the Medicare home health benefit. In accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2), we believe that both the existing requirements and the finalized revisions to the requirements at § 484.55(a)(2) and (b)(3) are exempt from the PRA. We believe patient assessment are a usual and customary business practice and we state such in the information collection request associated with the OASIS data set, which comprises the core of the patient assessment and is currently approved under OMB control number 0938–1279 (Expiration date: 06/30/2024). Therefore, we did not propose to seek PRA approval for any information collection or recordkeeping activities that may be conducted in connection with the proposed revisions to § 484.55(a)(2) and (b)(3), but we requested public comment on our determination that the time and effort necessary to comply with these evaluation requirements is usual and customary and would be incurred by home health staff even absent this regulatory requirement.

We did not receive comments on his section of the collection of information proposed and therefore are finalizing this provision without modification.

4. ICRs Regarding Medicare Provider and Supplier Enrollment Provisions

We did not anticipate any information collection burden associated with our provider and supplier enrollment proposed provisions. Since most of the provisions that we proposed and are finalizing have been in subregulatory guidance for a number of years and we are simply incorporating them into regulation, there would not be any change in burden on the provider community. Those provisions that are not in subregulatory guidance do not implicate information collection requirements.

5. ICRs Regarding Survey and Enforcement Requirements for Hospices

a. Wage Data

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2020 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). In this regard, Table 40 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 40: U.S. BUREAU OF LABOR STATISTICS' MAY 2020 NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

BLS Occupation Title	Occupation Code	Mean Hourly Wage	Fringe Benefits and Overhead	Adjusted Hourly Wages
Computer and Information Analysts	15-1210	$48.40	$48.40	$96.80
Home Health and Personal Care Aides; and Nursing Assistants, Orderlies, and Psychiatric Aides	31-1100	$14.10	$14.10	$28.20
Medical or Health Services Manager	11-9111	$55.37	$55.37	$110.74
Registered Nurse (RN)	29-1141	$38.47	$38.47	$76.94

We did not receive comments on the ICR proposal for hospice survey and enforcement requirements and therefore are finalizing the application and re-application procedures for national accrediting organizations without modification. CMS has removed the proposed burden estimates for the surveyor qualifications and prohibition of conflicts of interest because no information collection is actually required.

b. Application and Re-application Procedures for National Accrediting Organizations (§ 488.5)

We proposed at § 488.5(a)(4)(x) to require AOs with CMS-approved hospice programs to include a statement of deficiencies, (that is, the Form CMS–2567 or a successor form) to document findings of the hospice Medicare CoPs and to submit such in a manner specified by CMS. At the time of the proposed rule, the information collection request for the Form CMS–2567, titled ''Statement Of Deficiencies And Plan Of Correction'' was active an approved under OMB control number 0938–0391 (Expiration date: 6/30/2021); however, it did not account for any information collection related burden associated with AO use. As discussed in section VII.B.2.b. of the proposed rule, we note that the Form CMS–2567 did not include a place for the name of the AO completing the survey and AOs are not addressed in the instructions. These were minor revisions to the form and we submitted the revised information collection request to OMB for approval.

We discussed in section VII.B.2.b. of the proposed rule, how AOs conduct hospice program surveys and gather deficiency findings into a report that is provided to the surveyed hospice. CMS believes the statutory requirement and subsequent proposed rule for the inclusion of Form CMS–2567 would not add significant burden to AOs as they already develop deficiency finding reports as part of their existing process just in a different format. We noted that AOs would need to make a one-time update to their existing proprietary electronic documentation systems to include the Form CMS–2567. We

estimated that this task would be performed by a computer and information analyst. According to the U.S Bureau of Labor statistics, the mean hourly wages for a computer and information analyst is $48.40. This wage adjusted for the employer's fringe benefits and overhead would be $96.80.

We estimated that it would take at least two persons working on a full-time basis for 3 days for the AO staff to revise their system to add the required Form CMS–2567. Therefore, we estimated that the total time required for the two team members to perform this task would be 48 hours. As of March 2021, there are three AOs that accredit Medicare certified hospice programs. The total time burden across these three AOs would be 144 hours.

We estimated that the cost burden related to the work performed by two computer and information analysts would be $4,646.40 (24 hours × $193.60 ($96.80 × 2)). The total cost across the three AOs would be $13,939.20 (3 AOs × $4,646.40). The burden associated with this requirement was submitted to OMB for approval under OMB control number 0938–0391. We sought comments that would help us to develop an accurate estimate of the cost and time burden that would result from this collection of information. No comments were received through the proposed rule public comment period.

We sought OMB approval via the required notice and comment periods separate from the proposed rulemaking. The revised information collection request was announced in the **Federal Register** on July 13, 2021 (86 FR 36751) and the public had the opportunity to review and comment. We received one comment on the Form CMS–2567 which was outside the scope of the information collection request. OMB approved the revised Form CMS–2567, titled ''Statement Of Deficiencies And Plan Of Correction'' under OMB control number 0938–0391 (Expiration date: 02/28/2022) on August 25, 2021.

6. HHVBP Expanded Model

In section III. of the final rule, we proposed policies necessary to implement the expanded Home Health Value-Based Purchasing Model (see final §§ 484.340 through 484.375), which is aimed at increasing quality and reducing spending through payment adjustments based on quality performance for HHAs nationwide. Section 1115A(d)(3) of the Act exempts Innovation Center model tests and expansions, which include the HHVBP expanded model, from the provisions of the PRA. Specifically, this section provides that the provisions of the PRA does not apply to the testing and evaluation of Innovation Center models or to the expansion of such models.

7. COVID–19 Reporting Requirements for Long Term Care Facilities

Section 483.80(g) sets forth the requirements for COVID–19 reporting for LTC facilities. Currently, § 483.80(g)(1) states that LTC facilities must electronically report information about COVID–19 in a standardized format specified by the Secretary. Specific pieces of information that must be reported are set forth in that subsection. The required information includes, ''(viii) The COVID–19 vaccine status of residents and staff, including total numbers of residents and staff, numbers of residents and staff vaccinated, numbers of each dose of COVID–19 vaccine received, and COVID–19 vaccination adverse events.'' In this rule, we are revising the requirements, in response to comments that expressed concern about burden, to modify the reporting frequency to weekly, unless the Secretary specifies a lesser frequency, to add the potential for the data elements to be reduced in the future, contingent on the state of the pandemic and at the discretion of the Secretary. In addition, we are providing a sunset, or expiration date, of December 31, 2024, for all of the required information in paragraph (g)(1), except for the information set out at paragraph (g)(1)(viii) that covers that COVID–19 vaccine status of residents and staff.

Since the infection prevention and control program (IPCP) is the responsibility of the infection preventionist (IP), the IP would be responsible for making the necessary changes to the policies and procedures to comply with the requirements in this rule (42 CFR 483.80(b)). According to the Bureau of Labor Statistics (BLS), a registered nurse in an LTC facility earns a mean hourly wage of $34.66.[221] For the total hourly cost, we doubled the mean hourly wage for a 100 percent increase to cover overhead and fringe benefits, according to standard HHS estimating procedures. Hence, the hourly-adjusted wage for an IP in an LTC facility is $69.

We estimate that it would require 1 hour of the IP's time to update the required policies and procedures to comply with the changes in this rule. For each LTC facility, the burden would be 1 hour at an estimated cost of $69. According to CMS, there are currently 15,401 LTC facilities. Hence, the total burden for these requirements would be 15,401 hours (1 × 15,401) at an estimated cost of $1,062,699 (15,401 × $69).

Comment: Some commenters disagreed with the estimate in the IFC that reporting takes about 30 minutes, and instead they indicated that it would take about 1 to 2 hours to complete. Additionally, many commenters noted that the time by which the weekly reporting would have to be submitted (every Sunday by 11:59 p.m.) is not realistic. This requirement, they argue, is challenging to meet as there are often less staff working on the weekends, new residents are often admitted on the weekend, and Mondays are often holidays.

Response: After reviewing this comment and other feedback that we have received, we have made modifications to the reporting requirement for LTC facilities regarding COVID–19 in order to address public commenter's concerns regarding burden. The changes in this rule will provide the Secretary with the discretion to reduce the amount of information they must report to the NHSN in the future. Currently they must report no less frequently than weekly. This rule changes that to weekly, unless the Secretary specifies a lesser frequency. In addition, we have inserted a sunset provision for all of the information elements, except for the COVID–19 vaccine status for its residents and staff. The sunset or expiration date is December 31, 2024. After consideration of the public comments we received, we are finalizing the requirements at § 483.80(g)(1) through (3) with the following modifications: Reporting frequency is modified to weekly, unless the Secretary specifies a lesser frequency; (2) Reporting data elements are unchanged, but may be reduced, contingent on the state of the pandemic and at the discretion of the Secretary; and (3) with a sunset date of December 31, 2024 for all reporting requirements with the exclusion of § 483.80(g)(1)(viii).

C. Submission of PRA-Related Comments

We have submitted a copy of this final rule to OMB for its review of the rule's information collection requirements. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the collections discussed in this rule, please visit the CMS Web site at *https://*

[221] BLS. May 2020 National Occupational Employment and Wage Estimates United States. United States Department of Labor. Accessed at *https://www.bls.gov/oes/current/oes_nat.htm.* Accessed on August 25, 2021.

www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.

D. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

In section IV.D.2.d. of this final rule, we include a technical change to § 484.50(d)(5) that was not proposed. We believe that a notice-and-comment rulemaking procedure is unnecessary for the technical change that added ''or allowed practitioner'' at § 484.50(d)(5) because we inadvertently omitted the reference at this location during prior rulemaking (85 FR 27550). This change is technical in nature and ensures that all that all providers, physicians and allowed practitioners issuing orders for the patient are informed of a discharge of the patient. This technical correction aligns with changes made throughout the HHA CoPs in which we amended the home health regulations by adding ''or allowed practitioner(s)''. Therefore, we find good cause to waive the notice of proposed rulemaking.

XII. Regulatory Impact Analysis

A. Statement of Need

1. 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 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 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, required the Secretary to implement a 30-day unit of service, for 30-day periods beginning on and after January 1, 2020. The HH PPS wage index utilizes the wage adjustment factors used by the Secretary for purposes of Sections 1895(b)(4)(A)(ii) and (b)(4)(C) of the Act for hospital wage adjustments.

2. HHVBP Model

Section 1115A(c) of the Act provides the Secretary with the authority to expand (including implementation on a nationwide basis), through notice and comment rulemaking, the duration and scope of a model that is being tested under section 1115A(b) of the Act if the following findings are made, taking into account the evaluation of the model under section 1115A(b)(4) of the Act: (1) The Secretary determines that the expansion is expected to either reduce spending without reducing quality of care or improve the quality of patient care without increasing spending; (2) the CMS Chief Actuary certifies that the expansion would reduce (or would not result in any increase in) net program spending; and (3) the Secretary determines that the expansion would not deny or limit the coverage or provision of benefits. On January 8, 2021, we announced that the HHVBP Model (the original Model) had been certified for expansion nationwide,[222] as well as our intent to expand the Model through notice and comment rulemaking beginning no sooner than CY 2022. The original Model has resulted in an average 4.6 percent improvement in home health agencies' quality scores as well as average annual savings of $141 million to Medicare. The CMS Chief Actuary has determined that HHVBP Model would reduce Medicare expenditures if expanded to all States.

We are finalizing in this rule that all Medicare-certified HHAs in the 50 States, District of Columbia and the territories would be required to participate in the expanded HHVBP Model beginning January 1, 2022 with CY 2022 as a pre-implementation year. As discussed in the preamble, CY 2023 will be the first performance year, beginning January 1, 2023; and CY 2025 will be the first payment year. These HHAs would compete on value based on an array of quality measures that capture the services provided by HHAs. The savings impacts related to the HHVBP Model expansion are estimated at a total projected 5-year gross FFS savings, CYs 2023 through 2027, of $3,376,000,000. The savings under the original Model are already assumed in the baseline and therefore are not included in the 5-year gross estimated savings under HHVBP Model expansion. As noted in section III.A.3.b. of the final rule, under the expanded duration and scope of this Model, we would continue to examine whether the adjustments to the Medicare payment amounts that would otherwise be made to competing HHAs would result in statistically significant improvements in the quality of care being delivered to

[222] *https://www.cms.gov/files/document/certification-home-health-value-based-purchasing-hhvbp-model.pdf.*

Medicare beneficiaries, as well as reductions in Medicare spending.

3. HH QRP

Section 1895(b)(3)(B)(v) of the Act authorizes the HH QRP which requires HHAs to submit data in accordance with the requirements of the 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 an HHA for that calendar year by 2 percentage points.

Finalizing the removal of the Drug Education on All Medications Provided to Patient/Caregiver measure supports the CMS Meaningful measures framework by reducing where possible the burden on providers and clinicians. The addition of the Potentially Preventable Hospitalization measure, which is claims-based, to the HH QRP effective January 1, 2022 as a replacement of the Acute Care Hospitalization During the First 60 Days of Home Health (NQF # 0171) measure and Emergency Department Use Without Hospitalization During the First 60 Days of Home Health (NQF #0173) beginning with the CY 2023 HH QRP addresses attribution issues identified and would capture observation stay which are currently not addressed with the existing measures. The public reporting of the Application of Percent of Residents Experiencing One or More Major Falls with Injury (NQF #0674) and The Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Function Assessment and a Care Plan That Addresses Function (NQF #2631) supports the requirements that the Secretary provide public reporting of PAC provider performance, including HHAs, on quality measures under section 1899B(c)(1) of the Act. Given the recent Executive order on ''Advancing Racial Equity and Support for Underserved Communities throughout the Federal Government,'' [223] we proposed an earlier effective date for the adoption of the assessment instruments whereby HHAs would begin reporting on January 1, 2023 on items related to Social Determinants of Health.

a. Virtual Supervision of HHA Aides

In accordance with sections 1861(o) and 1891 of the Act, the Secretary has established in regulations the requirements that an HHA must meet to participate in the Medicare program. In this rule, we are finalizing our proposed changes to make permanent selected regulatory blanket waivers related to home health aide supervision that we extended to Medicare participating home health agencies during the COVID–19 PHE.

b. Permitting Occupational Therapists To Conduct the Initial Assessment Visit and Complete the Comprehensive Assessment for Home Health Agencies Under the Medicare Program

Division CC, section 115 of CAA 2021 requires CMS to permit an occupational therapist to conduct the initial assessment visit and complete the comprehensive assessment under the Medicare program, but only when occupational therapy is on the home health plan of care with either physical therapy or speech therapy, and skilled nursing services are not initially on the plan of care. These conforming changes are being finalized in this regulation.

5. Medicare Coverage of 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. This payment system requires a single payment to 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. 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 percentage increase in the CPI–U for all urban consumers for the 12-month period ending with June of the preceding year, reduced by the productivity adjustment. The unit of single payment for each infusion drug administration calendar day, including the required adjustments and the annual update, cannot exceed the amount determined under the fee schedule under section 1848 of the Act for infusion therapy services if furnished in a physician's office, and the single payment amount cannot reflect more than 5 hours of infusion for a particular therapy per calendar day. Finally, Division N, section 101 of CAA 2021 amended section 1848(t)(1) of the Act and modified the CY 2021 PFS rates by providing a 3.75 percent increase in PFS payments only for CY 2021.

6. Medicare Provider and Supplier Enrollment Provisions

Our provisions concerning Medicare provider and supplier enrollment are needed to: (1) Incorporate various subregulatory policies into 42 CFR part 424, subpart P, and (2) clarify several policy issues. We believe these provisions will increase transparency by allowing the provider community to furnish public comments on them while eliminating uncertainty regarding the scope and applicability of the provisions in question.

7. Survey and Enforcement Requirements for Hospice Providers

In accordance with section 407 of the CAA 2021, we are making conforming regulations which establish new hospice program survey and enforcement requirements. We believe these provisions not only meet the statutory requirements but will increase public transparency by encouraging a consistent survey and enforcement process and providing the public with information necessary to make an informed decision regarding where they seek high quality, safe care hospice program organizations for themselves or loved ones.

8. COVID–19 Reporting Requirements for Long Term Care Facilities

The COVID–19 PHE has precipitated the greatest health crises since the 1918 Influenza pandemic. Of the approximately 666,440 Americans estimated to have died from COVID–19

[223] Executive Order On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government $verbar; The White House.

through September 2021,[224] over one-third are estimated to have died during or after a nursing home stay.[225] The development and large-scale utilization of vaccines to prevent COVID–19 cases have the potential to end future COVID–19 related nursing home deaths. In addition, continued reporting of COVID–19 data in LTC facilities, beyond the COVID–19 PHE, will have a significant positive impact by maintaining effective surveillance of this novel virus. This final rule finalizes the important reporting requirements that were issued in previous IFCs so that CMS can continue to respond to facilities in need of additional technical support and oversight, should they experience new COVID–19 infections.

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 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), and the Congressional Review Act (5 U.S.C. 801(a)(1)(B)(i)).

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.

Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). Accordingly, we have prepared, to the best of our ability, a final Regulatory Impact Analysis that presents the costs and benefits of the rulemaking.

C. Detailed Economic Analysis

1. Impacts for the HH PPS

This final rule updates Medicare payments under the HH PPS for CY 2022. The net transfer impact related to the changes in payments under the HH PPS for CY 2022 is estimated to be $570 million (3.2 percent). The $570 million increase in estimated payments for CY 2022 reflects the effects of the CY 2022 home health payment update percentage of 2.6 percent ($465 million increase), an estimated 0.7 percent increase that reflects the effects of an updated FDL ($125 million increase) and an estimated 0.1 percent decrease in payments due to the changes in the rural add-on percentages for CY 2022 ($20 million decrease). We note that we inadvertently did not account for the impact of the proposed changes to the FDL in the CY 2022 HH PPS proposed rule (86 FR 35873). However, in this final rule we have included the payment effects of the new lower FDL in Table 41.

We use the latest data and analysis available. However, 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 home health benefit, based primarily on Medicare claims data for periods that began in CY 2020 and ended on or before December 31, 2020. 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 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 41 represents how HHA revenues are likely to be affected by the finalized policy changes for CY 2022. For this analysis, we used an analytic file with linked CY 2020 OASIS assessments and home health claims data for dates of service that ended on or before December 31, 2020. The first column of Table 41 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 recalibration of the case-Mix weights offset by the case-mix weights budget neutrality factor.

The fourth column shows the payment effects of updating to the CY 2022 wage index. The fifth column shows the payment effects of the CY 2022 rural add-on payment provision in statute. The sixth column shows the payment effects of the final CY 2022 home health payment update percentage. The seventh column shows the payment effects of the new lower FDL and the last column shows the combined effects of all the finalized provisions.

Overall, it is projected that aggregate payments in CY 2022 would increase by 3.2 percent which reflects the 2.6 payment update percentage increase, the 0.7 percent increase from lowering the FDL and the 0.1 percent decrease from the effects of the rural add-on policy. As illustrated in Table 41, 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 2022 wage index, the percentage of total HH PPS payments that were subject to the LUPA or paid as outlier payments, and the degree of Medicare utilization.

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[224] *https://covid.cdc.gov/covid-data-tracker/#trends_dailycases.*

[225] *https://www.kff.org/coronavirus-covid-19/issue-brief/state-covid-19-data-and-policy-actions/.*

TABLE 41: ESTIMATED HHA IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY, CY 2022

	Number of Agencies	CY 2022 Case-mix Weights	CY 2022 Updated Wage Index	CY 2022 Rural Add-On	CY 2022 HH Payment Update Percentage	Fixed-Dollar Loss (FDL) Update	Total
All Agencies	**9,490**	**0.0%**	**0.0%**	**-0.1%**	**2.6%**	**0.7%**	**3.2%**
Facility Type and Control							
Free-Standing/Other Vol/NP	947	0.4%	-0.3%	-0.1%	2.6%	0.8%	3.4%
Free-Standing/Other Proprietary	7,680	-0.2%	0.0%	-0.1%	2.6%	0.6%	2.9%
Free-Standing/Other Government	180	0.7%	0.1%	-0.4%	2.6%	0.7%	3.7%
Facility-Based Vol/NP	483	0.5%	-0.1%	-0.2%	2.6%	1.0%	3.8%
Facility-Based Proprietary	48	0.3%	0.0%	-0.2%	2.6%	0.6%	3.3%
Facility-Based Government	152	0.4%	0.3%	-0.3%	2.6%	0.8%	3.8%
Subtotal: Freestanding	8,807	0.0%	0.0%	-0.1%	2.6%	0.6%	3.1%
Subtotal: Facility-based	683	0.5%	0.0%	-0.2%	2.6%	0.9%	3.8%
Subtotal: Vol/NP	1,430	0.4%	-0.3%	-0.1%	2.6%	0.8%	3.4%
Subtotal: Proprietary	7,728	-0.2%	0.0%	-0.1%	2.6%	0.6%	2.9%
Subtotal: Government	332	0.5%	0.2%	-0.3%	2.6%	0.8%	3.8%
Facility Type and Control: Rural							
Free-Standing/Other Vol/NP	224	0.3%	0.0%	-0.7%	2.6%	0.7%	2.9%
Free-Standing/Other Proprietary	808	-0.2%	0.1%	-0.3%	2.6%	0.4%	2.6%
Free-Standing/Other Government	122	0.8%	0.1%	-0.8%	2.6%	0.8%	3.5%
Facility-Based Vol/NP	213	0.6%	0.0%	-0.7%	2.6%	0.9%	3.4%
Facility-Based Proprietary	19	0.3%	-0.3%	-0.6%	2.6%	0.6%	2.6%
Facility-Based Government	113	0.4%	0.4%	-0.7%	2.6%	1.0%	3.7%
Facility Type and Control: Urban							
Free-Standing/Other Vol/NP	723	0.4%	-0.3%	-0.1%	2.6%	0.8%	3.4%
Free-Standing/Other Proprietary	6,872	-0.1%	0.0%	0.0%	2.6%	0.6%	3.1%
Free-Standing/Other Government	58	0.6%	0.0%	-0.1%	2.6%	0.6%	3.7%
Facility-Based Vol/NP	270	0.5%	-0.1%	-0.1%	2.6%	1.0%	3.9%
Facility-Based Proprietary	29	0.3%	0.2%	-0.1%	2.6%	0.7%	3.7%
Facility-Based Government	39	0.4%	0.3%	0.0%	2.6%	0.7%	4.0%
Facility Location: Urban or Rural							
Rural	1,499	0.0%	0.1%	-0.4%	2.6%	0.5%	2.8%
Urban	7,991	0.0%	0.0%	0.0%	2.6%	0.7%	3.3%
Facility Location: Region of the Country (Census Region)							
New England	327	0.2%	-0.7%	-0.1%	2.6%	0.8%	2.8%
Mid Atlantic	433	0.7%	-0.6%	-0.1%	2.6%	0.7%	3.3%
East North Central	1,603	0.0%	-0.3%	-0.2%	2.6%	0.6%	2.7%
West North Central	622	0.3%	0.1%	-0.3%	2.6%	0.9%	3.6%
South Atlantic	1,552	0.2%	0.5%	-0.1%	2.6%	0.6%	3.8%
East South Central	370	-0.1%	-0.4%	-0.1%	2.6%	0.4%	2.4%
West South Central	2,224	-0.3%	-0.3%	0.0%	2.6%	0.6%	2.6%
Mountain	682	-0.1%	0.1%	-0.1%	2.6%	0.8%	3.3%
Pacific	1,634	-0.5%	0.4%	0.0%	2.6%	0.7%	3.2%
Outlying	43	0.8%	-1.4%	-0.4%	2.6%	0.6%	2.2%
Facility Size (Number of 30-day Periods)							
< 100 periods	1,984	0.3%	-0.1%	-0.1%	2.6%	0.9%	3.6%
100 to 249	1,508	0.0%	-0.1%	-0.1%	2.6%	0.8%	3.2%
250 to 499	1,709	-0.2%	0.0%	-0.1%	2.6%	0.7%	3.0%
500 to 999	1,928	-0.2%	0.0%	-0.1%	2.6%	0.7%	3.0%
1,000 or More	2,361	0.1%	0.0%	-0.1%	2.6%	0.6%	3.2%

Source: CY 2020 Medicare claims data for periods with matched OASIS records (only) starting and ending in CY2020 (as of July 12, 2021).

REGION KEY:
New England=Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont
Middle Atlantic=Pennsylvania, New Jersey, New York

South Atlantic=Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia
East North Central=Illinois, Indiana, Michigan, Ohio, Wisconsin
East South Central-Alabama, Kentucky, Mississippi, Tennessee
West North Central=Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota
West South Central=Arkansas, Louisiana, Oklahoma, Texas
Mountain=Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming
Pacific=Alaska, California, Hawaii, Oregon, Washington
Other=Guam, Puerto Rico, Virgin Islands

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2. Impacts for the Expanded HHVBP Model

Based on finalized policies discussed in section III.A. of this final rule, Tables 43 and 44 display our analysis of the distribution of possible payment adjustments using 2019 data as the performance year, while Table 42 provides information on the estimated impact of this finalized expansion. We note that this impact analysis is based on the aggregate value of savings associated with all Medicare-certified HHAs in each State, territory, and the District of Columbia.

Table 43 shows the value-based incentive payment adjustments for the estimated 7,500–plus HHAs that would qualify to compete in the HHVBP Model expansion based on the CY 2019 data stratified by size, as defined in section III.F. of the final rule. For example, Table 43 shows California has 69 HHAs that do not provide services to at least 60 unique beneficiaries in the prior calendar year, and therefore, would be considered to be in the smaller-volume cohort under the Model expansion. Using 2019 performance year data and the finalized payment adjustment of 5-percent, based on 8 outcome measures, the smaller-volume HHAs in California would have a mean payment adjustment of positive 0.042 percent. Only 10-percent of home health agencies would be subject to downward payment adjustments of more than minus 3.139 percent (−3.139 percent). The next columns provide the distribution of scores by percentile. We see that the value–based incentive percentage payments for smaller-volume home health agencies in California range from −3.139 percent at the 10th percentile to +3.899 percent at the 90th percentile, while the value-based incentive payment at the 50th percentile is −0.607 percent. The smaller-volume HHA cohort table identifies that some locations do not have any qualifying HHAs in the smaller-volume cohort, including Connecticut, the District of Columbia, and Delaware.

It was brought to our attention after the close of the comment period for the proposed rule that the larger-volume cohort section of Table 43: HHA Cohort Payment Adjustment Distributions as presented in the proposed rule (86 FR 35994 and 35995) inadvertently ended with the entry for the state of Montana (MT). In this final rule, we are presenting Table 43 from the proposed rule in its entirety, along with the other impact tables included in the proposed rule.

Table 43 provides the payment adjustment distribution based on proportion of dual eligible beneficiaries, average case mix (using HCC scores), proportion that reside in rural areas, as well as HHA organizational status. To define cutoffs for the ''percentage of dual eligible beneficiaries,'' low, medium, or high percentage dual-eligible are based on less than the 25th percentile, between the 25th and 75th percentiles, and greater than the 75th percentile of percent dual eligible beneficiaries, respectively, across HHAs in CY 2019. To define case mix cutoffs, low, medium, or high acuity are also based on less than the 25th percentile, between the 25th and 75th percentiles, and greater than the 75th percentile of average HCC scores, respectively, across HHAs in CY 2019. To define cutoffs for percentage of rural beneficiaries, all non-rural, up to 50 percent rural, and over 50 percent rural are based on the home health beneficiaries' core-based statistical area (CBSA) urban versus rural designation. We would note that, based on 2019 data, a higher proportion of dually-eligible beneficiaries served is associated with better performance.

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TABLE 42. ESTIMATED GROSS FFS SAVINGS UNDER EXPANDED HHVBP MODEL CYs 2023-2027

CY 2023	CY 2024	CY 2025	CY 2026	CY 2027
$373,000,000	$715,000,000	$713,000,000	$761,000,000	$814,000,000

TABLE 43: HHA COHORT PAYMENT ADJUSTMENT DISTRIBUTIONS
(Based on a maximum 5 percent payment adjustment)

Smaller-volume Cohort											
			Payment Adjustment Percentile Distribution (%)								
State	# of HHAs	Average Payment Adjustment (%)	10%	20%	30%	40%	50%	60%	70%	80%	90%
AK	1	(0.646)	(0.646)	(0.646)	(0.646)	(0.646)	(0.646)	(0.646)	(0.646)	(0.646)	(0.646)
AL	1	1.601	1.601	1.601	1.601	1.601	1.601	1.601	1.601	1.601	1.601
AR	2	0.794	(2.454)	(2.454)	(2.454)	(2.454)	0.794	4.041	4.041	4.041	4.041
AZ	2	0.710	(2.446)	(2.446)	(2.446)	(2.446)	0.710	3.866	3.866	3.866	3.866
CA	69	0.042	(3.139)	(2.503)	(1.748)	(1.495)	(0.607)	0.878	1.586	2.605	3.899
CO	4	0.127	(2.367)	(2.367)	0.445	0.445	0.572	0.698	0.698	1.733	1.733
CT	0										
DC	0										
DE	0										
FL	51	0.756	(3.080)	(1.928)	(1.016)	(0.014)	0.612	1.482	3.336	3.935	5.000
GA	0										
GU	0										
HI	0										
IA	7	(0.840)	(2.816)	(1.831)	(1.641)	(1.641)	(1.422)	(1.096)	(1.096)	(0.082)	3.009
ID	1	(2.206)	(2.206)	(2.206)	(2.206)	(2.206)	(2.206)	(2.206)	(2.206)	(2.206)	(2.206)
IL	61	0.652	(3.275)	(2.451)	(1.614)	(0.772)	1.170	1.856	2.794	3.627	5.000
IN	11	0.596	(2.821)	(1.241)	(0.390)	0.683	0.729	1.028	1.367	2.944	3.059
KS	4	0.321	(3.256)	(3.256)	(1.255)	(1.255)	0.031	1.317	1.317	4.476	4.476
KY	0										
LA	0										
MA	5	(0.709)	(4.469)	(4.107)	(3.744)	(2.321)	(0.898)	0.489	1.876	2.784	3.692
MD	2	0.345	(2.576)	(2.576)	(2.576)	(2.576)	0.345	3.265	3.265	3.265	3.265
ME	1	(2.179)	(2.179)	(2.179)	(2.179)	(2.179)	(2.179)	(2.179)	(2.179)	(2.179)	(2.179)
MI	52	0.896	(2.662)	(2.081)	(0.494)	0.397	1.011	1.790	2.787	3.255	4.814
MN	7	(2.227)	(4.577)	(4.453)	(3.677)	(3.677)	(3.244)	(0.514)	(0.514)	(0.480)	1.359
MO	7	(1.996)	(4.370)	(3.431)	(3.223)	(3.223)	(2.419)	(2.106)	(2.106)	0.176	1.399
MP	0										
MS	0										
MT	2	2.049	(0.847)	(0.847)	(0.847)	(0.847)	2.049	4.944	4.944	4.944	4.944
NC	4	(0.681)	(2.371)	(2.371)	(1.204)	(1.204)	(0.473)	0.259	0.259	0.592	0.592
ND	0										
NE	8	(0.751)	(4.403)	(3.062)	(2.029)	(0.282)	(0.165)	(0.047)	0.750	1.211	1.851
NH	1	(4.501)	(4.501)	(4.501)	(4.501)	(4.501)	(4.501)	(4.501)	(4.501)	(4.501)	(4.501)
NJ	0										
NM	3	0.394	(1.562)	(1.562)	(1.562)	(0.746)	(0.746)	(0.746)	3.490	3.490	3.490
NV	8	(0.691)	(3.671)	(3.033)	(1.997)	(1.029)	(0.905)	(0.780)	(0.181)	0.164	5.000
NY	0										
OH	8	(2.409)	(4.307)	(4.178)	(3.890)	(3.739)	(3.618)	(3.497)	(1.041)	(0.905)	2.286
OK	8	(2.008)	(4.351)	(3.004)	(2.942)	(2.347)	(2.068)	(1.788)	(1.747)	0.042	0.076
OR	1	(0.938)	(0.938)	(0.938)	(0.938)	(0.938)	(0.938)	(0.938)	(0.938)	(0.938)	(0.938)
PA	9	(1.965)	(4.263)	(4.023)	(3.537)	(3.056)	(2.969)	(1.039)	(0.725)	0.543	1.385
PR	0										
RI	0										
SC	0										
SD	4	(1.081)	(3.754)	(3.754)	(2.073)	(2.073)	(1.170)	(0.267)	(0.267)	1.770	1.770
TN	1	(1.921)	(1.921)	(1.921)	(1.921)	(1.921)	(1.921)	(1.921)	(1.921)	(1.921)	(1.921)
TX	85	(0.727)	(4.121)	(3.224)	(2.548)	(1.714)	(0.565)	0.303	0.875	1.215	2.576
UT	6	0.244	(1.724)	(1.517)	(1.517)	(0.461)	(0.115)	0.231	1.618	1.618	3.319
VA	5	0.794	(4.066)	(1.925)	0.216	0.860	1.504	1.864	2.223	3.158	4.093
VI	0										
VT	0										

Smaller-volume Cohort											
			Payment Adjustment Percentile Distribution (%)								
State	# of HHAs	Average Payment Adjustment (%)	10%	20%	30%	40%	50%	60%	70%	80%	90%
WA	0										
WI	0										
WV	0										
WY	2	(1.247)	(2.474)	(2.474)	(2.474)	(2.474)	(1.247)	(0.020)	(0.020)	(0.020)	(0.020)
All	**443**	**(0.079)**	**(3.677)**	**(2.703)**	**(1.967)**	**(1.141)**	**(0.267)**	**0.635**	**1.413**	**2.621**	**3.975**

Larger-volume Cohort											
			Payment Adjustment Percentile Distribution (%)								
State	# of HHAs	Average Payment Adjustment (%)	10%	20%	30%	40%	50%	60%	70%	80%	90%
AK	12	(0.627)	(3.202)	(2.588)	(2.199)	(1.448)	(1.007)	(0.774)	1.275	1.423	1.897
AL	114	1.632	(1.583)	(0.520)	0.510	1.110	1.856	2.392	3.058	3.833	4.653
AR	90	1.114	(1.830)	(1.158)	(0.185)	0.854	1.403	2.060	2.643	3.090	4.097
AZ	106	0.441	(2.830)	(2.073)	(1.522)	(0.188)	0.547	1.077	1.774	2.880	4.504
CA	991	0.799	(2.856)	(1.930)	(1.130)	(0.306)	0.381	1.528	2.710	4.200	5.000
CO	104	0.059	(3.260)	(2.293)	(1.588)	(0.912)	(0.219)	0.392	1.246	1.946	4.482
CT	74	(0.829)	(3.321)	(2.908)	(2.511)	(1.846)	(1.481)	(0.390)	0.059	1.206	2.448
DC	7	(0.428)	(3.672)	(2.455)	(1.306)	(1.306)	(0.938)	0.289	0.289	0.767	4.319
DE	12	0.141	(2.604)	(1.897)	(1.874)	(1.282)	(0.076)	0.965	1.626	2.274	2.798
FL	676	0.933	(2.436)	(1.416)	(0.655)	0.139	0.760	1.471	2.448	3.530	5.000
GA	99	(0.021)	(2.516)	(1.652)	(1.037)	(0.654)	(0.186)	0.435	0.966	1.653	2.274
GU	3	(1.612)	(1.897)	(1.897)	(1.897)	(1.703)	(1.703)	(1.703)	(1.236)	(1.236)	(1.236)
HI	14	0.760	(2.334)	(2.053)	(0.805)	0.284	1.318	1.711	2.149	2.998	4.064
IA	94	0.344	(2.920)	(2.173)	(1.254)	(0.604)	0.638	1.208	1.865	2.880	3.762
ID	42	0.245	(2.673)	(2.309)	(0.645)	(0.236)	0.028	0.865	1.383	2.297	3.059
IL	398	0.407	(2.854)	(2.065)	(1.441)	(0.656)	(0.008)	0.823	1.873	3.137	5.000
IN	138	(0.149)	(3.068)	(2.166)	(1.455)	(0.890)	(0.452)	0.226	0.991	1.629	3.179
KS	84	0.252	(3.170)	(1.706)	(1.103)	(0.348)	0.131	0.675	1.328	2.425	3.665
KY	90	0.990	(2.331)	(0.892)	(0.404)	0.332	0.781	1.381	2.258	3.365	4.290
LA	167	1.333	(1.902)	(0.762)	0.078	0.597	1.367	2.234	2.865	3.746	4.840
MA	127	(0.162)	(2.991)	(2.207)	(1.508)	(0.943)	(0.091)	0.356	0.752	1.582	2.980
MD	49	0.823	(1.649)	(1.207)	(0.831)	(0.260)	0.298	1.769	2.378	2.867	4.019
ME	19	1.081	(1.718)	(0.501)	0.039	0.505	0.704	0.917	2.069	2.862	4.562
MI	322	0.802	(2.660)	(1.818)	(1.197)	(0.270)	0.657	1.634	2.672	3.671	5.000
MN	97	(0.799)	(3.469)	(2.791)	(2.154)	(1.559)	(1.130)	(0.629)	(0.127)	1.111	2.747
MO	122	0.512	(2.814)	(2.014)	(1.458)	(0.482)	0.222	1.345	2.042	3.280	4.334
MP	1	(0.515)	(0.515)	(0.515)	(0.515)	(0.515)	(0.515)	(0.515)	(0.515)	(0.515)	(0.515)
MS	45	1.325	(1.351)	(0.689)	(0.102)	0.776	1.448	2.121	2.718	3.370	4.414
MT	22	(0.839)	(3.220)	(2.745)	(1.807)	(1.760)	(1.373)	(0.874)	(0.009)	0.957	1.328
NC	152	0.616	(2.257)	(1.285)	(0.666)	(0.012)	0.448	1.006	1.614	2.613	3.762
ND	12	2.004	0.142	0.465	1.497	1.589	2.186	2.644	3.232	3.503	4.315
NE	40	0.279	(3.014)	(2.221)	(1.674)	(0.356)	0.114	0.780	1.370	2.965	4.103
NH	20	(0.376)	(3.127)	(2.041)	(1.361)	(0.813)	(0.189)	(0.036)	0.814	1.494	2.083
NJ	42	(0.730)	(2.343)	(1.931)	(1.734)	(1.582)	(1.311)	(0.870)	(0.178)	0.656	1.208
NM	58	(0.460)	(3.833)	(2.687)	(1.863)	(1.169)	(0.568)	0.110	0.623	1.249	3.225
NV	96	(0.189)	(3.176)	(2.313)	(1.590)	(1.193)	(0.486)	0.155	0.815	1.849	3.523
NY	104	(0.462)	(2.848)	(2.342)	(1.803)	(1.221)	(0.854)	(0.111)	0.481	1.287	2.364
OH	286	(0.139)	(3.402)	(2.490)	(1.704)	(1.166)	(0.423)	0.303	1.166	2.347	3.416
OK	183	0.335	(2.631)	(1.817)	(1.009)	(0.395)	0.237	0.889	1.567	2.451	3.611
OR	43	(0.310)	(3.107)	(1.910)	(1.480)	(0.975)	(0.349)	(0.075)	0.702	1.413	2.627
PA	228	0.280	(2.600)	(1.832)	(1.167)	(0.706)	0.010	0.712	1.460	2.573	3.769

Larger-volume Cohort											
			Payment Adjustment Percentile Distribution (%)								
State	# of HHAs	Average Payment Adjustment (%)	10%	20%	30%	40%	50%	60%	70%	80%	90%
PR	31	(0.018)	(3.553)	(2.449)	(1.745)	(1.616)	(0.124)	0.358	1.822	3.215	3.871
RI	18	0.504	(2.851)	(1.925)	(0.527)	(0.256)	0.663	1.176	1.496	1.658	4.907
SC	63	0.572	(1.607)	(0.821)	(0.586)	(0.066)	0.608	1.248	1.692	2.047	2.317
SD	19	0.574	(2.095)	(1.940)	(1.215)	0.354	0.796	1.388	1.543	2.167	4.535
TN	112	1.031	(2.095)	(0.708)	(0.149)	0.553	0.900	1.633	2.061	2.929	3.796
TX	978	0.154	(3.261)	(2.350)	(1.577)	(0.914)	(0.090)	0.826	1.758	2.732	4.087
UT	68	0.892	(2.072)	(1.279)	(0.552)	0.067	0.392	0.989	1.910	3.410	4.416
VA	186	(0.030)	(3.072)	(2.361)	(1.144)	(0.606)	0.029	0.517	0.968	1.630	3.062
VI	1	(1.511)	(1.511)	(1.511)	(1.511)	(1.511)	(1.511)	(1.511)	(1.511)	(1.511)	(1.511)
VT	10	(1.145)	(3.557)	(2.771)	(2.155)	(1.759)	(1.555)	(1.435)	(1.006)	0.310	2.546
WA	56	(0.248)	(2.946)	(1.795)	(1.467)	(1.001)	(0.352)	0.096	0.937	1.367	2.383
WI	73	0.204	(2.398)	(1.908)	(1.361)	(0.520)	0.353	0.754	1.281	2.179	3.032
WV	50	1.274	(1.393)	(0.795)	0.261	0.711	1.090	1.718	2.131	3.175	4.930
WY	16	(0.500)	(3.502)	(2.228)	(1.931)	(0.548)	(0.506)	(0.225)	0.690	0.777	2.007
All	**7,064**	**0.429**	**(2.812)**	**(1.919)**	**(1.219)**	**(0.502)**	**0.244**	**0.969**	**1.787**	**2.857**	**4.414**

TABLE 44: PAYMENT ADJUSTMENT DISTRIBUTIONS BY CHARACTERISTICS (Based on a maximum 5 percent payment adjustment)

			Payment Adjustment Percentile Distribution (%)								
Percentage of Dually-eligible Beneficiaries	**# of HHAs**	**Average Payment Adjustment (%)**	**10%**	**20%**	**30%**	**40%**	**50%**	**60%**	**70%**	**80%**	**90%**
Low % dually-eligible	2,061	0.464	(2.592)	(1.656)	(0.970)	(0.313)	0.295	0.991	1.658	2.618	3.889
Medium % dually-eligible	4,118	0.153	(2.962)	(2.134)	(1.447)	(0.774)	(0.051)	0.662	1.446	2.425	3.832
High % dually-eligible	1,316	1.066	(3.145)	(1.943)	(1.043)	0.200	1.059	2.226	3.327	4.710	5.000
Acuity (HCC)	**# of HHAs**	**Average Payment Adjustment (%)**	**10%**	**20%**	**30%**	**40%**	**50%**	**60%**	**70%**	**80%**	**90%**
Low acuity	1,479	1.283	(2.545)	(1.426)	(0.457)	0.435	1.275	2.276	3.265	4.451	5.000
Middle acuity	4,290	0.320	(2.756)	(1.905)	(1.247)	(0.560)	0.187	0.851	1.604	2.601	3.913
High acuity	1,726	(0.162)	(3.283)	(2.446)	(1.753)	(1.143)	(0.460)	0.255	1.081	2.104	3.545
% Rural Beneficiaries	**# of HHAs**	**Average Payment Adjustment (%)**	**10%**	**20%**	**30%**	**40%**	**50%**	**60%**	**70%**	**80%**	**90%**
All non-rural	3,849	0.483	(2.969)	(2.046)	(1.318)	(0.552)	0.266	1.099	2.020	3.249	5.000
Up to 50% rural	2,265	0.024	(2.873)	(2.089)	(1.438)	(0.822)	(0.140)	0.469	1.200	2.108	3.323
Over 50% rural	1,368	0.783	(2.408)	(1.539)	(0.672)	0.066	0.819	1.390	2.214	3.121	4.414
Organizational Type	**# of HHAs**	**Average Payment Adjustment (%)**	**10%**	**20%**	**30%**	**40%**	**50%**	**60%**	**70%**	**80%**	**90%**
Religious affiliation	289	0.085	(2.658)	(1.807)	(1.294)	(0.794)	(0.252)	0.465	1.123	2.062	3.232
Private not-for-profit	579	(0.010)	(2.961)	(2.053)	(1.432)	(0.891)	(0.262)	0.422	1.098	2.055	3.562
Other not-for-profit	478	0.230	(2.618)	(1.812)	(1.144)	(0.470)	0.160	0.752	1.314	2.296	3.280
Private for-profit	5,869	0.459	(2.913)	(1.997)	(1.271)	(0.500)	0.278	1.044	1.918	3.039	4.677
State	186	0.548	(3.244)	(1.790)	(0.699)	(0.225)	0.441	1.317	2.151	3.047	4.263
Gov't & voluntary	10	1.059	(0.356)	(0.171)	0.073	0.322	0.879	1.395	1.565	1.618	3.134
Local	96	0.583	(2.604)	(1.584)	(0.797)	(0.102)	0.507	1.361	1.834	2.749	3.799

Note: The total number of HHAs differ by category due to missing HHAs in some data sources.

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3. Impacts for the HH QRP for CY 2022

Estimated impacts for the HH QRP for CY 2022 are based on analysis discussed in section XI.B. of this final rule. Finalizing the HH QRP requirements reduces burden to the active collection under OMB control number #0938–1279 (CMS–10545; expiration 12/31/21).

Failure to submit HH QRP 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 an HHA for that calendar year by 2 percentage points. For the CY 2021, representing HH QRP data collected from July 1, 2019 to June 30, 2020, by HHAs, 527 of the 11,196 active Medicare-certified HHAs, or approximately 4.7 percent, did not receive the full annual percentage increase (the methodology accommodated the COVID–19 PHE exception). These 527 HHAs represented $253 million in home health claims payment dollars during the reporting period out of a total $16.7B for all HHAs.

As discussed in section IV.C. of this final rule, we are finalizing the removal of one OASIS-based measure beginning with the CY 2023 HH QRP. The assessment-based measure we are removing is: (1) Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care. We also are replacing the Acute Care Hospitalization During the First 60 Days of Home Health (NQF # 0171) measure and Emergency Department Use Without Hospitalization During the First 60 Days of Home Health (NQF #0173) measure with the Home Health Within Stay Potentially Preventable Hospitalization measure beginning with the CY 2023 HH QRP under our measure removal Factor 6: A measure that is more strongly associated with desired patient outcomes for the particular topic is available. Because these three measures are claims-based, there would be no impact to our collection of information.

Section XI.B. of this final rule provides a detailed description of the net decrease in burden associated with these proposed changes. The associated burden is for CY 2023 because HHAs would submit HH QRP data beginning CY 2023. The cost impact related to OASIS item collection as a result of the changes to the HH QRP is estimated to be a net decrease of $2,762,277 in

annualized cost to HHAs, discounted at 7 percent relative to year 2020, over a perpetual time horizon beginning in CY 2023.

We described the estimated burden and cost reductions for these measures in section XI.B. of this final rule.

In summary, the HH QRP measure removals results in a burden reduction of $242 per HHA annually, or $2,762,277 for all HHAs annually. We have described the burden costs savings in Table 45:

TABLE 45: BURDEN SAVINGS CALCULATIONS

Time Point	Costs with 2020 data	Removal of M2016	Estimate Cost
Transfer of Care	$4,969,755.73	$4,259,790.63	$709,965
Discharge from agency	$230,885,202.34	$228,832,890.59	$2,052,312
TOTAL			**2,762,277** **$242 per HHA (2,762,277/11,400)**

We did not receive comments on the outlined burden estimates for the HH QRP proposals.

4. Changes to the Home Health CoPs

a. Virtual Supervision of HHA Aides

In section IV.D. we are finalizing the 14-day aide supervisory visit at § 484.80(h)(1) with modification. We will permit the one virtual supervisory visit per patient per 60-day episode. This visit must only be permitted only in rare instances for circumstances outside the HHA's control and must include notations in the medical record detailing the circumstances. We are finalizing the supervisory visit requirements for non-skilled patients with modification. We are modifying the proposed semi-annual onsite visit to require that this visit be conducted on ''each'' patient the aide is providing services to rather than ''a'' patient. Lastly, we are finalizing the assessment of deficient skills as proposed. We believe the burden associated with addressing skills related to those identified as deficient skills is minimal. Moreover, supervising employees to ensure the safe and effective provision of patient care is standard business practice throughout the health care community. Likewise, documenting that this supervision has occurred for internal personnel, accreditation, and State and Federal compliance purposes constitutes a usual and customary business practice. Therefore, the regulatory impact is negligible.

b. Permitting Occupational Therapists To Conduct the Initial Assessment Visit and Complete the Comprehensive Assessment for Home Health Agencies Under the Medicare Program

In accordance with Division CC, section 115 of CAA 2021, we finalizing conforming regulations text changes to permit the occupational therapist to complete the initial and comprehensive assessments for Medicare patients when ordered with another rehabilitation therapy service (speech language pathology or physical therapy) that establishes program eligibility, in the case where skilled nursing services are also not ordered. We do not expect any increase in burden for any of these modifications. In fact, for home health agencies, this may facilitate efficiencies by expanding the type of therapy discipline able to complete the initial and comprehensive assessments, in some circumstances, for Medicare patients. We do not expect the changes for these provisions would cause any appreciable amount of expense or anticipated saving and we do not believe this standard would impose any additional regulatory burden.

5. Impact of the CY 2022 Payment for Home Infusion Therapy Services

We are finalizing two provisions in this final rule related to payments for home infusion therapy services in CY 2022: The proposal to maintain the CY 2021 percentages for the initial subsequent policy and the proposal to wage adjust home infusion therapy service payments using the CY 2022 GAFs. The provision to maintain the percentages for the initial subsequent policy as well as the provision to use the CY 2022 GAFs to wage adjust home infusion therapy service payments are both implemented in a budget neutral manner, therefore, there is no estimated impact on payments to HIT suppliers due to these policies. As noted previously, Division N, section 101 of CAA 2021 amended added section 1848(t)(1) of the Act, which applied and modified the CY 2021 PFS rates by providing a 3.75 percent increase in PFS payment amounts only for CY 2021.[226] For CY 2022, we will remove the 3.75 percent increase from the PFS amounts used to establish the CY 2021 home infusion therapy payment rates and use the unadjusted CY 2021 rates for the CY 2022 home infusion therapy services payment amounts. The unadjusted CY 2021 rates will be updated for CY 2022 in accordance with section 1834(u)(3) of the Act using the 5.4 percentage increase in the CPI–U for the 12-month period ending in June of 2021 reduced by the productivity adjustment of 0.3 percentage point, which results in a 5.1 percent increase ($300,000) to HIT suppliers for CY 2022.

6. Medicare Provider and Supplier Enrollment Provisions

a. General Impact

Similar to our position regarding information collection requirements, and except as discussed in section XI.C.6.b. of this final rule, we did not anticipate any costs, savings, or transfers associated with our proposed provider and supplier enrollment provisions. Most of these provisions have been in sub-regulatory guidance for a number of years, and we are merely incorporating them into regulation; those provisions that are not in subregulatory guidance do not involve any costs, savings, or transfers.

b. Deactivation of Billing Privileges—Payment Prohibition

As explained in section VI.B. of the proposed rule, we proposed in new § 424.540(e) that a provider or supplier may not receive payment for services or items furnished while deactivated under § 424.540(a). Existing sub-regulatory guidance permits the provider or supplier to bill for services or items furnished up to 30 days prior to the

[226] Medicare Learning Network Connects ''Special Edition: Physician Fee Schedule Update'' (January 7, 2021). *https://www.cms.gov/files/document/2021–01–07-mlnc-se.pdf.*

effective date of the reactivation of the provider's or supplier's billing privileges. Our proposal would reverse this policy for the reasons stated in section VI.B. of the proposed rule.

Although the figure varies widely by individual provider or supplier, internal CMS data suggests that the average provider/supplier impacted by the aforementioned proposal receives roughly $50,000 in Medicare payments each year. (We used a similar $50,000 annual payment estimate for our provider enrollment provisions in a CMS final rule published in the **Federal Register** on November 15, 2019 titled, ''CY 2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies'' (84 FR 62568).) As with annual payment amounts, the number of deactivations vary per year. Nonetheless, and again based on internal CMS data, we estimate 13,000 deactivations annually. This results in an approximate burden of $54,145,000 per year ($13{,}000 \times 50{,}000 \times 0.0833$). (The 0.0833 figure represents 30 days, or 1/12 of a year.) The following table reflects the estimated transfers associated with our proposed addition of new § 424.540(e) concerning payments for services and items furnished by deactivated providers and suppliers:

PROHIBITION OF PAYMENT FOR SERVICES OR ITEMS FURNISHED BY DEACTIVATED PROVIDERS AND SUPPLIERS FROM CY 2021 TO 2022	
Providers/Suppliers to Federal Government	$54.1 million

We did not receive comments on this estimate and are therefore finalizing it as proposed and without modification.

7. Survey and Enforcement Requirements for Hospice Providers

Estimated impacts for the Survey and Certification Requirements for Hospice Program Providers are based on analysis discussed in section VII. of the proposed rule.

a. Application and Re-application Procedures for National Accrediting Organizations (§ 488.5)

We proposed at § 488.5(a)(4)(x) to require AOs with CMS-approved hospice programs to include a statement of deficiencies, (that is, the Form CMS–2567 or a successor form) to document survey findings of the hospice Medicare CoPs and to submit such in a manner specified by CMS. This implements new section 1822(a)(2)(A)(ii) of the Act. We anticipate effects on AO administrative expenses but are not able to provide an accurate estimate of how much cost and time will result from including the Form CMS–2567 into their proprietary IT systems and subsequently submitting the information to CMS. Currently, there are three AOs with CMS-approved hospice programs affected by this proposal. We sought comments that would help us to develop an accurate estimate of the cost and time burden that would result from this collection of information.

We did not receive comments on this estimated impact and therefore are finalizing this section without modification.

b. Release and Use of Accreditation Surveys (§ 488.7)

CAA 2021 adds section 1822(a)(2)(B) of the Act which requires that CMS publish hospice survey information from the Form CMS–2567 in a way that is readily understandable and useable by the public in a meaningful way. We anticipate the need for CMS to develop some type of a standard framework that would identify salient survey findings in addition to other relevant data about the hospices' performance. CMS recognizes that the implications of releasing national survey data will require collaboration with industry stakeholders to assure the development is fair and equitable across all hospice programs.

We did not receive comments on this estimated impact and therefore are finalizing this section without modification.

c. Hospice Hotline (§ 488.1110)

Section 1864(a) of the Act was amended by inserting ''hospice programs'' after information on the home health toll-free hotline. The infrastructure for a State or local agency toll-free hotline is already in place for HHAs to collect and maintain complaint information related to HHAs. The requirement allows the existing hotline to collect complaint information on hospices. We do not expect the changes for this provision will cause any appreciable amount of expense or anticipated saving and we do not believe this standard would impose any additional regulatory burden.

We did not receive comments on this estimated impact and therefore are finalizing this section without modification.

d. Surveyor Qualifications and Prohibition of Conflicts of Interest (§ 488.1115)

We proposed at § 488.1115, to require AO hospice program surveyors to complete the CMS hospice basic training currently available online. We have removed the proposed burden estimates for the surveyor qualifications because we do not expect any increase in burden for this provision. In fact, for AOs with hospice programs, this may facilitate efficiencies by removing the need for AOs to develop and maintain their own training courses based on the CMS regulations and process. Therefore, the regulatory impact (including benefits of such provisions) is negligible. Additionally, we did not receive comments on the estimated impact.

We also proposed to set out the circumstances that will disqualify a surveyor from surveying a particular hospice in accordance with new section 1822(a)(4)(B) of the Act. We do not expect these changes would cause any appreciable amount of expense or anticipated saving because the provisions codify longstanding policies and basic principles to ensure there is no conflict of interest between organizations and surveyors.

We did not receive comments on this estimated impact and therefore are finalizing this section without modification.

e. Survey Teams (§ 488.1120)

We proposed at § 488.1120 that when the survey team comprises more than one surveyor, the additional slots would be filled by multidisciplinary professionals such as physicians, nurses, medical social workers, pastoral or other counselors—bereavement, nutritional, and spiritual. At this time, we do not have specific information related to current survey team compositions but we do know there are approximately 977 hospice surveys per year, with at least one member of the survey team being a registered nurse. The proposed inclusion of multidisciplinary survey team members could potentially increase the overall cost of surveys if SA and AOs were not already using a mixed team.

The 2020 Bureau of Labor Statistics estimates RN adjusted hourly wages at $76.94 (including fringe benefits and overhead). Other potential disciplines fall below and above the RN adjusted hourly wage, for example: social workers-$50.12 per hour, pharmacists-$120.64 per hour, and psychologists-$108.36 per hour. A survey team of all nurses (assuming a two-person team) costs $153.88 ($76.94 × 2) per hour. However, CMS believes the most common multidisciplinary team for hospice program surveys may include a nurse and a social worker. Using this assumption, we calculate it will cost $127.06 ($76.94 × $50.12) per hour for this multidisciplinary 2-person survey team composition. Therefore, a two-person multidisciplinary team at $127.06 per hour, assuming a 5-day survey (8 hours per day × 5 days = 40 hours), would cost $5,082.40 per survey, times 960 surveys per year, or $4,879,104 per year. We sought comments on the current professional makeup of the AO and SA survey teams, and providers' estimates of the time needed to effectuate multidisciplinary teams where they do not currently exist.

We did not receive comments on this estimated impact and therefore are finalizing this section without modification.

f. Consistency of Survey Results (§ 488.1125)

Actions to improve consistency of survey results are discussed elsewhere in terms of implementing the use of the Form CMS–2567 across surveying entities and utilizing a common training platform. We do not anticipate additional costs or burdens to surveying entities. Some cost will be incurred by CMS to develop the system (technical and personnel) to analyze and apply correction where needed.

We did not receive comments on this estimated impact and therefore are finalizing this section without modification.

g. Enforcement Remedies (§§ 488.1200 through § 488.1265)

We proposed enforcement remedies for hospices consistent with the established alternative sanctions for HHAs. In CY 2019, out of 11,738 deemed and non-deemed HHAs enrolled in the Medicare program, 749 HHA providers had the potential to be sanctioned based on repeat deficiencies during two consecutive standard or complaint surveys. This was approximately 15 percent of the HHAs, which is less than 37.5 percent of the total HHAs surveyed. Of all the alternative sanctions available for implementation, very few HHA enforcement actions were imposed. In CY 2019, less than 10 percent of all HHAs with surveys identifying an immediate jeopardy level deficiency citation received an alternative sanction.

The probability of impact for alternative enforcement remedies imposed against hospices is based on CY 2019 data for 5,065 deemed and non-deemed hospices enrolled in the Medicare program. These data were examined using the survey data for the CY 2019 in the CMS QCOR system. Of the total number of CMS-certified hospices, 4,399 received an unannounced standard and/or complaint survey and 236 were cited for noncompliance with one or more condition-level deficiencies. Therefore, approximately 5 percent of the total hospices surveyed had the potential to receive an enforcement remedy based on noncompliance with one or more CoPs.

The enforcement remedy provisions in this proposed rule mirror the alternative sanctions used in HHAs that have already been incorporated into CMS policy. Therefore, in terms of the administrative expenses to design and manage these types of remedies, the infrastructure is already in place. In terms of training for Federal and State surveyors, it is common for surveyors that survey HHAs to be cross-trained to survey hospices. Since the enforcement remedies for hospice are similar to those for HHAs, we expect that there will be a minimal burden on seasoned surveyors to become familiar with these provisions. Additionally, the data analysis described previously for hospices in CY 2019 reflects the probability of a low impact for civil monetary penalties to be imposed on hospice providers.

We did not receive comments on this estimated impact and therefore are finalizing this section without modification. However, we have removed the SFP regulatory impact analysis because we are not finalizing the SFP in this rule.

8. Certain Compliance Date Changes for the IRF QRP and LTCH QRP

a. Impacts for the Inpatient Rehabilitation Facility Quality Reporting Program for FY 2023

This final rule does not impose any new information collection requirements under the IRF QRP. However, this final rule does reference associated information collections that are not discussed in the regulation text contained in this document. The following is a discussion of this information collection, which have already received OMB approval.

In accordance with section 1886(j)(7)(A) of the Act, the Secretary must reduce by 2 percentage points the annual market basket increase factor otherwise applicable to an IRF for a fiscal year if the IRF does not comply with the requirements of the IRF QRP for that fiscal year. As stated in section VIII.A. of the proposed rule, for purposes of calculating the FY 2023 Annual Increase Factor (AIF), we proposed that IRFs would begin collecting data on the TOH Information to Provider-PAC and the TOH Information to Patient-PAC measures beginning with admissions and discharges on October 1, 2022. We also proposed that IRFs would begin collecting data on certain Standardized Patient Assessment Data Elements, beginning with admissions and discharges (except for the hearing, vision, race, and ethnicity Standardized Patient Assessment Data Elements, which would be collected at admission only) on October 1, 2022. If finalized as proposed, IRFs would use the IRF–PAI V4.0 to submit IRF QRP data.

We are finalizing the proposed IRF QRP requirements, which do not additional burden or cost to the active collection under OMB control number 0938–0842 (expiration 12/31/2022).

b. Impacts for the Long-Term Care Hospital Quality Reporting Program for FY 2023

This proposed provision does not impose any new information collection requirements under the LTCH QRP. However, this proposed provision does reference associated information collections that are not discussed in the regulation text of the proposed or this final rule. The following is a discussion of this information collection discussed in section XI. of the proposed rule, which have already received OMB approval.

In accordance with section 1886(m)(5) of the Act, the Secretary must reduce by 2 percentage points the annual market basket payment update otherwise applicable to a LTCH for a fiscal year if the LTCH does not comply with the requirements of the LTCH QRP for that fiscal year. As stated in section VIII.B. of the proposed rule for purposes of calculating the FY 2023 Annual Payment Update (APU), we proposed that LTCHs would begin collecting data on the TOH Information to Provider-PAC and the TOH Information to Patient-PAC measures beginning with admissions and discharges on October 1, 2022. We also proposed that LTCHs would begin to collect data on certain

Standardized Patient Assessment Data Elements, beginning with admissions and discharges (except for the hearing, vision, race, and ethnicity Standardized Patient Assessment Data Elements, which would be collected at admission only) on October 1, 2022. If finalized as proposed, LTCHs would use the LTCH Continuity Assessment Record and Evaluation (CARE) Data Set (LCDS) V5.0 to submit LTCH QRP data.

The proposed LTCH QRP requirements would add no additional burden or cost to the active collection under OMB control number 0938–1163 (expiration 12/31/2022).

9. COVID–19 Reporting Requirements for Long Term Care Facilities

a. Anticipated Cost

Section 483.80(g) sets forth the requirements for COVID–19 reporting for LTC facilities. Currently, § 483.80(g)(1) states that LTC facilities must electronically report information about COVID–19 in a standardized format specified by the Secretary. Specific pieces of information that must be reported are set forth in that subsection. One of the information requirements is ''the COVID–19 vaccine status of residents and staff, including total numbers of residents and staff, numbers of residents and staff vaccinated, numbers of each dose of COVID–19 vaccine received, and COVID–19 vaccination adverse events''.

This final rule requires LTC facilities to continue to report certain information required by CDC's NHSN. However, this change will provide flexibility if there are future changes to the information NHSN requires to be reported. In addition, we are revising paragraph (g)(1) to include a sunset, or expiration date, of December 31, 2024, for all of the required information in paragraph (g)(1), except for the information set out at (g)(1)(viii) that covers that COVID–19 vaccine status of residents and staff. In § 483.80(g)(2), we are removing the ''less'' after ''no'' and inserting ''more'' so that the required frequency of reporting is no more than weekly instead of no less than weekly.

For the estimated costs contained in the analysis below, we used data from the United States Bureau of Labor Statistics (BLS) to determine the mean hourly wage for the positions used in this analysis.[227] For the total hourly cost, we doubled the mean hourly wage for a 100 percent increase to cover overhead and fringe benefits, according to standard HHS estimating procedures. If the total cost after doubling resulted in .50 or more, the cost was rounded up to the next dollar. If it was 0.49 or below, the total cost was rounded down to the next dollar. The total costs used in this analysis are indicated in the chart below.

TABLE 46 - SUMMARY TABLE FOR LTC FACILITY POSITIONS

Occupation Code	BLS Occupation Title	Associated Position Title in this Regulation	Mean Hourly Wage ($/hour)	Adjusted Hourly Wage (with 100% markup for fringe benefits & overhead) ($/hour) (rounded to nearest dollar)
29-1228	Physicians, All Others; and Ophthalmologist, except Pediatric) (General Medical and Surgical Hospitals)	LTC Medical Director	$85.70	$171
29-1141	Registered Nurses (Nursing Facilities/ Skilled Nursing Facilities)	LTC Infection Preventionist (IP);	$34.66	$69
11-9111	Medical and Health Services Managers (Nursing Facilities/Skilled Nursing Facilities)	LTC Director of Nursing (DON); LTC Administrator	$48.15	$96

As determined in the COI section, the burden for ICR requirements for this rule would be 15,401 hours (1 × 15,401) at an estimated cost of $1,062,669 (15,401 × $69). In addition to the ICR requirements, there would be addition requirements for the IP to report on these changes in policies and procedures to the medical director, director of nursing (DON), and an administrator. We believe this would require an addition 10 minutes or 0.1666 hours for the IP, medical director, DON, and administrator. According to Table 1 above, the medical director earns an adjusted hourly wage of $171. Thus, the burden for the medical director would be 0.1666 hours at an estimated cost of $28.50 (0.1666 × $171). The adjusted hourly wage for both the DON and administrator is $96. Thus, the burden for each of them would be 0.1666 hours at an estimated cost of $16 (0.1666 × $96) and for both it would be 0.3332 hours at an estimated cost of $32. The adjust hourly wage for the IP is $69. The burden for the IP would be 0.1666 hours at an estimated cost of $11.50 (0.1666 × $69). Thus, the burden for each LTC facility would be 0.67 hour or about 40 minutes (0.1666 × 4) at an estimated cost of $72 ($28.50 + $16 + $16 + $11.50). For all 15,401 LTC facilities the total burden would be 10,319 hours (0.67 × 15,401) at an estimated cost of $1,108,872 (15,401 × $72).

Thus, the total burden for the requirements in this rule is 25,720 hours (15,401 + 10,319) at an estimated cost of $2,171,541 ($1,062,669 + $1,108,872).

b. Anticipated Benefits

These changes will provide LTC facilities will more flexibility and eliminate unnecessary burden on these facilities by revising the requirements for the reporting frequency to no more

[227] BLS. May 2020 National Occupational Employment and Wage Estimates United States. United States Department of Labor. Accessed at *https://www.bls.gov/oes/current/oes_nat.htm.* Accessed on August 25, 2021.

than weekly, with the possibility of reduced reporting at the discretion of the Secretary and the data reporting elements may be changed in the future. The reporting requirements, with the exception of the requirements at § 483.80 (g)(1)(viii), will end on December 31, 2024. We did not receive comments on this proposal and therefore are finalizing this provision without modification.

D. Limitations of Our Analysis

Our estimates of the effects of this final rule are subject to significant uncertainty. It is difficult to estimate the burden and savings from the proposed changes that are being finalized in this rule because they depend on several factors previously described. We appreciate that our assumptions are simplified and that actual results could be considerably higher or lower. Although there is uncertainty concerning the magnitude of all of our estimates, we do not have the data to provide specific estimates for each proposal, as to the range of possibilities, or to estimate all categories of possible benefits. We sought comments on all aspects of this analysis.

E. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, we must estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that would review the rule, we assume that the total number of unique reviewers of this year's final rule would be the similar to the number of reviewers on this year's proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed this year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we believe that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We 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. 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 is $114.24 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 5.73 hours for the staff to review half of this final rule, which consists of approximately 171,832 words. For each HHA that reviews the rule, the estimated cost is $654.34 (5.73 hours × $114.24). Therefore, we estimate that the total cost of reviewing this final rule is $135,447.61 ($654.34 × 207 reviewers). For purposes of this estimate, the number of reviewers of this year's rule is equivalent to the number of comments received for the CY 2022 HH PPS proposed rule.

F. Alternatives Considered

1. HH PPS

For the CY 2022 HH PPS final rule, we considered alternatives to the provisions articulated in section II. of this final rule. We considered using CY 2019 data for ratesetting. However, our analysis showed there were only small differences in the payment rates and impacts in the aggregate when using CY 2019 data compared to CY 2020 data. These differences in payment rates reflect small differences in the wage index budget neutrality factors calculated using CY 2020 data compared to using CY 2019 claims data. We note, we would not have recalibrated the case-mix weights using CY 2019 data because CY 2019 data would use simulated 30-day periods from 60-episodes as CY 2020 is the first year of actual PDGM data. Therefore, no case-mix weight budget neutrality factor using CY 2019 utilization data would be applied. We believe it is best to continue with our established policy of using the most recent, complete data at the time of rulemaking for CY 2022 rate setting, which would be CY 2020 claims data. Additionally, we considered alternatives to our case-mix recalibration proposal. These alternatives included an option to do a full recalibration of the case-mix weights, including the functional impairment levels, comorbidity subgroups as proposed, but also updating the LUPA thresholds, as well as an option to not recalibrate the case-mix weights, functional impairment levels, comorbidity subgroups and LUPA thresholds. However, we believe that recalibrating the PDGM case-mix weights, functional levels, and comorbidity adjustment subgroups while maintaining the LUPA thresholds for CY 2022 would more accurately adjust home health payments because the data would reflect 30-day periods under the new PDGM system based on actual data rather than data that simulated 30-day episodes under the old system. The recalibrated case-mix weights would also more accurately reflect the types of patients currently receiving home health services while mitigating instability by maintaining the LUPA thresholds. As stated previously, the LUPA thresholds are based on the number of overall visits in a particular case-mix group (the threshold is the 10th percentile of visits or 2 visits, whichever is greater) instead of a relative value (as is used to generate the case-mix weight) that would control for the impacts of the PHE. We note that visit patterns and some of the decrease in overall visits in CY 2020 may not be representative of visit patterns in CY 2022. Also, our analysis shows that there is more variation in the case-mix weights with the full recalibration (including updates to the LUPA thresholds) than the recalibration with the case-mix weights maintained. Maintaining the LUPA thresholds creates more stability in the weights. The recalibrated case-mix weights using the current LUPA thresholds are more similar to the CY 2020 weights than the recalibrated case-mix weights with the updated LUPA thresholds. For these reasons, we believe it is best to maintain the LUPA thresholds for CY 2022 instead of the alternative full recalibration including updates to the LUPA thresholds.

2. HHVBP

We considered alternatives to the proposed policies in sections III.A. and III.B. of the proposed rule. Specifically, we considered not expanding the HHVBP Model at this point in time, and waiting until we have final evaluation results from the original HHVBP Model before pursuing a national expansion. However, we considered that we have evaluation results from multiple years of the original HHVBP Model, showing significant reductions in spending and improvements in quality. We believe this evidence is sufficient for a national expansion of the Model, and note that we will continue to review evaluation results as they come in for the later years of the original HHVBP Model.

For the expanded HHVBP Model, we also considered utilizing the same State- and volume-based cohorts as the original HHVBP Model in lieu of the national volume-based cohorts we proposed. However, this approach could

require grouping together of certain States, territories, and the District of Columbia that have an insufficient number of HHAs at the end of the performance year, based solely on their lower HHA counts. This would also preclude providing benchmarks and achievement thresholds prospectively. An analysis of the State-level impacts of using the revised cohorts, including our proposed option, nationwide with volume-based cohorts, and our alternative, State-level without volume-based cohorts, demonstrates minimal impacts at the State-level. We refer readers to Table 43 of this final rule for an analysis of the shifts of expenditures, as represented by the average payment adjustments for small- and large-volume HHAs in each of the States, territories, and the District of Columbia, simulated with the proposed national size-based cohorts using 2019 data and a maximum adjustment of ± 5 percent. When the small- and large-volume HHAs in each of the States, territories, and the District of Columbia are combined, the average payment adjustment for the majority of States, territories, and the District of Columbia is within ± 1 percent, with none exceeding ± 2 percent. Relative to the State- and volume-based cohorts, the national volume-based cohorts resulted in the largest increases in overall payment amounts to Alabama (+1.8 percent), Mississippi (+1.8 percent), and TN (+1.4 percent). The largest decreases in overall payment amounts are from Minnesota (−1.7 percent), Connecticut (−1.6 percent), and the Marianas Islands (−1.6 percent). We do not see any obvious correlation of the impacts within States that are currently in the original Model versus those that will be new to the expanded Model.

3. Deactivation Payment Prohibition

As discussed in section VI.B. of the proposed rule, we proposed in new § 424.540(e) that a provider or supplier may not receive payment for services or items furnished while deactivated under § 424.540(a). Current subregulatory guidance permits the provider or supplier to bill for services or items furnished up to 30 days prior to the effective date of the reactivation of the provider's or supplier's billing privileges. We considered the alternative of retaining this 30-day retroactive period. After careful consideration, however, we concluded that prohibiting such retroactive payments would be the best approach from a program integrity perspective. As we stated in section VI.B. of the proposed and final rules, we do not believe a provider or supplier should be effectively rewarded for its non-adherence to enrollment requirements by receiving retroactive payment for services or items furnished while out of compliance. Moreover, the prospect of a payment prohibition could well spur providers and suppliers to avoid such non-compliance.

4. COVID–19 Reporting in Long-Term Care Facilities

We considered retaining all of the requirements in § 483.80(g). However, we anticipate that NHSN will change the information items that are required in the future. The change made to this section will enable LTC facilities to continue to report the information required by the NHSN without requiring the facilities to report information that the NHSN no longer requires. We also considered not setting a sunset or expiration date for all of the requirements for the information elements in paragraph (g)(1). However, we do not believe that all of this information will be needed in the future. The information on the vaccine status for the residents and staff is necessary so that health authorities can assess the needs in this area though. Thus, we have added the sunset date of December 31, 2024 for all of the information elements, except for paragraph (g)(1)(viii) which covers the vaccinations. Hence, this reduces the burden for the LTC facilities while maintaining the requirement to report information so that health authorities can assess the COVID–19 vaccination environment in LTC facilities. There has also been some confusion created by the language in (g)(2), which indicated that the frequency of the reporting was to be ''no less than weekly''. We considered retaining the language in (g)(2); however, we believe that the confusion was adding undue burden to some LTC facilities. Thus, we have changed the language to read, ''no more than weekly'' to address any confusion. LTC facilities should report as NHSN requires.

G. Accounting Statement and Tables

1. HH PPS

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 46, we have prepared an accounting statement showing the classification of the transfers and benefits associated with the CY 2022 HH PPS provisions of this rule.

TABLE 46: ACCOUNTING STATEMENT: HH PPS CLASSIFICATION OF ESTIMATED TRANSFERS AND BENEFITS, FROM CY 2021 TO 2022

Category	Transfers
Annualized Monetized Transfers	$570 million
From Whom to Whom?	Federal Government to HHAs

2. HHVBP Model Expansion

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 47, we have prepared an accounting statement showing the classification of the expenditures associated with this final rule as they relate to hospitals and SNFs. Table 47 provides our best estimate of the decrease in Medicare payments under the expanded HHVBP Model.

TABLE 47: ACCOUNTING STATEMENT: EXPANDED HHVBP MODEL CLASSIFICATION OF ESTIMATED TRANSFERS FOR CYs 2023 – 2027

Category	Transfers	Discount Rate	Period Covered
Annualized Monetized Transfers	-$662.4 Million	7%	CYs 2023-2027
Annualized Monetized Transfers	-$669.7 Million	3%	CYs 2023-2027
From Whom to Whom?	Federal Government to Hospitals and SNFs		

3. HHQRP

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 48, we have prepared an accounting statement showing the classification of the expenditures associated with this final rule as they relate to HHAs. Table 48 provides our best estimate of the decrease in Medicare payments.

TABLE 48: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS OF OASIS ITEM COLLECTION, FROM CY 2021 TO CY 2022

Category	Costs
Annualized Net Monetary Burden for HHAs' Submission of the OASIS	$-2,762,277

H. Regulatory Flexibility Act (RFA)

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. In addition, HHAs and home infusion therapy suppliers are small entities, as that is the term used in the RFA. Individuals and States are not included in the definition of a small entity.

The North American Industry Classification System (NAICS) was adopted in 1997 and is the current standard used by the Federal statistical agencies related to the U.S. business economy. We utilized the NAICS U.S. industry title ''Home Health Care Services'' and corresponding NAICS code 621610 in determining impacts for small entities. The NAICS code 621610 has a size standard of $16.5 million [228] and approximately 96 percent of HHAs and home infusion therapy suppliers are considered small entities. Table 49 shows the number of firms, revenue, and estimated impact per home health care service category.

TABLE 49: NUMBER OF FIRMS, REVENUE, AND ESTIMATED IMPACT OF HOME HEALTH CARE SERVICES BY NAICS CODE 621610

NAICS Code	NAICS Description	Enterprise Size	Number of Firms	Receipts ($1,000)	Estimated Impact ($1,000) per Enterprise Size
621610	Home Health Care Services	<100	5,861	210,697	$35.95
621610	Home Health Care Services	100-499	5,687	1,504,668	$264.58
621610	Home Health Care Services	500-999	3,342	2,430,807	$727.35
621610	Home Health Care Services	1,000-2,499	4,434	7,040,174	$1,587.77
621610	Home Health Care Services	2,500-4,999	1,951	6,657,387	$3,412.29
621610	Home Health Care Services	5,000-7,499	672	3,912,082	$5,821.55
621610	Home Health Care Services	7,500-9,999	356	2,910,943	$8,176.81
621610	Home Health Care Services	10,000-14,999	346	3,767,710	$10,889.34
621610	Home Health Care Services	15,000-19,999	191	2,750,180	$14,398.85
621610	Home Health Care Services	≥20,000	961	51,776,636	$53,877.87
621610	Home Health Care Services	Total	23,801	82,961,284	$3,485.62

Source: Data obtained from United States Census Bureau table "us_6digitnaics_rcptsize_2017" (SOURCE: 2017 County Business Patterns and Economic Census) Release Date: 5/28/2021: https://www2.census.gov/programs-surveys/susb/tables/2017/
Notes: Estimated impact is calculated as Receipts ($1,000)/Enterprise Size.

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

[228] *https://www.sba.gov/sites/default/files/2019-08/SBA%20Table%20of%20Size%20Standards_Effective%20Aug%2019%2C%202019_Rev.pdf.*

reach a threshold of 3 to 5 percent or more of total revenue or total costs. The majority of HHAs' visits are Medicare paid visits and therefore the majority of HHAs' revenue consists of Medicare payments. Based on our analysis, we conclude that the policies proposed in this rule would not result in an estimated total impact of 3 to 5 percent or more on Medicare revenue for greater than 5 percent of HHAs. We note also, and as discussed in section XI.C.6. of this final rule, our provision to prohibit payments for services and items furnished by deactivated providers and suppliers will affect only a very limited number of Medicare providers and suppliers. Therefore, the Secretary has determined that this HH PPS final rule would not have significant economic impact on a substantial number of small entities.

Guidance issued by the Department of Health and Human Services interpreting the Regulatory Flexibility Act considers the 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. Among the over 7,500 HHAs that are estimated to qualify to compete in the expanded HHVBP Model, we estimate that the percent payment adjustment resulting from this rule would be larger than 3 percent, in magnitude, for about 28 percent of competing HHAs (estimated by applying a 5-percent maximum payment adjustment under the expanded Model to CY 2019 data). As a result, more than the RFA threshold of 5-percent of HHA providers nationally would be significantly impacted. We refer readers to Tables 43 and 44 of this final rule for our analysis of payment adjustment distributions by State, HHA characteristics, HHA size and percentiles.

Thus, the Secretary has certified that this final rule would have a significant economic impact on a substantial number of small entities. Though the RFA requires consideration of alternatives to avoid economic impacts on small entities, the intent of the rule, itself, is to encourage quality improvement by HHAs through the use of economic incentives. As a result, alternatives to mitigate the payment reductions would be contrary to the intent of the rule, which is to test the effect on quality and costs of care of applying payment adjustments based on HHAs' performance on quality measures.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of 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 certified that this final rule will not have a significant economic impact on the operations of small rural hospitals.

I. Unfunded Mandates Reform Act (UMRA)

Section 202 of UMRA 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 2021, that threshold is approximately $158 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 $158 million or more.

J. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. We have reviewed this final rule under these criteria of Executive Order 13132, and have determined that it will not impose substantial direct costs on State or local governments.

K. Conclusion

In conclusion, we estimate that the provisions in this final rule will result in an estimated net increase in home health payments 3.2 percent for CY 2022 ($570 million). The $570 million increase in estimated payments for CY 2022 reflects the effects of the CY 2022 home health payment update percentage of 2.6 percent ($465 million increase), a 0.7 percent increase in payments due to the new lower FDL ratio, which will increase outlier payments in order to target to pay no more than 2.5 percent of total payments as outlier payments ($125 million increase) and an estimated 0.1 percent decrease in payments due to the rural add-on percentages mandated by the Bipartisan Budget Act of 2018 for CY 2022 ($20 million decrease).

L. Executive Order 12866

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget reviewed this final rule.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 28, 2021.

List of Subjects

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 424

Emergency medical centers, Health facilities, Health professions, Medicare, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 483

Grant programs-health, Health facilities, Health professions, Health records, Medicaid, Medicare, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

42 CFR Part 484

Health facilities, Health professions, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare Reporting and recordkeeping requirements.

42 CFR Part 498

Administrative practice and procedure, 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 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—
■ a. By revising the paragraph (b) heading;
■ b. In paragraph (c)(1)(i)(C) by removing the phrase ''physician's orders'' and adding in its place the phrase ''physician's or allowed practitioner's orders'';
■ c. In paragraphs (c)(1)(i)(D), (c)(2)(i), and (c)(3) by removing the term ''physician'' and adding in its place the phrase ''physician or allowed practitioner''; and

■ d. In paragraph (d) by removing the phrase ''based on a physician's oral orders'' and adding in its place the phrase ''based on a physician's or allowed practitioner's oral orders''.

The revision reads as follows:

§ 409.43 Plan of care requirements.

* * * * *

(b) *Physician's or allowed practitioner's orders.* * * *

* * * * *

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 3. The authority for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 4. Section 424.520 is amended by revising paragraph (d) to read as follows:

§ 424.520 Effective date of Medicare billing privileges.

* * * * *

(d) *Additional provider and supplier types.* (1) The effective date of billing privileges for the provider and supplier types identified in paragraph (d)(2) of this section is the later of—

(i) The date of filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor; or

(ii) The date that the provider or supplier first began furnishing services at a new practice location.

(2) The provider and supplier types to which paragraph (d)(1) of this section applies are as follows:

(i) Physicians.

(ii) Non-physician practitioners.

(iii) Physician organizations.

(iv) Non-physician practitioner organizations.

(v) Ambulance suppliers.

(vi) Opioid treatment programs.

(vii) Part B hospital departments.

(viii) Clinical Laboratory Improvement Amendment labs.

(ix) Intensive cardiac rehabilitation facilities.

(x) Mammography centers.

(xi) Mass immunizers/pharmacies.

(xii) Radiation therapy centers.

(xiii) Home infusion therapy suppliers.

(xiv) Physical therapists.

(xv) Occupational therapists.

(xvi) Speech language pathologists.

■ 5. Section 424.521 is amended by revising the section heading and paragraph (a) to read as follows:

§ 424.521 Request for payment by certain provider and supplier types.

(a) *Request for payment by certain provider and supplier types.* (1) The providers and suppliers identified in paragraph (a)(2) of this section may retrospectively bill for services when the provider or supplier has met all program requirements (including State licensure requirements), and services were provided at the enrolled practice location for up to—

(i) Thirty days prior to their effective date if circumstances precluded enrollment in advance of providing services to Medicare beneficiaries; or

(ii) Ninety days prior to their effective date if a Presidentially-declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (Stafford Act) precluded enrollment in advance of providing services to Medicare beneficiaries.

(2) The provider and supplier types to which paragraph (a)(1) of this section applies are as follows:

(i) Physicians.

(ii) Non-physician practitioners.

(iii) Physician organizations.

(iv) Non-physician practitioner organizations.

(v) Ambulance suppliers.

(vi) Opioid treatment programs.

(vii) Part B hospital departments.

(viii) Clinical Laboratory Improvement Amendment labs.

(ix) Intensive cardiac rehabilitation facilities.

(x) Mammography centers.

(xi) Mass immunizers/pharmacies.

(xii) Radiation therapy centers.

(xiii) Home infusion therapy suppliers.

(xiv) Physical therapists.

(xv) Occupational therapists.

(xvi) Speech language pathologists.

* * * * *

■ 6. Section 424.522 is added to read as follows:

§ 424.522 Additional effective dates.

(a) *Reassignments.* A reassignment of benefits under § 424.80 is effective beginning 30 days before the Form CMS–855R is submitted if all applicable requirements during that period were otherwise met.

(b) *Form CMS–855O enrollment.* The effective date of a Form CMS–855O enrollment is the date on which the Medicare contractor received the Form CMS–855O application if all other requirements are met.

■ 7. Section 424.525 is amended—

■ a. By revising the section heading and paragraph (a)(1);

■ b. In paragraphs (a)(2) and (3) and (b) by removing the phrase ''prospective provider'' and adding the word ''provider'' in its place; and

■ c. By adding paragraph (e).

The revision and addition read as follows:

§ 424.525 Rejection of a provider's or supplier's application for Medicare enrollment.

(a) * * *

(1) The provider or supplier fails to furnish complete information on the provider/supplier enrollment application within 30 calendar days from the date of the Medicare contractor's request for the missing information. This includes the following situations:

(i) The application is missing data required by CMS or the Medicare contractor to process the application (such as, but not limited to, names, Social Security Number, contact information, and practice location information).

(ii) The application is unsigned or undated.

(iii) The application contains a copied or stamped signature.

(iv) The application is signed more than 120 days prior to the date on which the Medicare contractor received the application.

(v) The application is signed by a person unauthorized to do so under this subpart.

(vi) For paper applications, the required certification statement is missing.

(vii) The paper application is completed in pencil.

(viii) The application is submitted via fax or e-mail when the provider or supplier was not otherwise permitted to do so.

(ix) The provider or supplier failed to submit all of the forms needed to process a Form CMS–855 reassignment package within 30 days of receipt.

(x) The provider or supplier submitted the incorrect Form CMS–855 application.

* * * * *

(e) *Applicability.* Except as otherwise specified in the applicable reason for rejection under paragraph (a) of this section, this section applies to all CMS Medicare provider enrollment application submissions, including, but not limited to, the following:

(1) Form CMS–855 initial applications, change of information requests, changes of ownership, revalidations, and reactivations.

(2) Form CMS–588 (Electronic Funds Transfer (EFT) Authorization Agreement) submissions.

(3) Form CMS–20134 (Medicare Enrollment Application; Medicare Diabetes Prevention Program (MDPP) Suppliers) submissions.

(4) Any electronic or successor versions of the forms identified in

paragraphs (e)(1) through (3) of this section.

■ 8 Section 424.526 is added to read as follows:

§ 424.526 Return of a provider's or supplier's enrollment application.

(a) *Reasons for return.* CMS may return a provider's or supplier's enrollment application for any of the following reasons:

(1) The provider or supplier sent its paper Form CMS–855, Form CMS–588, or Form CMS–20134 application to the incorrect Medicare contractor for processing.

(2) The Medicare contractor received the application more than 60 days prior to the effective date listed on the application. (This paragraph (a)(2) does not apply to providers and suppliers submitting a Form CMS–855A application, ambulatory surgical centers, or portable x-ray suppliers.)

(3) The seller or buyer in a change of ownership submitted its Form CMS–855A or Form CMS–855B application more than 90 days prior to the anticipated date of the sale.

(4) The Medicare contractor received an initial application more than 180 days prior to the effective date listed on the application from a provider or supplier submitting a Form CMS–855A application, an ambulatory surgical center, or a portable x-ray supplier.

(5) The Medicare contractor confirms that the provider or supplier submitted an initial enrollment application prior to the expiration of the time period in which it is entitled to appeal the denial of its previously submitted application.

(6) The provider or supplier submitted an initial enrollment application prior to the expiration of their existing re-enrollment bar under § 424.535 or reapplication bar under § 424.530(f).

(7) The application is not needed for (or is inapplicable to) the transaction in question.

(8) The provider or supplier submitted a revalidation application more than 7 months prior to the provider's or supplier's revalidation due date.

(9) A Medicare Diabetes Prevention Program supplier submitted an application with a coach start date more than 30 days in the future.

(10) The provider or supplier requests that their application be withdrawn prior to or during the Medicare contractor's processing thereof.

(11) The provider or supplier submits an application that is an exact duplicate of an application that has already been processed or is currently being processed or is pending processing.

(12) The provider or supplier submits a paper Form CMS–855 or Form CMS–20134 enrollment application that is outdated or has been superseded by a revised version.

(13) The provider or supplier submits a Form CMS–855A or Form CMS–855B initial application followed by a Form CMS–855A or Form CMS–855B change of ownership application. If the Medicare contractor—

(i) Has not yet made a recommendation for approval concerning the initial application, both applications may be returned.

(ii) Has made a recommendation for approval concerning the initial application, the Medicare contractor may return the change of ownership application. If, per the Medicare contractor's written request, the provider or supplier fails to submit a new initial Form CMS–855A or Form CMS–855B application containing the new owner's information within 30 days of the date of the letter, the Medicare contractor may return the originally submitted initial Form CMS–855A or Form CMS–855B application.

(b) *Appeals.* A provider or supplier is not afforded appeal rights if their application is returned under this section.

(c) *Applicability.* Except as otherwise specified in the applicable return reason under paragraph (a) of this section, this section applies to all CMS Medicare provider enrollment application submissions including, but not limited to, the following:

(1) Form CMS–855 initial applications, change of information requests, changes of ownership, revalidations, and reactivations.

(2) Form CMS–588 submissions.

(3) Form CMS–20134 submissions.

(4) Any electronic or successor versions of the forms identified in paragraphs (c)(1) through (3) of this section.

■ 9. Section 424.540 is amended—

■ a. By revising paragraph (a)(2);

■ b. By adding paragraphs (a)(4) through (8);

■ c. By revising paragraphs (b)(1) and (c); and

■ d. By adding paragraphs (d) and (e).

The revisions and additions read as follows:

§ 424.540 Deactivation of Medicare billing privileges.

(a) * * *

(2) The provider or supplier does not report a change to the information supplied on the enrollment application within the applicable time period required under this title.

* * * * *

(4) The provider or supplier is not in compliance with all enrollment requirements in this title.

(5) The provider's or supplier's practice location is non-operational or otherwise invalid.

(6) The provider or supplier is deceased.

(7) The provider or supplier is voluntarily withdrawing from Medicare.

(8) The provider is the seller in an HHA change of ownership under § 424.550(b)(1).

(b) * * *

(1) In order for a deactivated provider or supplier to reactivate its Medicare billing privileges, the provider or supplier must recertify that its enrollment information currently on file with Medicare is correct, furnish any missing information as appropriate, and be in compliance with all applicable enrollment requirements in this title.

* * * * *

(c) *Effect of deactivation.* The deactivation of Medicare billing privileges does not have any effect on a provider's or supplier's participation agreement or any conditions of participation.

(d) *Effective dates.* (1)(i) Except as provided in paragraph (d)(1)(ii) of this section, the effective date of a deactivation is the date on which the deactivation is imposed under this section.

(ii) A retroactive deactivation effective date (based on the date that the provider's or supplier's action or non-compliance occurred or commenced (as applicable)) may be imposed in the following instances:

(A) For the deactivation reasons in paragraphs (a)(2) through (4) of this section, the effective date is the date on which the provider or supplier became non-compliant.

(B) For the deactivation reason in paragraph (a)(5) of this section, the effective date is the date on which the provider's or supplier's practice location became non-operational or otherwise invalid.

(C) For the deactivation reason in paragraph (a)(6) of this section, the effective date is the date of death of the provider or supplier.

(D) For the deactivation reason in paragraph (a)(7) of this section, the effective date is the date on which the provider or supplier voluntarily withdrew from Medicare.

(E) For the deactivation reason in paragraph (a)(8) of this section, the effective date is the date of the sale.

(2) The effective date of a reactivation of billing privileges under this section is the date on which the Medicare

contractor received the provider's or supplier's reactivation submission that was processed to approval by the Medicare contractor.

(e) *Payment prohibition.* A provider or supplier may not receive payment for services or items furnished while deactivated under this section.

■ 10. Section 424.550 is amended by revising paragraph (b)(2)(i) to read as follows:

§ 424.550 Prohibitions on the sale or transfer of billing privileges.

* * * * *

(b) * * *

(2)(i) The HHA submitted two consecutive years of full cost reports since initial enrollment or the last change in majority ownership, whichever is later. For purposes of the exception in this paragraph (b)(2)(i), low utilization or no utilization cost reports do not qualify as full cost reports.

* * * * *

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

■ 11. The authority for part 483 continues to read as follows:

Authority: 42 U.S.C. 1302, 1320a–7, 1395i, 1395hh and 1396r.

■ 12. Section 483.80 is amended by revising paragraph (g) to read as follows:

§ 483.80 Infection control.

* * * * *

(g) *COVID–19 reporting.* Until December 31, 2024, with the exception of the requirements in paragraph (g)(1)(viii) of this section, the facility must do all of the following:

(1) Electronically report information about COVID–19 in a standardized format specified by the Secretary. To the extent as required by the Secretary, this report must include the following:

(i) Suspected and confirmed COVID–19 infections among residents and staff, including residents previously treated for COVID–19.

(ii) Total deaths and COVID–19 deaths among residents and staff.

(iii) Personal protective equipment and hand hygiene supplies in the facility.

(iv) Ventilator capacity and supplies in the facility.

(v) Resident beds and census.

(vi) Access to COVID–19 testing while the resident is in the facility.

(vii) Staffing shortages.

(viii) The COVID–19 vaccine status of residents and staff, including total numbers of residents and staff, numbers of residents and staff vaccinated, numbers of each dose of COVID–19 vaccine received, and COVID–19 vaccination adverse events.

(ix) Therapeutics administered to residents for treatment of COVID–19.

(2) Provide the information specified in paragraph (g)(1) of this section weekly, unless the Secretary specifies a lesser frequency, to the Centers for Disease Control and Prevention's National Healthcare Safety Network. This information will be posted publicly by CMS to support protecting the health and safety of residents, personnel, and the general public.

(3) Inform residents, their representatives, and families of those residing in facilities by 5 p.m. the next calendar day following the occurrence of either a single confirmed infection of COVID–19, or three or more residents or staff with new-onset of respiratory symptoms occurring within 72 hours of each other. This information must do all of the following:

(i) Not include personally identifiable information.

(ii) Include information on mitigating actions implemented to prevent or reduce the risk of transmission, including if normal operations of the facility will be altered.

(iii) Include any cumulative updates for residents, their representatives, and families at least weekly or by 5 p.m. the next calendar day following the subsequent occurrence of either: Each time a confirmed infection of COVID–19 is identified, or whenever three or more residents or staff with new onset of respiratory symptoms occur within 72 hours of each other.

* * * * *

PART 484—HOME HEALTH SERVICES

■ 13. The authority citation for part 484 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

§ 484.50 [Amended]

■ 14. Section 484.50 is amended in paragraph (d)(5)(i) by removing the phrase ''representative (if any), the physician(s) issuing orders'' and adding in its place the phrase ''the representative (if any), the physician(s) or allowed practitioner(s) issuing orders''.

■ 15. Section 484.55 is amended by revising paragraphs (a)(2) and (b)(3) to read as follows:

§ 484.55 Condition of participation: Comprehensive assessment of patients.

* * * * *

(a) * * *

(2) When rehabilitation therapy service (speech language pathology, physical therapy, or occupational therapy) is the only service ordered by the physician or allowed practitioner who is responsible for the home health plan of care, the initial assessment visit may be made by the appropriate rehabilitation skilled professional. For Medicare patients, an occupational therapist may complete the initial assessment when occupational therapy is ordered with another qualifying rehabilitation therapy service (speech-language pathology or physical therapy) that establishes program eligibility.

(b) * * *

(3) When physical therapy, speech-language pathology, or occupational therapy is the only service ordered by the physician or allowed practitioner, a physical therapist, speech-language pathologist, or occupational therapist may complete the comprehensive assessment, and for Medicare patients, determine eligibility for the Medicare home health benefit, including homebound status. For Medicare patients, the occupational therapist may complete the comprehensive assessment when occupational therapy is ordered with another qualifying rehabilitation therapy service (speech-language pathology or physical therapy) that establishes program eligibility.

* * * * *

■ 16. Section 484.80 is amended by:

■ a. Revising paragraph (h)(1)(i);

■ b. Redesignating paragraphs (h)(1)(ii) and (iii) as paragraphs (h)(1)(iii) and (iv), respectively;

■ c. Adding a new paragraph (h)(1)(ii); and

■ d. Revising paragraphs (h)(2) and (3).

The revisions and addition read as follows:

§ 484.80 Condition of participation: Home health aide services.

* * * * *

(h) * * *

(1)(i) If home health aide services are provided to a patient who is receiving skilled nursing, physical or occupational therapy, or speech language pathology services—

(A) A registered nurse or other appropriate skilled professional who is familiar with the patient, the patient's plan of care, and the written patient care instructions described in paragraph (g) of this section, must complete a supervisory assessment of the aide services being provided no less frequently than every 14 days; and

(B) The home health aide does not need to be present during the supervisory assessment described in paragraph (h)(1)(i)(A) of this section.

(ii) The supervisory assessment must be completed onsite (that is, an in person visit), or on the rare occasion by

using two-way audio-video telecommunications technology that allows for real-time interaction between the registered nurse (or other appropriate skilled professional) and the patient, not to exceed 1 virtual supervisory assessment per patient in a 60-day episode.

* * * * *

(2)(i) If home health aide services are provided to a patient who is not receiving skilled nursing care, physical or occupational therapy, or speech language pathology services—

(A) The registered nurse must make an onsite, in person visit every 60 days to assess the quality of care and services provided by the home health aide and to ensure that services meet the patient's needs; and

(B) The home health aide does not need to be present during this visit.

(ii) Semi-annually the registered nurse must make an on-site visit to the location where each patient is receiving care in order to observe and assess each home health aide while he or she is performing non-skilled care.

(3) If a deficiency in aide services is verified by the registered nurse or other appropriate skilled professional during an on-site visit, then the agency must conduct, and the home health aide must complete, retraining and a competency evaluation for the deficient and all related skills.

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■ 17. The heading for subpart F is revised to read as follows:

Subpart F—Home Health Value-Based Purchasing (HHVBP) Models

■ 18. Add an undesignated center heading before § 484.300 to read as follows:

HHVBP Model Components for Competing Home Health Agencies Within State Boundaries for the Original HHVBP Model

* * * * *

■ 19. Section 484.305 is amended by revising the definition of ''Applicable percent'' to read as follows:

§ 484.305 Definitions.

* * * * *

Applicable percent means a maximum upward or downward adjustment for a given performance year, not to exceed the following:

(1) For CY 2018, 3-percent.

(2) For CY 2019, 5-percent.

(3) For CY 2020, 6-percent.

(4) For CY 2021, 7-percent.

* * * * *

§ 484.315 [Amended]

■ 20. Section 484.315 is amended by removing paragraph (d).

■ 21. Add an undesignated center heading and §§ 484.340 through 484.375 to read as follows:

HHVBP Model Components for Competing Home Health Agencies (HHAs) for HHVBP Model Expansion—Effective January 1, 2022

Sec.

HHVBP Model Components for Competing Home Health Agencies (HHAs) for HHVBP Model Expansion—Effective January 1, 2022

§ 484.340 Basis and scope of this subpart.

This subpart is established under sections 1102, 1115A, and 1871 of the Act (42 U.S.C. 1315a), which authorizes the Secretary to issue regulations to operate the Medicare program and test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to individuals under Titles XVIII and XIX of the Act.

§ 484.345 Definitions.

As used in this subpart—

Achievement threshold means the median (50th percentile) of home health agency performance on a measure during a baseline year, calculated separately for the larger- and smaller-volume cohorts.

Applicable measure means a measure (OASIS- and claims-based measures) or a measure component (HHCAHPS survey measure) for which a competing HHA has provided a minimum of one of the following:

(1) Twenty home health episodes of care per year for each of the OASIS-based measures.

(2) Twenty home health episodes of care per year for each of the claims-based measures.

(3) Forty completed surveys for each component included in the HHCAHPS survey measure.

Applicable percent means a maximum upward or downward adjustment for a given payment year based on the applicable performance year, not to exceed 5 percent.

Baseline year means the year against which measure performance in a performance year will be compared.

Benchmark refers to the mean of the top decile of Medicare-certified HHA performance on the specified quality measure during the baseline year, calculated separately for the larger- and smaller-volume cohorts.

Competing home health agency or agencies (HHA or HHAs) means an agency or agencies that meet the following:

(1) Has or have a current Medicare certification; and

(2) Is or are being paid by CMS for home health care services.

Home health prospective payment system (HH PPS) refers to the basis of payment for HHAs as set forth in §§ 484.200 through 484.245.

Improvement threshold means an individual competing HHA's performance level on a measure during the baseline year.

Larger-volume cohort means the group of competing HHAs that are participating in the HHCAHPS survey in accordance with § 484.245.

Linear exchange function is the means to translate a competing HHA's Total Performance Score into a value-based payment adjustment percentage.

Nationwide means the 50 States and the U.S. territories, including the District of Columbia.

Payment adjustment means the amount by which a competing HHA's final claim payment amount under the HH PPS is changed in accordance with the methodology described in § 484.370.

Payment year means the calendar year in which the applicable percent, a maximum upward or downward adjustment, applies.

Performance year means the calendar year during which data are collected for the purpose of calculating a competing HHA's performance on measures.

Pre-Implementation year means CY 2022.

Smaller-volume cohort means the group of competing HHAs that are exempt from participation in the HHCAHPS survey in accordance with § 484.245.

Total Performance Score (TPS) means the numeric score ranging from 0 to 100

awarded to each competing HHA based on its performance under the expanded HHVBP Model.

§ 484.350 Applicability of the Expanded Home Health Value-Based Purchasing (HHVBP) Model.

(a) *General rule.* The expanded HHVBP Model applies to all Medicare-certified HHAs nationwide.

(b) *New HHAs.* For an HHA that is certified by Medicare on or after January 1, 2019, the baseline year is the first full calendar year of services beginning after the date of Medicare certification, with the exception of HHAs certified on January 1, 2019 through December 31, 2019, for which the baseline year is calendar year (CY) 2021, and the first performance year is the first full calendar year (beginning with CY 2023) following the baseline year.

§ 484.355 Data reporting for measures and evaluation and the public reporting of model data under the expanded Home Health Value-Based Purchasing (HHVBP) Model.

(a) Competing home health agencies will be evaluated using a set of quality measures.

(1) *Data submission.* Except as provided in paragraph (d) of this section, for the pre-implementation year and each performance year, an HHA must submit all of the following to CMS in the form and manner, and at a time, specified by CMS:

(i) Data on measures specified under the expanded HHVBP model.

(ii) HHCAHPS survey data. For purposes of HHCAHPS Survey data submission, the following additional requirements apply:

(A) *Survey requirements.* An HHA must contract with an approved, independent HHCAHPS survey vendor to administer the HHCAHPS survey on its behalf.

(B) *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.

(C) *Definition of survey of individuals.* For the HHCAHPS survey, 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.

(D) *Administration of the HHCAHPS survey.* 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 approved by CMS as HHCAHPS survey vendors.

(E) *Compliance by HHCAHPS survey vendors.* Approved HHCAHPS survey vendors must fully comply with all HHCAHPS survey oversight activities, including allowing CMS and its HHCAHPS survey team to perform site visits at the vendors' company locations.

(F) *Patient count exemption.* An HHA that has less than 60 eligible unique HHCAHPS survey patients must annually submit to CMS its total HHCAHPS survey patient count to be exempt from the HHCAHPS survey reporting requirements for a calendar year.

(2) [Reserved]

(b) Competing home health agencies are required to collect and report such information as the Secretary determines is necessary for purposes of monitoring and evaluating the expanded HHVBP Model under section 1115A(b)(4) of the Act (42 U.S.C. 1315a).

(c) For each performance year of the expanded HHVBP Model, CMS publicly reports applicable measure benchmarks and achievement thresholds for each cohort as well as all of the following for each competing HHA that qualified for a payment adjustment for the applicable performance year on a CMS website:

(1) The Total Performance Score.

(2) The percentile ranking of the Total Performance Score.

(3) The payment adjustment percentage.

(4) Applicable measure results and improvement thresholds.

(d) CMS may grant an exception with respect to quality data reporting requirements in the event of extraordinary circumstances beyond the control of the HHA. CMS may grant an exception as follows:

(1) A competing HHA that wishes to request an exception with respect to quality data reporting requirements must submit its request to CMS within 90 days of the date that the extraordinary circumstances occurred. Specific requirements for submission of a request for an exception are available on the CMS website.

(2) CMS may grant an exception to one or more HHAs that have not requested an exception if CMS determines either of the following:

(i) That a systemic problem with CMS data collection systems directly affected the ability of the HHA to submit data.

(ii) That an extraordinary circumstance has affected an entire region or locale.

§ 484.360 Calculation of the Total Performance Score.

A competing HHA's Total Performance Score for a performance year is calculated as follows:

(a) CMS awards points to the competing home health agency for performance on each of the applicable measures.

(1) CMS awards greater than or equal to 0 points and less than 10 points for achievement to each competing home health agency whose performance on a measure during the applicable performance year meets or exceeds the applicable cohort's achievement threshold but is less than the applicable cohort's benchmark for that measure.

(2) CMS awards greater than 0 but less than 9 points for improvement to each competing home health agency whose performance on a measure during the applicable performance year exceeds the improvement threshold but is less than the applicable cohort's benchmark for that measure.

(3) CMS awards 10 points to a competing home health agency whose performance on a measure during the applicable performance year meets or exceeds the applicable cohort's benchmark for that measure.

(b) For all performance years, CMS calculates the weighted sum of points awarded for each applicable measure within each category of measures (OASIS-based, claims-based, and HHCAHPS Survey-based) weighted at 35 percent for the OASIS-based measure category, 35 percent for the claims-based measure category, and 30 percent for the HHCAHPS survey measure category when all three measure categories are reported, to calculate a value worth 100 percent of the Total Performance Score.

(1) Where a single measure category is not included in the calculation of the Total Performance Score for an individual HHA, due to insufficient volume for all of the measures in the category, the remaining measure categories are reweighted such that the proportional contribution of each remaining measure category is consistent with the weights assigned when all three measure categories are available. Where two measure categories are not included in the calculation of the Total Performance Score for an individual HHA, due to insufficient volume for all measures in those measure categories, the remaining measure category is weighted at 100 percent of the Total Performance Score.

(2) When one or more, but not all, of the measures in a measure category are not included in the calculation of the Total Performance Score for an

individual HHA, due to insufficient volume for at least one measure in the category, the remaining measures in the category are reweighted such that the proportional contribution of each remaining measure is consistent with the weights assigned when all measures within the category are available.

(c) The sum of the weight-adjusted points awarded to a competing HHA for each applicable measure is the competing HHA's Total Performance Score for the calendar year. A competing HHA must have a minimum of five applicable measures to receive a Total Performance Score.

§ 484.365 Payments for home health services under the Expanded Home Health Value–Based Purchasing (HHVBP) Model.

CMS determines a payment adjustment up to the applicable percent, upward or downward, under the expanded HHVBP Model for each competing HHA based on the agency's Total Performance Score using a linear exchange function that includes all other HHAs in its cohort that received a Total Performance Score for the applicable performance year. Payment adjustments made under the expanded HHVBP Model are calculated as a percentage of otherwise-applicable payments for home health services provided under section 1895 of the Act (42 U.S.C. 1395fff).

§ 484.370 Process for determining and applying the value-based payment adjustment under the Expanded Home Health Value-Based Purchasing (HHVBP) Model.

(a) *General.* Competing home health agencies are ranked within the larger-volume and smaller-volume cohorts nationwide based on the performance standards in this part that apply to the expanded HHVBP Model for the baseline year, and CMS makes value-based payment adjustments to the competing HHAs as specified in this section.

(b) *Calculation of the value-based payment adjustment amount.* The value-based payment adjustment amount is calculated by multiplying the home health prospective payment final claim payment amount as calculated in accordance with § 484.205 by the payment adjustment percentage.

(c) *Calculation of the payment adjustment percentage.* The payment adjustment percentage is calculated as the product of all of the following:

(1) The applicable percent as defined in § 484.345.

(2) The competing HHA's Total Performance Score divided by 100.

(3) The linear exchange function slope.

§ 484.375 Appeals process for the Expanded Home Health Value-Based Purchasing (HHVBP) Model.

(a) *Requests for recalculation*—(1) *Matters for recalculation.* Subject to the limitations on judicial and administrative review under section 1115A of the Act, a HHA may submit a request for recalculation under this section if it wishes to dispute the calculation of the following:

(i) Interim performance scores.

(ii) Annual total performance scores.

(iii) Application of the formula to calculate annual payment adjustment percentages.

(2) *Time for filing a request for recalculation.* A recalculation request must be submitted in writing within 15 calendar days after CMS posts the HHA-specific information on the CMS website, in a time and manner specified by CMS.

(3) *Content of request.* (i) The provider's name, address associated with the services delivered, and CMS Certification Number (CCN).

(ii) The basis for requesting recalculation to include the specific data that the HHA believes is inaccurate or the calculation the HHA believes is incorrect.

(iii) Contact information for a person at the HHA with whom CMS or its agent can communicate about this request, including name, email address, telephone number, and mailing address (must include physical address, not just a post office box).

(iv) The HHA may include in the request for recalculation additional documentary evidence that CMS should consider. Such documents may not include data that was to have been filed by the applicable data submission deadline, but may include evidence of timely submission.

(4) *Scope of review for recalculation.* In conducting the recalculation, CMS reviews the applicable measures and performance scores, the evidence and findings upon which the determination was based, and any additional documentary evidence submitted by the HHA. CMS may also review any other evidence it believes to be relevant to the recalculation.

(5) *Recalculation decision.* CMS issues a written notification of findings. A recalculation decision is subject to the request for reconsideration process in accordance with paragraph (b) of this section.

(b) *Requests for reconsideration*—(1) *Matters for reconsideration.* A home health agency may request reconsideration of the recalculation of its annual total performance score and payment adjustment percentage following a decision on the HHA's recalculation request submitted under paragraph (a) of this section, or the decision to deny the recalculation request submitted under paragraph (a) of this section.

(2) *Time for filing a request for reconsideration.* The request for reconsideration must be submitted via the CMS website within 15 calendar days from CMS' notification to the HHA contact of the outcome of the recalculation process.

(3) *Content of request.* (i) The name of the HHA, address associated with the services delivered, and CMS Certification Number (CCN).

(ii) The basis for requesting reconsideration to include the specific data that the HHA believes is inaccurate or the calculation the HHA believes is incorrect.

(iii) Contact information for a person at the HHA with whom CMS or its agent can communicate about this request, including name, email address, telephone number, and mailing address (must include physical address, not just a post office box).

(iv) The HHA may include in the request for reconsideration additional documentary evidence that CMS should consider. The documents may not include data that was to have been filed by the applicable data submission deadline, but may include evidence of timely submission.

(4) *Scope of review for reconsideration.* In conducting the reconsideration review, CMS reviews the applicable measures and performance scores, the evidence and findings upon which the determination was based, and any additional documentary evidence submitted by the HHA. CMS may also review any other evidence it believes to be relevant to the reconsideration. The HHA must prove its case by a preponderance of the evidence with respect to issues of fact.

(5) *Reconsideration decision.* CMS reconsideration officials issue a written final determination.

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

■ 22. The authority citation for part 488 continues to read as follows:

Authority: 42 U.S.C 1302 and 1395hh.

■ 23. Section 488.2 is amended by adding provision ''1822'' in numerical order to read as follows:

§ 488.2 Statutory basis.

* * * * *

1822—Hospice Program survey and enforcement procedures.

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■ 24. Section 488.5 is amended by adding paragraph (a)(4)(x) to read as follows:

§ 488.5 Application and re-application procedures for national accrediting organizations.

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(x) For accrediting organizations applying for approval or re-approval of CMS–approved hospice programs, a statement acknowledging that the accrediting organization (AO) will include a statement of deficiencies (that is, the Form CMS–2567 or a successor form) to document findings of the hospice Medicare conditions of participation in accordance with section 1822(a)(2)(A)(ii) of the Act and will submit such in a manner specified by CMS.

* * * * *

■ 25. Section 488.7 is amended by revising paragraph (b) and adding paragraph (c) to read as follows.

§ 488.7 Release and use of accreditation surveys.

* * * * *

(b) With the exception of home health agency and hospice program surveys, general disclosure of an accrediting organization's survey information is prohibited under section 1865(b) of the Act. CMS may publicly disclose an accreditation survey and information related to the survey, upon written request, to the extent that the accreditation survey and survey information are related to an enforcement action taken by CMS.

(c) CMS posts inspection reports from a State or local survey agency or accrediting organization conducted on or after October 1, 2022, for hospice programs, including copies of a hospice program's survey deficiencies, and enforcement actions (for example, involuntary terminations) taken as a result of such surveys, on its public website in a manner that is prominent, easily accessible, readily understandable, and searchable for the general public and allows for timely updates.

■ 26. Section 488.28 is amended by revising the section heading to read as follows:

§ 488.28 Providers or suppliers, other than SNFs, NFs, HHAs, and Hospice programs with deficiencies.

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■ 27. Add subparts M and N to read as follows:

Subpart M—Survey and Certification of Hospice Programs

Sec.
488.1100 Basis and scope.
488.1105 Definitions.
488.1110 Hospice program: surveys and hotline.
488.1115 Surveyor qualifications and prohibition of conflicts of interest.
488.1120 Survey teams.
488.1125 Consistency of survey results.

Subpart N—Enforcement Remedies for Hospice Programs With Deficiencies

Sec.
488.1200 Statutory basis.
488.1205 Definitions.
488.1210 General provisions.
488.1215 Factors to be considered in selecting remedies.
488.1220 Available remedies.
488.1225 Action when deficiencies pose immediate jeopardy.
488.1230 Action when deficiencies are at the condition-level but do not pose immediate jeopardy.
488.1235 Temporary management.
488.1240 Suspension of payment for all new patient admissions.
488.1245 Civil money penalties.
488.1250 Directed plan of correction.
488.1255 Directed in-service training.
488.1260 Continuation of payments to a hospice program with deficiencies.
488.1265 Termination of provider agreement.

Subpart M—Survey and Certification of Hospice Programs

§ 488.1100 Basis and scope.

Sections 1812, 1814, 1822, 1861, 1864, and 1865 of the Act establish requirements for Hospice programs and to authorize surveys to determine whether they meet the Medicare conditions of participation.

§ 488.1105 Definitions.

As used in this subpart—

Abbreviated standard survey means a focused survey other than a standard survey that gathers information on hospice program's compliance with specific standards or conditions of participation. An abbreviated standard survey may be based on complaints received or other indicators of specific concern.

Complaint survey means a survey that is conducted to investigate substantial allegations of noncompliance as defined in § 488.1.

Condition-level deficiency means noncompliance as described in § 488.24.

Deficiency is a violation of the Act and regulations contained in part 418, subparts C and D, of this chapter, is determined as part of a survey, and can be either standard or condition-level.

Noncompliance means any deficiency found at the condition-level or standard-level.

Standard-level deficiency means noncompliance with one or more of the standards that make up each condition of participation for hospice programs.

Standard survey means a survey conducted in which the surveyor reviews the hospice program's compliance with a select number of standards or conditions of participation or both to determine the quality of care and services furnished by a hospice program.

Substantial compliance means compliance with all condition-level requirements, as determined by CMS or the State.

§ 488.1110 Hospice program: surveys and hotline.

(a) *Basic period.* Each hospice program as defined in section 1861(dd) of the Act is subject to a standard survey by an appropriate State or local survey agency, or an approved accreditation agency, as determined by the Secretary, not less frequently than once every 36 months. Additionally, a survey may be conducted as frequently as necessary to –

(1) Assure the delivery of quality hospice program services by determining whether a hospice program complies with the Act and conditions of participation; and

(2) Confirm that the hospice program has corrected deficiencies that were previously cited.

(b) *Complaints.* A standard survey, or abbreviated standard survey-

(1) Must be conducted of a hospice program when complaints against the hospice program are reported to CMS, the State, or local agency.

(2) The State, or local agency is responsible for maintaining a toll-free hotline to collect, maintain, and continually update information on Medicare-participating hospice programs including significant deficiencies found regarding patient care, corrective actions, and remedy activity during its most recent survey, and to receive complaints and answer questions about hospice programs. The State or local agency is also responsible for maintaining a unit for investigating such complaints.

§ 488.1115 Surveyor qualifications and prohibition of conflicts of interest.

(a) *Minimum qualifications.* Surveyors must meet minimum qualifications prescribed by CMS. Before any accrediting organization, State or Federal surveyor may serve on a hospice survey team (except as a trainee), he/she must have successfully completed the relevant CMS–sponsored Basic Hospice Surveyor Training

Course, and additional training as specified by CMS.

(b) *Disqualifications.* Surveyor(s) must disclose actual or perceived conflicts of interest prior to participating in a hospice program survey and be provided the opportunity to recuse themselves as necessary. Any of the following circumstances disqualifies a surveyor from surveying a particular hospice program:

(1) The surveyor currently serves, or, within the previous 2 years has served, with the hospice program to be surveyed as one of the following:

(i) A direct employee.

(ii) An employment agency staff at the hospice program.

(iii) An officer, consultant, or agent for the hospice program to be surveyed concerning compliance with conditions of participation specified in or in accordance with sections 1861(dd) of the Act.

(2) The surveyor has a financial interest or an ownership interest in the hospice program to be surveyed.

(3) The surveyor has an immediate family member, as defined at § 411.351 of this chapter, who has a financial interest or an ownership interest with the hospice program to be surveyed.

(4) The surveyor has an immediate family member, as defined at § 411.351 of this chapter, who is a patient of the hospice program to be surveyed.

§ 488.1120 Survey teams.

Standard surveys conducted by more than one surveyor must be conducted by a multidisciplinary team of professionals typically involved in hospice care and identified as professionals providing hospice core services at § 418.64 of this chapter. The multidisciplinary team must include a registered nurse. Surveys conducted by a single surveyor, must be conducted by a registered nurse.

§ 488.1125 Consistency of survey results.

A survey agency or accrediting organization must provide a corrective action plan to CMS for any disparity rates that are greater than the threshold established by CMS.

Subpart N—Enforcement Remedies for Hospice Programs With Deficiencies

§ 488.1200 Statutory basis.

Section 1822 of the Act authorizes the Secretary to take actions to remove and correct deficiencies in a hospice program through an enforcement remedy or termination or both. This section specifies that these remedies are in addition to any others available under State or Federal law, and, except for the final determination of civil money penalties, are imposed prior to the conduct of a hearing.

§ 488.1205 Definitions.

As used in this subpart—

Directed plan of correction means CMS or the temporary manager (with CMS/survey agency (SA) approval) may direct the hospice program to take specific corrective action to achieve specific outcomes within specific timeframes.

Immediate jeopardy means a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a patient(s).

New admission means an individual who becomes a patient or is readmitted to the hospice program on or after the effective date of a suspension of payment remedy.

Per instance means a single event of noncompliance identified and corrected during a survey, for which the statute authorizes CMS to impose a remedy.

Plan of correction means a plan developed by the hospice program and approved by CMS that is the hospice program's written response to survey findings detailing corrective actions to cited deficiencies and specifies the date by which those deficiencies will be corrected.

Repeat deficiency means a condition-level deficiency that is cited on the current survey and is substantially the same as or similar to, a finding of a standard-level or condition-level deficiency cited on the most recent previous standard survey or on any intervening survey since the most recent standard survey. Repeated non-compliance is not on the basis that the exact regulation (that is, tag number) for the deficiency was repeated.

Temporary management means the temporary appointment by CMS or by a CMS authorized agent, of a substitute manager or administrator. The hospice program's governing body must ensure that the temporary manager has authority to hire, terminate or reassign staff, obligate funds, alter procedures, and manage the hospice program to correct deficiencies identified in the hospice program's operation.

§ 488.1210 General provisions.

(a) *Purpose of remedies.* The purpose of remedies is to ensure prompt compliance with program requirements in order to protect the health and safety of individuals under the care of a hospice program.

(b) *Basis for imposition of remedies.* When CMS chooses to apply one or more remedies specified in § 488.1220, the remedies are applied on the basis of noncompliance with one or more conditions of participation and may be based on failure to correct previous deficiency findings as evidenced by repeat condition-level deficiencies.

(c) *Number of remedies.* CMS may impose one or more remedies specified in § 488.1220 for each condition-level deficiency constituting noncompliance.

(d) *Plan of correction requirement.* Regardless of which remedy is applied, a non-compliant hospice program must submit a plan of correction for approval by CMS or the State Survey Agency.

(e) *Notification requirements*—(1) *Notice of intent.* CMS provides written notification to the hospice program of the intent to impose the remedy, the statutory basis for the remedy, the nature of the noncompliance, the proposed effective date of the sanction, and the appeal rights. For civil money penalties, the notice of intent would also include the amount being imposed.

(2) *Final notice.* With respect to civil money penalties, CMS provides a written final notice to the hospice program, as set forth in § 488.1245(e), once the administrative determination is final.

(3) *Date of enforcement action.* The notice periods specified in §§ 488.1225(b) and 488.1230(b) begin the day after the hospice receives the notice of intent.

(f) *Appeals.* (1) The hospice program may request a hearing on a determination of noncompliance leading to the imposition of a remedy, including termination of the provider agreement, under the provisions of part 498 of this chapter.

(2) A pending hearing does not delay the effective date of a remedy, including termination, against a hospice program. Remedies continue to be in effect regardless of the timing of any appeals proceedings.

§ 488.1215 Factors to be considered in selecting remedies.

CMS bases its choice of remedy or remedies on consideration of one or more factors that include, but are not limited to, the following:

(a) The extent to which the deficiencies pose immediate jeopardy to patient health and safety.

(b) The nature, incidence, manner, degree, and duration of the deficiencies or noncompliance.

(c) The presence of repeat deficiencies, the hospice program's overall compliance history and any history of repeat deficiencies at either the parent hospice program or any of its multiple locations.

(d) The extent to which the deficiencies are directly related to a failure to provide quality patient care.

(e) The extent to which the hospice program is part of a larger organization with performance problems.

(f) An indication of any system-wide failure to provide quality care.

§ 488.1220 Available remedies.

The following enforcement remedies are available instead of, or in addition to, termination of the hospice program's provider agreement under § 489.53 of this chapter, for a period not to exceed 6 months:

(a) Civil money penalties.

(b) Suspension of payment for all new patient admissions.

(c) Temporary management of the hospice program.

(d) Directed plan of correction.

(e) Directed in-service training.

§ 488.1225 Action when deficiencies pose immediate jeopardy.

(a) *Immediate jeopardy.* If there is immediate jeopardy to the hospice program's patient health or safety, the following rules apply:

(1) CMS immediately terminates the hospice program provider agreement in accordance with § 489.53 of this chapter.

(2) CMS terminates the hospice program provider agreement no later than 23 calendar days from the last day of the survey, if the immediate jeopardy has not been removed by the hospice program.

(3) In addition to a termination, CMS may impose one or more enforcement remedies, as appropriate.

(b) *2-calendar day notice.* Except for civil money penalties, for all remedies specified in § 488.1220 imposed when there is immediate jeopardy, notice must be given at least 2 calendar days before the effective date of the enforcement action. The requirements of the notice are set forth in § 488.1210(e).

(c) *Transfer of care.* A hospice program, if its provider agreement is terminated, is responsible for providing information, assistance, and arrangements necessary for the proper and safe transfer of patients to another local hospice program within 30 calendar days of termination.

§ 488.1230 Action when deficiencies are at the condition-level but do not pose immediate jeopardy.

(a) *Noncompliance with conditions of participation.* If the hospice program is no longer in compliance with the conditions of participation, either because the condition-level deficiency or deficiencies substantially limit the provider's capacity to furnish adequate care but do not pose immediate jeopardy, or the hospice program has repeat condition-level deficiencies based on the hospice program's failure to correct and sustain compliance, CMS does either of the following.

(1) Terminates the hospice program's provider agreement.

(2) Imposes one or more enforcement remedies set forth in § 488.1220(a) through (e) in lieu of termination, for a period not to exceed 6 months.

(b) *15-calendar day notice.* Except for civil money penalties, for all remedies specified in § 488.1220 imposed when there is no immediate jeopardy, notice must be given at least 15 calendar days before the effective date of the enforcement action. The requirements of the notice are set forth in § 488.1210(e).

(c) *Not meeting criteria for continuation of payment.* If a hospice program does not meet the criteria for continuation of payment under § 488.1260(a), CMS terminates the hospice program's provider agreement in accordance with § 488.1265.

(d) *Termination timeframe when there is no immediate jeopardy.* CMS terminates a hospice program within 6 months of the last day of the survey, if the hospice program is not in compliance with the conditions of participation, and the terms of the plan of correction have not been met.

(e) *Transfer of care.* A hospice program, if its provider agreement terminated, is responsible for providing information, assistance, and arrangements necessary for the proper and safe transfer of patients to another local hospice program within 30 calendar days of termination. The State must assist the hospice program in the safe and orderly transfer of care and services for the patients to another local hospice program.

§ 488.1235 Temporary management.

(a) *Application.* CMS may impose temporary management of a hospice program if it determines that a hospice program has a condition-level deficiency and CMS determines that management limitations or the deficiencies are likely to impair the hospice program's ability to correct the noncompliance and return the hospice program to compliance with all of the conditions of participation within the timeframe required.

(b) *Procedures*—(1) *Notice of intent.* Before imposing the remedy in paragraph (a) of this section, CMS notifies the hospice program in accordance with § 488.1210(e) that a temporary manager is being appointed.

(2) *Termination.* If the hospice program fails to relinquish authority and control to the temporary manager, CMS terminates the hospice program's provider agreement in accordance with § 488.1265.

(c) *Duration and effect of remedy.* Temporary management continues until one of the following occur:

(1) CMS determines that the hospice program has achieved substantial compliance and has the management capability to ensure continued compliance with all the conditions of participation.

(2) CMS terminates the provider agreement.

(3) The hospice program resumes management control without CMS approval. In this case, CMS initiates termination of the provider agreement and may impose additional remedies.

(4) Temporary management will not exceed a period of 6 months from the date of the survey identifying noncompliance.

(d) *Payment of salary.* (1) The temporary manager's salary must meet the following:

(i) Is paid directly by the hospice program while the temporary manager is assigned to that hospice program.

(ii) Must be at least equivalent to the sum of the following:

(A) The prevailing salary paid by providers for positions of this type in what the State considers to be the hospice program's geographic area (prevailing salary based on the Bureau of Labor Statistics, National Occupational Employment and Wage Estimates).

(B) Any additional costs that would have reasonably been incurred by the hospice program if such person had been in an employment relationship.

(C) Any other costs incurred by such a person in furnishing services under such an arrangement or as otherwise set by the State.

(2) A hospice program's failure to pay the salary and other costs of the temporary manager described in paragraph (d)(1) of this section is considered a failure to relinquish authority and control to temporary management.

§ 488.1240 Suspension of payment for all new patient admissions.

(a) *Application.* (1) CMS may suspend payment for all new admissions to a hospice program on or after the date on which the Secretary determines that remedies should be imposed.

(2) CMS considers the remedy in paragraph (a)(1) of this section for any deficiency related to poor patient care outcomes, regardless of whether the deficiency poses immediate jeopardy.

(b) *Procedures*—(1) *Notice of intent.* (i) Before suspending payments for all

new admissions, CMS provides the hospice program notice of the suspension of payment in accordance with § 488.1210(e).

(ii) The hospice program may not charge a newly admitted hospice patient who is a Medicare beneficiary for services for which Medicare payment is suspended unless the hospice program can show that, before initiating care, it gave the patient or his or her representative oral and written notice of the suspension of Medicare payment in a language and manner that the beneficiary or representative can understand.

(2) *Restriction.* (i) The suspension of payment for all new admissions remedy may be imposed anytime a hospice program is found to be out of substantial compliance with the conditions of participation.

(ii) The suspension of payment for all new admissions remains in place until CMS determines that the hospice program has achieved substantial compliance with the conditions of participation or is terminated, as determined by CMS.

(3) *Resumption of payments.* Payments for all new admissions to the hospice program resume prospectively on the date that CMS determines that the hospice program has achieved substantial compliance with the conditions of participation.

(c) *Duration and effect of remedy.* The remedy in paragraph (a) of this section ends when any of the following occur—

(1) CMS determines that the hospice program has achieved substantial compliance with all of the conditions of participation.

(2) When the hospice program is terminated or CMS determines that the hospice program is not in compliance with the conditions of participation at a maximum of 6 months from the date of the survey identifying the noncompliance.

§ 488.1245 Civil money penalties.

(a) *Application.* (1) CMS may impose a civil money penalty against a hospice program for either the number of days the hospice program is not in compliance with one or more conditions of participation or for each instance that a hospice program is not in compliance, regardless of whether the hospice program's deficiencies pose immediate jeopardy.

(2) CMS may impose a civil money penalty for the number of days of immediate jeopardy.

(3) A per-day and a per-instance civil money penalty (CMP) may not be imposed simultaneously for the same deficiency in conjunction with a survey.

(4) CMS may impose a civil money penalty for the number of days of noncompliance since the last standard survey, including the number of days of immediate jeopardy.

(b) *Amount of penalty*—(1) *Factors considered.* CMS takes into account the following factors in determining the amount of the penalty:

(i) The factors set out at § 488.1215.

(ii) The size of a hospice program and its resources.

(iii) Evidence that the hospice program has a built-in, self-regulating quality assessment and performance improvement system to provide proper care, prevent poor outcomes, control patient injury, enhance quality, promote safety, and avoid risks to patients on a sustainable basis that indicates the ability to meet the conditions of participation and to ensure patient health and safety.

(2) *Adjustments to penalties.* Based on revisit survey findings, adjustments to penalties may be made after a review of the provider's attempted correction of deficiencies.

(i) CMS may increase a CMP in increments based on a hospice program's inability or failure to correct deficiencies, the presence of a system-wide failure in the provision of quality care, or a determination of immediate jeopardy with actual harm versus immediate jeopardy with potential for harm.

(ii) CMS may also decrease a CMP in increments to the extent that it finds, in accordance with a revisit, that substantial and sustainable improvements have been implemented even though the hospice program is not yet in compliance with the conditions of participation.

(iii) No penalty assessment exceeds $10,000, as adjusted annually under 45 CFR part 102, for each day a hospice program is not in substantial compliance with one or more conditions of participation.

(3) *Upper range of penalty.* Penalties in the upper range of $8,500 to $10,000 per day, as adjusted annually under 45 CFR part 102, are imposed for a condition-level deficiency that is immediate jeopardy. The penalty in this range continues until substantial compliance can be determined based on a revisit survey.

(i) $10,000, as adjusted annually under 45 CFR part 102, per day for a deficiency or deficiencies that are immediate jeopardy and that result in actual harm.

(ii) $9,000, as adjusted annually under 45 CFR part 102, per day for a deficiency or deficiencies that are immediate jeopardy and that result in a potential for harm.

(iii) $8,500, as adjusted annually under 45 CFR part 102, per day for a deficiency based on an isolated incident in violation of established hospice policy.

(4) *Middle range of penalty.* Penalties in the range of $1,500 up to $8,500, as adjusted annually under 45 CFR part 102, per day of noncompliance are imposed for a repeat or condition-level deficiency or both that does not constitute immediate jeopardy but is directly related to poor quality patient care outcomes.

(5) *Lower range of penalty.* Penalties in this range of $500 to $4,000, as adjusted annually under 45 CFR part 102, are imposed for a repeat or condition-level deficiency or both that does not constitute immediate jeopardy and that are related predominately to structure or process-oriented conditions rather than directly related to patient care outcomes.

(6) *Per instance penalty.* Penalty imposed per instance of noncompliance may be assessed for one or more singular events of condition-level deficiency that are identified and where the noncompliance was corrected during the onsite survey. When penalties are imposed for per instance of noncompliance, or more than one per instance of noncompliance, the penalties will be in the range of $1,000 to $10,000 per instance, not to exceed $10,000 each day of noncompliance, as adjusted annually under 45 CFR part 102.

(7) *Decreased penalty amounts.* If the immediate jeopardy situation is removed, but a condition-level deficiency exists, CMS shifts the penalty amount imposed per day from the upper range to the middle or lower range. An earnest effort to correct any systemic causes of deficiencies and sustain improvement must be evident.

(8) *Increased penalty amounts.* (i) In accordance with paragraph (b)(2) of this section, CMS increases the per day penalty amount for any condition-level deficiency or deficiencies which, after imposition of a lower-level penalty amount, become sufficiently serious to pose potential harm or immediate jeopardy.

(ii) CMS increases the per day penalty amount for deficiencies that are not corrected and found again at the time of revisit survey(s) for which a lower-level penalty amount was previously imposed.

(iii) CMS may impose a more severe amount of penalties for repeated noncompliance with the same condition-level deficiency or

uncorrected deficiencies from a prior survey.

(c) *Procedures*—(1) *Notice of intent.* CMS provides the hospice program with written notice of the intent to impose a civil money penalty in accordance with § 488.1210(e).

(2) *Appeals*—(i) *Appeals procedures.* A hospice program may request a hearing on the determination of the noncompliance that is the basis for imposition of the civil money penalty. The request must meet the requirements in § 498.40 of this chapter.

(ii) *Waiver of a hearing.* A hospice program may waive the right to a hearing, in writing, within 60 calendar days from the date of the notice imposing the civil money penalty. If a hospice program timely waives its right to a hearing, CMS reduces the penalty amount by 35 percent, and the amount is due within 15 calendar days of the hospice program agreeing in writing to waive the hearing. If the hospice program does not waive its right to a hearing in accordance to the procedures specified in this section, the civil money penalty is not reduced by 35 percent.

(d) *Accrual and duration of penalty*—(1) *Accrual of per day penalty.* (i) The per day civil money penalty may start accruing as early as the beginning of the last day of the survey that determines that the hospice program was out of compliance, as determined by CMS.

(ii) A civil money penalty for each per instance of noncompliance is imposed in a specific amount for that particular deficiency, with a maximum of $10,000 per day per hospice program.

(2) *Duration of per day penalty when there is immediate jeopardy.* (i) In the case of noncompliance that poses immediate jeopardy, CMS must terminate the provider agreement within 23 calendar days after the last day of the survey if the immediate jeopardy is not removed.

(ii) A penalty imposed per day of noncompliance will stop accruing on the day the provider agreement is terminated or the hospice program achieves substantial compliance, whichever occurs first.

(3) *Duration of penalty when there is no immediate jeopardy.* (i) In the case of noncompliance that does not pose immediate jeopardy, the daily accrual of per day civil money penalties is imposed for the days of noncompliance prior to the notice of intent specified in paragraph (c)(1) of this section and an additional period of no longer than 6 months following the last day of the survey.

(ii) If the hospice program has not achieved compliance with the conditions of participation within 6 months following the last day of the survey, CMS terminates the provider agreement. The accrual of civil money penalty stops on the day the hospice program agreement is terminated or the hospice program achieves substantial compliance, whichever is earlier.

(e) *Computation and notice of total penalty amount.* (1) When a civil money penalty is imposed on a per day basis and the hospice program achieves compliance with the conditions of participation as determined by a revisit survey, once the administrative determination is final, CMS sends a final notice to the hospice program containing of the following information:

(i) The amount of penalty assessed per day.

(ii) The total number of days of noncompliance.

(iii) The total amount due.

(iv) The due date of the penalty.

(v) The rate of interest to be assessed on any unpaid balance beginning on the due date, as provided in paragraph (f)(6) of this section.

(2) When a civil money penalty is imposed per instance of noncompliance, once the administrative determination is final, CMS sends a final notice to the hospice program containing all of the following information:

(i) The amount of the penalty that was assessed.

(ii) The total amount due.

(iii) The due date of the penalty.

(iv) The rate of interest to be assessed on any unpaid balance beginning on the due date, as provided in paragraph (f)(6) of this section.

(3) In the case of a hospice program for which the provider agreement has been involuntarily terminated, CMS sends the final notice after one of the following actions has occurred:

(i) The administrative determination is final.

(ii) The hospice program has waived its right to a hearing in accordance with paragraph (c)(2)(ii) of this section.

(iii) Time for requesting a hearing has expired and the hospice program has not requested a hearing.

(f) *Due date for payment of penalty.* A penalty is due and payable 15 calendar days from notice of the final administrative decision.

(1) Payments are due for all civil money penalties within 15 calendar days of any of the following:

(i) After a final administrative decision when the hospice program achieves substantial compliance before the final decision or the effective date of termination occurs before the final decision.

(ii) After the time to appeal has expired and the hospice program does not appeal or fails to timely appeal the initial determination.

(iii) After CMS receives a written request from the hospice program requesting to waive its right to appeal the determinations that led to the imposition of a remedy.

(iv) After the effective date of termination.

(2) A request for hearing does not delay the imposition of any penalty; it only potentially delays the collection of the final penalty amount.

(3) If a hospice program waives its right to a hearing according to paragraph (c)(2)(ii) of this section, CMS applies a 35 percent reduction to the CMP amount for any of the following:

(i) The hospice program achieved compliance with the conditions of participation before CMS received the written waiver of hearing.

(ii) The effective date of termination occurs before CMS received the written waiver of hearing.

(4) The period of noncompliance may not extend beyond 6 months from the last day of the survey.

(5) The amount of the penalty, when determined, may be deducted (offset) from any sum then or later owing by CMS or State Medicaid to the hospice program.

(6) Interest is assessed and accrues on the unpaid balance of a penalty, beginning on the due date. Interest is computed at the rate specified in § 405.378(d) of this chapter.

(g) *Review of the penalty.* When an administrative law judge finds that the basis for imposing a civil monetary penalty exists, as specified in this part, the administrative law judge, may not do any of the following:

(1) Set a penalty of zero or reduce a penalty to zero.

(2) Review the exercise of discretion by CMS to impose a civil monetary penalty.

(3) Consider any factors in reviewing the amount of the penalty other than those specified in paragraph (b) of this section.

§ 488.1250 Directed plan of correction.

(a) *Application.* CMS may impose a directed plan of correction when a hospice program—

(1) Has one or more condition-level deficiencies that warrant directing the hospice program to take specific actions; or

(2) Fails to submit an acceptable plan of correction.

(b) *Procedures.* (1) Before imposing the remedy in paragraph (a) of this section, CMS notifies the hospice program in accordance with § 488.1210(e).

(2) CMS or the temporary manager (with CMS approval) may direct the hospice program to take corrective action to achieve specific outcomes within specific timeframes.

(c) *Duration and effect of remedy.* If the hospice program fails to achieve compliance with the conditions of participation within the timeframes specified in the directed plan of correction, which may not to exceed 6 months, CMS does one of the following:

(1) May impose one or more other remedies set forth in § 488.1220.

(2) Terminates the provider agreement.

§ 488.1255 Directed in-service training.

(a) *Application.* CMS may require the staff of a hospice program to attend in-service training program(s) if CMS determines all of the following:

(1) The hospice program has condition-level deficiencies.

(2) Education is likely to correct the deficiencies.

(3) The programs are conducted by established centers of health education and training or consultants with background in education and training with Medicare hospice providers, or as deemed acceptable by CMS or the State (by review of a copy of curriculum vitas or resumes and references to determine the educator's qualifications).

(b) *Procedures*—(1) *Notice of intent.* Before imposing the remedy in paragraph (a) of this section, CMS notifies the hospice program in accordance with § 488.1210(e).

(2) *Action following training.* After the hospice program staff has received in-service training, if the hospice program has not achieved substantial compliance, CMS may impose one or more other remedies specified in § 488.1220.

(3) *Payment.* The hospice program pays for the directed in-service training for its staff.

§ 488.1260 Continuation of payments to a hospice program with deficiencies.

(a) *Continued payments.* CMS may continue payments to a hospice program with condition-level deficiencies that do not constitute immediate jeopardy for up to 6 months from the last day of the survey if the criteria in paragraph (a)(1) of this section are met.

(1) *Criteria.* CMS may continue payments to a hospice program not in compliance with the conditions of participation for the period specified in paragraph (a) of this section if all of the following criteria are met:

(i) An enforcement remedy, or remedies, has been imposed on the hospice program and termination has not been imposed.

(ii) The hospice program has submitted a plan of correction approved by CMS.

(iii) The hospice program agrees to repay the Federal Government payments received under this paragaph (a) if corrective action is not taken in accordance with the approved plan and timetable for corrective action.

(2) *Termination.* CMS may terminate the hospice program's provider agreement any time if the criteria in paragraph (a)(1) of this section are not met.

(b) *Cessation of payments for new admissions.* If termination is imposed, either on its own or in addition to an enforcement remedy or remedies, or if any of the criteria set forth in paragraph (a)(1) of this section are not met, the hospice program will receive no Medicare payments, as applicable, for new admissions following the last day of the survey.

(c) *Failure to achieve compliance with the conditions of participation.* If the hospice program does not achieve compliance with the conditions of participation by the end of the period specified in paragraph (a) of this section, CMS terminates the provider agreement of the hospice program in accordance with § 488.1265.

§ 488.1265 Termination of provider agreement.

(a) *Effect of termination by CMS.* Termination of the provider agreement ends—

(1) Payment to the hospice program; and

(2) Any enforcement remedy.

(b) *Basis for termination.* CMS terminates a hospice program's provider agreement under any one of the following conditions:

(1) The hospice program is not in compliance with the conditions of participation.

(2) The hospice program fails to submit an acceptable plan of correction within the timeframe specified by CMS.

(3) The hospice program fails to relinquish control to the temporary manager, if that remedy is imposed by CMS.

(4) The hospice program fails to meet the eligibility criteria for continuation of payment as set forth in § 488.1260(a)(1).

(c) *Notice.* CMS notifies the hospice program and the public of the termination, in accordance with procedures set forth in § 489.53 of this chapter.

(d) *Procedures for termination.* CMS terminates the provider agreement in accordance with procedures set forth in § 489.53 of this chapter.

(e) *Payment post termination.* Payment is available for up to 30 calendar days after the effective date of termination for hospice care furnished under a plan established before the effective date of termination as set forth in § 489.55 of this chapter.

(f) *Appeal.* A hospice program may appeal the termination of its provider agreement by CMS in accordance with part 498 of this chapter.

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

■ 28. The authority citation for part 489 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395i-3, 1395x, 1395aa(m), 1395cc, 1395ff, and 1395hh.

■ 29. Section 489.28 is amended by revising paragraphs (d) and (e) to read as follows:

§ 489.28 Special capitalization requirements for HHAs.

* * * * *

(d) *Required proof of availability of initial reserve operating funds.* The HHA must provide CMS with adequate proof of the availability of initial reserve operating funds. Such proof, at a minimum, will include a copy of the statement(s) of the HHA's savings, checking, or other account(s) that contains the funds, accompanied by an attestation from an officer of the bank or other financial institution (if the financial institution offers such attestations) that the funds are in the account(s) and that the funds are immediately available to the HHA. In some cases, an HHA may have all or part of the initial reserve operating funds in cash equivalents. For the purpose of this section, cash equivalents are short-term, highly liquid investments that are readily convertible to known amounts of cash and that present insignificant risk of changes in value. A cash equivalent that is not readily convertible to a known amount of cash as needed during the initial 3-month period for which the initial reserve operating funds are required does not qualify in meeting the initial reserve operating funds requirement. Examples of cash equivalents for the purpose of this section are Treasury bills, commercial paper, and money market funds. As with funds in a checking, savings, or other account, the HHA also must be able to document the availability of any cash equivalents. CMS later may require the HHA to furnish another attestation from the financial institution that the funds remain available, or, if applicable, documentation from the HHA that any cash equivalents remain available, until a date when the HHA will have been surveyed by the State agency or by an

approved accrediting organization. The officer of the HHA who will be certifying the accuracy of the information on the HHA's cost report must certify what portion of the required initial reserve operating funds is non-borrowed funds, including funds invested in the business by the owner. That amount must be at least 50 percent of the required initial reserve operating funds. The remainder of the reserve operating funds may be secured through borrowing or line of credit from an unrelated lender.

(e) *Borrowed funds.* If borrowed funds are not in the same account(s) as the HHA's own non-borrowed funds, the HHA also must provide proof that the borrowed funds are available for use in operating the HHA, by providing, at a minimum, a copy of the statement(s) of the HHA's savings, checking, or other account(s) containing the borrowed funds, accompanied by an attestation from an officer of the bank or other financial institution (if the financial institution offers such attestations) that the funds are in the account(s) and are immediately available to the HHA. As with the HHA's own (that is, non-borrowed) funds, CMS later may require the HHA to establish the current availability of such borrowed funds, including furnishing an attestation from a financial institution or other source, as may be appropriate, and to establish that such funds will remain available until a date when the HHA will have been surveyed by the State agency or by an approved accrediting organization.

* * * * *

§ 489.53 [Amended]

■ 30. Section 489.53 is amended in paragraph (a)(17) by removing the phrase ''an HHA,'' and adding in its place the phrase ''an HHA or hospice program,''.

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFS/IID AND CERTAIN NFs IN THE MEDICAID PROGRAM

■ 31. The authority citation for part 498 continues to read as follows:

Authority: 42 U.S.C. 1302, 1320a–7j, and 1395hh.

■ 32. Section 498.1 is amended by adding paragraph (l) to read as follows:

§ 498.1 Statutory basis.

* * * * *

(l) Section 1822 of the Act provides that for hospice programs that are no longer in compliance with the conditions of participation, the Secretary may develop remedies to be imposed instead of, or in addition to, termination of the hospice program's Medicare provider agreement.

■ 33. Section 498.3 is amended—

■ a. By revising paragraph (b)(13);

■ b. In paragraph (b)(14) introductory text by removing the phrase ''NF, or HHA but only'' and adding in its place the phrase ''NF, HHA, or hospice program, but only'';

■ c. By revising paragraph (b)(14)(i); and

■ d. In paragraph (d)(10) introductory text by removing the phrase ''NF, or HHA—'' and adding in its place the phrase ''NF, HHA, or hospice program—''.

The revisions read as follows:

§ 498.3 Scope and applicability.

* * * * *

(b) * * *

(13) Except as provided at paragraph (d)(12) of this section for SNFs, NFs, HHAs, and hospice programs, the finding of noncompliance leading to the imposition of enforcement actions specified in § 488.406, § 488.820, or § 488.1170 of this chapter, but not the determination as to which sanction or remedy was imposed. The scope of review on the imposition of a civil money penalty is specified in § 488.438(e), § 488.845(h), or § 488.1195(h) of this chapter.

(14) * * *

(i) The range of civil money penalty amounts that CMS could collect (for SNFs or NFs, the scope of review during a hearing on imposition of a civil money penalty is set forth in § 488.438(e) of this chapter and for HHAs and hospice programs, the scope of review during a hearing on the imposition of a civil money penalty is set forth in §§ 488.845(h) and 488.1195(h) of this chapter); or

* * * * *

§ 498.60 [Amended]

■ 34. Section 498.60 is amended—

■ a. In paragraph (c)(1) by removing the reference ''§§ 488.438(e) and 488.845(h)'' and adding in its place the reference ''§§ 488.438(e), 488.845(h), and 488.1195(g)''.

■ b. In paragraph (c)(2) by removing the phrase ''or HHA'' and adding in its place the phrase ''HHA, or hospice program''.

Dated: October 29, 2021.

Xavier Becerra,

Secretary Department of Health and Human Services.

[FR Doc. 2021–23993 Filed 11–2–21; 4:15 pm]

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Part III

Department of the Interior

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Threatened Species Status With Section 4(d) Rule for Alligator Snapping Turtle; Proposed Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R4–ES–2021–0115; FF09E21000 FXES1111090FEDR 223]

RIN 1018–BG00

Endangered and Threatened Wildlife and Plants; Threatened Species Status With Section 4(d) Rule for Alligator Snapping Turtle

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce our 12-month finding on a petition to list the alligator snapping turtle (*Macrochelys temminckii*), North America's largest freshwater turtle species, as an endangered or threatened species under the Endangered Species Act of 1973, as amended (Act). After a review of the best available scientific and commercial information, we find that listing the species is warranted. Accordingly, we propose to list the alligator snapping turtle as a threatened species with a rule issued under section 4(d) of the Act (''4(d) rule''). If we finalize this rule as proposed, it will add the species to the List of Endangered and Threatened Wildlife and extend the Act's protections to the species.

DATES: We will accept comments received or postmarked on or before January 10, 2022. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES**, below) must be received by 11:59 p.m. Eastern Time on the closing date. We must receive requests for public hearings, in writing, at the address shown in **FOR FURTHER INFORMATION CONTACT** by December 27, 2021.

Public informational meeting and public hearing: We will hold a public informational meeting on December 7, 2021, from 6:00 p.m. to 7:30 p.m. Central Time, followed by a public hearing from 7:30 p.m. to 8:30 p.m. Central Time.

ADDRESSES: You may submit comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *https://www.regulations.gov.* In the Search box, enter the docket number or RIN for this rulemaking (presented above in the document headings). For best results, do not copy and paste either number; instead, type the docket number or RIN into the Search box using hyphens. Then, click on the Search button. On the resulting page, in the Search panel on the left side of the screen, under the Document Type heading, check the Proposed Rule box to locate this document. You may submit a comment by clicking on ''Comment.''

(2) *By hard copy:* Submit by U.S. mail to: Public Comments Processing, Attn: FWS–R4–ES–2021–0115, U.S. Fish and Wildlife Service, MS: PRB/3W, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

We request that you send comments only by the methods described above. We will post all comments on *https://www.regulations.gov.* This generally means that we will post any personal information you provide us (see Information Requested, below, for more information).

FOR FURTHER INFORMATION CONTACT: Brigette Firmin, Deputy Field Supervisor, U.S. Fish and Wildlife Service, Louisiana Ecological Services Field Office, 200 Dulles Drive, Lafayette, LA 70506; telephone 337–291–3108. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under the Act, if we determine that a species warrants listing, we are required to promptly publish a proposal in the **Federal Register,** unless doing so is precluded by higher-priority actions and expeditious progress is being made to add and remove qualified species to or from the List of Endangered and Threatened Wildlife and Plants. The Service will make a determination on our proposal within 1 year. If there is substantial disagreement regarding the sufficiency and accuracy of the available data relevant to the proposed listing, we may extend the final determination for not more than six months. To the maximum extent prudent and determinable, we must designate critical habitat for any species that we determine to be an endangered or threatened species under the Act. Listing a species as an endangered or threatened species and designating critical habitat can be completed only by issuing a rule.

What this document does. We propose to list the alligator snapping turtle as a threatened species with a rule issued under section 4(d) of the Act.

The basis for our action. Under the Act, we may determine that a species is an endangered or threatened species because of any of 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. We have determined that the primary threats acting on the alligator snapping turtle include habitat loss or modification (Factor A), harvest and collection (Factor B), nest predation (Factor C), and hook ingestion, entanglement, and drowning due to bycatch associated with freshwater fishing (Factor E). Existing regulatory mechanisms (Factor D) are not adequate to address these threats. Disease (Factor C), nest parasites (Factor C), and the effects of climate change (Factor E) may negatively influence the species, but the impacts of these threats on the species are uncertain based on current information.

Section 4(a)(3) of the Act requires the Secretary of the Interior (Secretary) to designate critical habitat concurrent with listing to the maximum extent prudent and determinable. Section 3(5)(A) of the Act defines critical habitat as (i) the specific areas within the geographical area occupied by the species, at the time it is listed, on which are found those physical or biological features (I) essential to the conservation of the species and (II) which may require special management considerations or protections; and (ii) specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination by the Secretary that such areas are essential for the conservation of the species. Section 4(b)(2) of the Act states that the Secretary must make the designation on the basis of the best scientific data available and after taking into consideration the economic impact, the impact on national security, and any other relevant impacts of specifying any particular area as critical habitat. We have determined that designation of critical habitat is not determinable at this time.

Information Requested

We intend that any final action resulting from this proposed rule will be based on the best scientific and commercial data available and be as accurate and as effective as possible. Therefore, we request comments or information from other concerned governmental agencies, Native American Tribes, the scientific community, industry, or any other interested parties concerning this proposed rule.

We particularly seek comments concerning:

(1) The species' biology, range, and population trends, including:

(a) Biological or ecological requirements of the species, including habitat requirements for feeding, breeding, and sheltering;

(b) Genetics, taxonomy, and population structure;

(c) Historical and current range, including distribution patterns;

(d) Survival rates for adults, juveniles, hatchlings, or eggs;

(e) Historical and current population levels, and current and projected trends;

(f) Past and ongoing conservation measures for the species; and

(g) Tribal use or cultural significance of the species, including use of parts for ceremonial or traditional crafts.

(2) Information on threats to the species, particularly information on:

(a) Frequency of hook ingestion and entanglement associated with recreational or commercial fishing, effects on individual survival, and any population impacts;

(b) Magnitude of poaching and any population impacts from poaching; and

(c) Nest and hatchling predation rates and effects on recruitment and any population impacts.

(3) The spatial distribution and extent of threats to this species. Notably, we seek any information on areas within the species' range where these threats may overlap and potentially act synergistically or antagonistically as well as where there may be a complete absence of threats.

(4) The spatial variation in demographic rates related to reproduction, recruitment, and survival.

(5) Information regarding personal or commercial trade, not limited to the pet trade or breeding for personal collections.

(6) Information regarding habitat loss or degradation impacts to the species at the analysis unit level.

(7) Information, especially from the commercial and recreational fishing communities, about the design of a turtle escape or exclusion device, modified trot line techniques, or any other practices that would effectively eliminate or significantly reduce bycatch of alligator snapping turtles from recreational or commercial fishing.

(8) Information to address uncertainties regarding the future conditions analyses that informed the listing determination, including:

(a) Model input variables;

(b) Scientific or commercial information that would inform the model; and

(c) Treatment of uncertainty within the model.

(9) Information on regulations that are necessary and advisable to provide for the conservation of the alligator snapping turtle and that the Service can consider in developing a 4(d) rule for the species. In particular, we seek information concerning the extent to which we should include any of the Act's section 9 prohibitions in the 4(d) rule or whether we should consider any additional exceptions from the prohibitions in the 4(d) rule.

(10) Whether the measures outlined in the proposed 4(d) rule are necessary and advisable for the conservation and management of the alligator snapping turtle. We particularly seek comments concerning:

(a) Whether we should include a provision excepting incidental take resulting from legal recreational or commercial fishing activities for other targeted species, in compliance with State regulations. In addition, if we include such a provision, whether we should also include a requirement to report to the Service injured or dead turtles resulting from such legal fishing activities and how such reporting should be conducted;

(b) Whether the provision excepting activities such as take and interstate commerce for captive-bred specimens from State-approved captive breeding operations-should be revised or clarified regarding additional restrictions or requirements, or best management practices, or whether the Service should also except from the prohibited activities the foreign trade of live specimens from captive breeding operations;

(c) Whether the provisions excepting incidental take resulting from construction, operation, and maintenance activities; pesticide and herbicide application; and silviculture practices and forestry activities that follow best management practices should be revised or clarified to remove or add information, including spatial or temporal restrictions or deferments, or additional best management practices;

(d) Whether there are additional provisions the Service may wish to consider for the final 4(d) rule in order to conserve, recover, and manage the alligator snapping turtle, such as allowing take associated with certain infrastructure and other construction activities, riparian management activities, or wetland management activities;

(e) Methods for identifying, marking, and tracking captive brood-stock to differentiate them from wild-stock; and

(f) Whether there are any additional management activities not described within this proposed rule that contribute to the conservation of the alligator snapping turtle.

(11) The reasons why we should or should not designate habitat as ''critical habitat'' under section 4 of the Act (16 U.S.C. 1531 *et seq.*), including information to inform the following factors that the regulations identify as reasons why designation of critical habitat may be not prudent:

(a) The species is threatened by taking or other human activity and identification of critical habitat can be expected to increase the degree of such threat to the species;

(b) The present or threatened destruction, modification, or curtailment of a species' habitat or range is not a threat to the species, or threats to the species' habitat stem solely from causes that cannot be addressed through management actions resulting from consultations under section 7(a)(2) of the Act;

(c) Areas within the jurisdiction of the United States provide no more than negligible conservation value, if any, for a species occurring primarily outside the jurisdiction of the United States; or

(d) No areas meet the definition of critical habitat.

(12) Whether the designation of critical habitat is not prudent because it would more widely announce the exact locations of alligator snapping turtles and their highly suitable habitat which could facilitate poaching, exacerbating the existing threat of collection and contributing to further declines of the species' viability.

(13) Specific information on the possible risks or benefits of designating critical habitat, including risks associated with publication of maps designating any area on which this species may be located, now or in the future, as critical habitat. We specifically request information on the threats of taking or other human activity on the alligator snapping turtle and its habitat, and the extent to which designation might increase those threats, as well as the possible benefits of critical habitat designation to the species.

Please include sufficient information with your submission (such as scientific journal articles or other publications) to allow us to verify any scientific or commercial information you include.

Please note that submissions merely stating support for, or opposition to, the actions under consideration without providing supporting information, although noted, will not be considered in making a determination, as section 4(b)(1)(A) of the Act directs that determinations as to whether any species is an endangered or a threatened

species must be made ''solely on the basis of the best scientific and commercial data available.''

You may submit your comments and materials concerning this proposed rule by one of the methods listed in **ADDRESSES**. We request that you send comments only by the methods described in **ADDRESSES**.

If you submit information via *https://www.regulations.gov,* your entire submission—including any personal identifying information—will be posted on the website. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *https://www.regulations.gov.*

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on *https://www.regulations.gov.*

Because we will consider all comments and information we receive during the comment period, our final determinations may differ from this proposal. Based on the new information we receive (and any comments on that new information), we may conclude that the species is endangered instead of threatened, or we may conclude that the species does not warrant listing as either an endangered species or a threatened species. In addition, we may change the parameters of the prohibitions or the exceptions to those prohibitions in the 4(d) rule if we conclude it is appropriate in light of comments and new information we receive. For example, we may expand the prohibitions to include prohibiting additional activities if we conclude that those additional activities are not compatible with conservation of the species. Conversely, we may establish additional exceptions to the prohibitions in the final rule if we conclude that the activities would facilitate or are compatible with the conservation and recovery of the species.

Public Hearing

We are holding a public informational meeting followed by a public hearing on the date and at the time listed in **DATES**. We are holding the public informational meeting and public hearing via the Zoom online video platform and via teleconference so that participants can attend remotely. For security purposes, registration is required. All participants must register in order to listen and view the meeting and hearing via Zoom, listen to the meeting and hearing by telephone, or provide oral public comments at the public hearing by Zoom or telephone. For information on how to register, or if technical problems occur joining Zoom the day of the meeting, visit *https://www.fws.gov/southeast/lafayette/news/.* Registrants will receive the Zoom link and the telephone number for the public informational meeting and public hearing. If applicable, interested members of the public not familiar with the Zoom platform should view the Zoom video tutorials (*https://support.zoom.us/hc/en-us/articles/206618765-Zoom-video-tutorials*) prior to the public informational meeting and public hearing.

We are holding the public informational meeting to present information about the proposed rule to list the alligator snapping turtle as a threatened species and to provide interested parties an opportunity to ask questions about the proposed 4(d) rule. The public hearing will provide interested parties an opportunity to present verbal testimony (formal, oral comments) regarding the proposed rule to list the alligator snapping turtle as a threatened species and the proposed 4(d) rule. While the public informational meeting will be an opportunity for dialogue with the Service, the public hearing is not. The public hearing portion is a forum for accepting formal verbal testimony. In the event there is a large attendance, the time allotted for oral statements may be limited. Therefore, anyone wishing to make an oral statement at the public hearing for the record is encouraged to provide a prepared written copy of their statement to us through the Federal eRulemaking Portal, or U.S. mail (see **ADDRESSES**, above). There are no limits on the length of written comments submitted to us. Anyone wishing to make an oral statement at the public hearing must register before the hearing (*https://www.fws.gov/southeast/lafayette/news/*). The use of a virtual public hearing is consistent with our regulations at 50 CFR 424.16(c)(3).

Reasonable Accommodation

The Service is committed to providing access to the public informational meeting and public hearing for all participants. Closed captioning will be available during the public informational meeting and public hearing. Further, a full audio and video recording and transcript of the public hearing will be posted online at *https://www.fws.gov/southeast/lafayette/news/* after the hearing. Participants will also have access to live audio during the public informational meeting and public hearing via their telephone or computer speakers. Persons with disabilities requiring reasonable accommodations to participate in the meeting and/or hearing should contact the person listed under **FOR FURTHER INFORMATION CONTACT** at least 5 business days prior to the date of the meeting and hearing to help ensure accessibility. An accessible version of the Service's public informational meeting presentation will also be posted online at *https://www.fws.gov/southeast/lafayette/news/* prior to the meeting and hearing (see **DATES**, above). See *https://www.fws.gov/southeast/lafayette/news/* for more information about reasonable accommodation.

Previous Federal Actions

On July 11, 2012, the Service received a petition to list 53 amphibians and reptiles across the United States, including the alligator snapping turtle (*Macrochelys temminckii*), as endangered or threatened species. On July 1, 2015, we published a 90-day finding (80 FR 37568) that the petition contained substantial information indicating the alligator snapping turtle may warrant listing. On September 1, 2015, the petitioner submitted supplemental information to add to the petition that described new studies that could lead to taxonomic differentiation of the single *Macrochelys* species into multiple entities (Center for Biological Diversity 2015, entire). This information was considered and is described in further detail below in the Background discussion under I. Proposed Listing Determination in this document. New information since the time of the original petition, including that submitted to supplement the petition, provided sufficient evidence to support splitting the alligator snapping turtle (*M. temminckii*) into two separate species based on genetic and morphological differences as well as geographic isolation, resulting in alligator snapping turtle (*M. temminckii*) and Suwannee alligator snapping turtle (*M. suwanniensis*). This proposed rule serves as the 12-month finding for the alligator snapping turtle (*M. temminckii*).

Supporting Documents

A species status assessment (SSA) team prepared an SSA report for the alligator snapping turtle (Service 2021, entire). The SSA team was composed of Service biologists, in consultation with other species experts. The SSA report represents a compilation of the best scientific and commercial data available concerning the status of the species, including the impacts of factors (both

negative and beneficial) affecting the species in the past, present, and future. In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), and our August 22, 2016, memorandum updating and clarifying the role of peer review of listing actions under the Act, we sought the expert opinions of eight appropriate specialists regarding the SSA report and received three responses. We also requested review of the model that was used in the SSA analysis; we sent it to three reviewers and received two responses. We received review from 14 partners, most of which are State agencies. The SSA report and other materials relating to this proposal can be found at *https://www.regulations.gov* under Docket No. FWS.

I. Proposed Listing Determination

Background

A thorough review of the taxonomy, distribution, life history, and ecology of the alligator snapping turtle (*Macrochelys temminckii*) is presented in the SSA report (Service 2021, pp. 3–16); however, much of this information is based on the *Macrochelys* genus as a whole and is not specific to the alligator snapping turtle. Turtles in the genus *Macrochelys* are the largest species of freshwater turtle in North America, are highly aquatic, and are somewhat secretive. *Macrochelys* turtles are characterized as having a large head, a long tail, and an upper jaw with a strongly hooked beak. They have three raised keels with posterior elevations on the scutes of the carapace (upper shell), which is dark brown and often has algal growth that adds to their camouflage. The eyes are positioned on the side of the head and are surrounded by small, fleshy, pointed projections that are unique to the genus. The common name for *M. temminckii* is alligator snapping turtle, or occasionally, western alligator snapping turtle to differentiate between this species and Suwannee alligator snapping turtle.

Alligator snapping turtles are primarily freshwater turtles in freshwater bodies centralized in the southeastern United States and are confined to river systems that flow into the Gulf of Mexico, extending from the Apalachicola River in Florida to the San Jacinto and Trinity rivers in Texas. In the Mississippi Alluvial Valley, the species is widely distributed from the Gulf to as far north as Indiana, Illinois, southeastern Kansas, and eastern Oklahoma. In the Gulf Coastal Plain, the species' range extends from eastern Texas to southern Georgia and northern Florida. Historically, the alligator snapping turtle occurred over eastern Oklahoma, but today it is believed to be restricted to the east-central and southeastern portion of the State (Ernst and Lovich 2009, p. 139).

The historical range of alligator snapping turtles included 14 States: Alabama, Arkansas, Florida, Georgia, Illinois, Indiana, Kansas, Kentucky, Louisiana, Missouri, Mississippi, Oklahoma, Tennessee, and Texas. Currently, the species is known to occur in 12 States: Alabama, Arkansas, Florida, Georgia, Illinois, Kentucky, Louisiana, Missouri, Mississippi, Oklahoma, Tennessee, and Texas. This list includes all historically occupied States except for Indiana and Kansas, where occurrence is unknown. The range of the species has contracted in many areas of the historical distribution. The species once occupied eastern Oklahoma, but today it is believed to be restricted to the east-central and southeastern portion of the State (Ernst and Lovich 2009, p. 139). In Indiana, alligator snapping turtle eDNA (genetic material found within the environment) has been collected in the water, but presence has not been confirmed with trapping. In Kansas, the species has not been detected since a 1991 record in Montgomery County. Range contractions or declines in the species' abundance have occurred in several States along the northern extent of the species' distribution, including Illinois, Missouri, Tennessee. The physiography of the coastal plain, particularly in the States of Alabama, Mississippi, and Louisiana, provides good habitat conditions for the species and supports greater number of alligator snapping turtles than the northern fringe of the range. The estimated abundance of the species is around 360,000 individuals (Service 2021, p. 55).

The alligator snapping turtle is a member of the Family Chelydridae, Order Testudinata, Class Reptilia. The species was first described in 1789 as *Testudo planitia,* but it was placed in the genus *Macrochelys* in 1856 (Gray 1856, entire). Although subsequent authors referred to the genus as *Macrochelys,* this placement was refuted, and it was believed the alligator snapping turtle should be included in the genus *Macroclemys* (Smith 1955, p. 16). In 1995, Webb demonstrated that the genus *Macrochelys* has precedence over *Macroclemys,* and the Society for the Study of Amphibians and Reptiles adopted this revision in 2000 (Crother et al. 2000, p. 79). Accordingly, for the purpose of this proposed rule, we will use the taxonomic nomenclature, *Macrochelys,* as the genus for the alligator snapping turtle (*Macrochelys temminckii*).

The alligator snapping turtle (*Macrochelys temminckii*) was considered a single, wide-ranging species until a recent analysis of variation in morphology and genetic structure among *M. temminckii* specimens resulted in differentiation of three species of alligator snapping turtles: alligator snapping turtle (*M. temminckii*), Apalachicola alligator snapping turtle (*M. apalachicolae*), and Suwannee alligator snapping turtle (*M. suwanniensis*) (Thomas et al. 2014, entire). Subsequent morphological and genetic comparisons did not support distinguishing *M. apalachicolae* from *M. temminckii* (Folt and Guyer 2015, entire). The herpetology community, including the Society for the Study of Amphibians and Reptiles, recognizes two species of *Macrochelys:* (1) *M. temminckii* and (2) *M. suwanniensis* (Crother 2017, p. 88). The Turtle Taxonomy Working Group also concurs with the recognition of two species and provides evidence to support the distinction of *M. temminckii* (Rhodin et al. 2017, p. 26). According to the best available science, we consider *M. temminckii* and *M. suwanniensis* as the only two distinct species within the genus.

Throughout this document, we provide descriptions of alligator snapping turtle where the information is available specific to the species. We reference *Macrochelys* when describing the genus and *M. temminckii* when referring to the species, alligator snapping turtle. Since the taxonomic distinction of the two *Macrochelys* spp. is relatively recent, we may refer to the genus, or alligator snapping turtles in general, to describe life-history traits.

Summary of Biological Status and Threats

In this discussion, we review the biological condition of alligator snapping turtle and its resources, and the threats that influence the species' current and future conditions, in order to assess the species' overall viability and the risks to that viability. We provide the best available information on the species' life history and the threats acting on the species as provided in the SSA report (Service 2021, entire).

To assess the current condition and abundance levels to inform the current and future conditions, we compared the historical and current ranges of alligator snapping turtles by querying State biologists or those with access to the State's natural heritage program data. We sought expert estimates, using a 4-point elicitation procedure in a written

questionnaire (Speirs-Bridge et al. 2010, p. 515). Experts were asked to respond only for those analysis units for which they have experience or expertise. Experts were asked to provide what they estimated to be the lowest likely number, the highest likely number, and the most likely number of alligator snapping turtles in each analysis unit. They were then asked to report how confident they were that their interval (lowest estimate to highest estimate) captured the actual number of alligator snapping turtles (akin to a confidence interval). Finally, the experts were asked to describe how they generated their estimates (Service 2021, p. 51).

We also elicited information about the prevalence of negative and positive influences on alligator snapping turtles in each analysis unit. Using the same 4-point elicitation format, we asked the species experts to estimate the extent of occupied area in each analysis unit where alligator snapping turtles are exposed to each of the following threats: incidental hooking on trot and limb lines, commercial fishing bycatch, legal collection or harvest, illegal collection or harvest (poaching), and nest predation by subsidized or nonnative predators. In addition, we asked experts to describe and estimate the spatial extent of any other threats known to occur in their analysis units, as well as any conservation actions that are being implemented (Service 2021, pp. 51–52). In addition to soliciting information from the expert team about the spatial extent of different threats in each analysis unit, we also asked about the demographic impact of different threats rangewide. We used the 4-point elicitation to receive information regarding the effects that commercial bycatch, incidental hooking, hook ingestion, legal harvest, illegal harvest, and nest predation have on the survival of relevant life stages (adults, juveniles, hatchings, nests) in areas where the threat occurs. Given a lack of species-specific information in some places, we used this process to inform our analysis.

Biology

The alligator snapping turtle is found in a variety of habitats across its range. It typically uses fresh waterbodies; however, it can presumably tolerate some salinity and brackish waters, as barnacles have been found on the carapace of some turtles (Ernst and Lovich 2009, p. 141). The river systems within the species' range drain into the Gulf of Mexico, where there can be an increase in salinity near the mouths of the rivers. The species is generally found in deeper water of large rivers and their major tributaries; however, it is also found in a wide variety of habitats, including small streams, bayous, canals, swamps, lakes, reservoirs, ponds, and oxbows (a lake that forms when a meander of a river is cut off) (Ernst and Lovich 2009, p. 141).

The species is usually bottom-dwelling within the waterbodies it uses, but it surfaces periodically to breathe (Thomas 2014, p. 60). Adult females leave the water to nest on land. Beyond the nest, all life stages rely on submerged material (*i.e.,* deadhead logs and vegetation) as important structure for resting, foraging, and cover from predators (Enge et al. 2014, p. 39). Woody debris, undercut banks, and large rocks found throughout the rivers provide important habitat during low water levels (Enge et al. 2014, p. 10). The species selects areas with more aquatic structures (*e.g.,* tree root masses, stumps, submerged trees, etc.) than open water. Riparian canopy cover is also an important habitat feature, as alligator snapping turtles select sites with a high percentage of canopy cover (Howey and Dinkelacker 2009, p. 589).

The alligator snapping turtle is primarily carnivorous and forages on small fish and mussels; however, adults are opportunistic feeders and may also consume crayfish, mollusks, smaller turtles, insects, nutria, snakes, birds, and plant material such as acorns or other available vegetation (Elsey 2006, pp. 448–489). They have very fast reflexes and powerful jaws that aid in this type of foraging behavior where they sit and wait, then quickly strike, grasping the prey. *Macrochelys* turtles have a sublingual (under the tongue) feature that is unique to the genus and contributes to their predatory foraging strategy; it resembles a live, wiggling worm and serves as a lure to attract fish and other unsuspecting prey while the turtle is stationary with an open mouth. Both adults and juveniles use this lure to attract fish in striking range. The lure is white or pale pink in juveniles and mottled or gray in adults (Ernst and Lovich 2009, p. 147). The presence of this appendage indicates prey species that use visual cues, such as fish and aquatic crustaceans, and has contributed to the evolution of the alligator snapping turtle in developing this unique adaptation of the genus.

The general life stages of *Macrochelys* can be described as egg, hatchling (first year), juvenile (second year until age of sexual maturity), and adult (age of sexual maturity through death). Sexual maturity is achieved in 11 to 21 years for males and 13 to 21 years for females and may be dependent upon growth rate (Ernst and Lovich 2009, p. 144; Reed et al. 2002, p. 4). The size increases are greater when food resources and other environmental conditions are more favorable.

Each life stage has specific requirements in order to contribute to the productivity of the next life stage. Gravid (egg-bearing) females excavate nests in sandy soils or other dry substrate near freshwater sources that are within 8 to 656 feet (ft) (2.5 to 200 meters (m)) from the water's edge. The period for excavating, laying eggs, and covering the nest may take as long as 4 hours to complete (Ewert 1976, p. 153). The incubation period for alligator snapping turtle nests in Louisiana is between 98 to 121 days (Holcomb and Carr 2011, p. 225).

Nests require temperatures of 66 to 80 degrees Fahrenheit (°F) (19 to 26.5 degrees Celsius (°C)), increasing to 79 to 98 °F (26.1 to 36.5 °C) as the season progresses. The sex ratio of alligator snapping turtles in the nest is dependent on the temperature of the nest during embryonic development. The offspring's sex is influenced by the physiological mechanism—temperature-dependent sex determination—where more males are produced at intermediate incubation temperatures, and more females are produced at the two, warmer and cooler, temperature extremes (Ernst and Lovich 2009, pp. 16, 146). Alligator snapping turtles, in general, have a pivotal temperature range between 77 and 80.6 °F (25 and 27 °C) where more male hatchlings are produced than females (Ewert and Jackson 1994, pp. 12–13).

Once emerged from the nest, hatchlings need shallow water with riparian vegetative structure that provides canopy cover. Juveniles require small streams with mud and gravel bottoms that have submerged structures, such as tree root masses, stumps, and submerged live and dead trees, that allow for foraging and protection from predators. Juvenile survival rate is estimated at only about 5 percent, with most mortality occurring in the first 2 years of life (Ernst and Lovich 2009, p. 150).

Adult alligator snapping turtles require streams and rivers with submerged logs and undercut banks, clean water, and ample prey. Turtles found in higher quality habitat are more likely to become sexually mature at an earlier age and may also produce larger clutch sizes (Ernst and Lovich 2009, p. 145). Adult turtles require access to mates to fertilize eggs, with mating occurring underwater (Ernst and Lovich 2009, p. 144). Mating has been observed in captive alligator snapping turtles from February to October, but geographic variation within the wild

population is not well understood (Reed et al. 2002, p. 4). A gravid female will search for suitable nesting habitat on land to construct a nest, avoiding low forested areas with abundant leaf litter and root mats that may cause nesting obstructions. She will excavate a cavity, deposit the eggs, and bury the eggs at a depth of about 9.45 inches (in) (24 centimeters (cm)) in approximately 3.5 to 4 hours (Ewert 1976, p. 153; Powders 1978, p. 155; Thompson et al. 2016, entire). Once the female has completed the nest, she returns to the water, and there is no other parental care of the nest or offspring.

Female alligator snapping turtles may produce a single clutch once a year or every other year at most, even if the conditions are good (Reed et al. 2002, p. 4). Clutch size varies as reported from across the species' range with a mean clutch size of 27 eggs (Ernst and Lovich 2009, p. 145). Most nesting occurs from May to July (Reed et al. 2002, p. 4), but latitudinal differences are known to occur in turtle species (Moll 1979, entire).

Alligator snapping turtles are a long-lived species; provided suitable conditions, adults can reach carapace lengths of up to 29 in (74 cm) and 249 pounds (113 kilograms (kg)) for males, while females can reach lengths of 22 inches and 62 pounds. The oldest documented *Macrochelys* turtle in captivity survived to at least 80 years of age, but in the wild, the species may live longer (Ernst and Lovich 2009, p. 147). The generation time for the species is around 31 years (range = 28.6–34.0 years, 95 percent confidence interval; Folt et al. 2016, p. 27).

Threats

We provide information regarding past, present, and future influences, including both positive and negative, on the alligator snapping turtle's current and future viability including harvest/collection (Factor B), bycatch (Factor E), habitat degradation and loss (Factor A), nest predation (Factor C), and conservation measures that provide protections for the species. Existing regulatory mechanisms (Factor D) have not been adequate to reduce or ameliorate the identified threats. Additional threats such as historical commercial and recreational harvest targeting the species, disease, nest parasites, and climate change effects are described in the SSA report (Service 2021, pp. 17–27); these additional stressors may negatively affect individuals of the species or may have historically affected the species, particularly when compounded with other ongoing stressors or threats. However, based on the best available science, they do not currently pose a threat to the species' overall viability.

Harvest (Commercial, Recreational, and Poaching)

Commercial and Recreational Harvest—Past commercial and recreational turtle harvesting practices have resulted in a decline of the alligator snapping turtle across its range (Enge et al. 2014, p. 4; Huntzinger et al. 2019, p. 65). Commercial harvest of alligator snapping turtles reached its peak in the late 1960s and 1970s, when the meat was used for commercial turtle soup products and sold in large quantities for public consumption. In addition, many restaurants served turtle soup and purchased large quantities of alligator snapping turtles from trappers in the southeastern States (Reed et al. 2002, p. 5). In the 1970s, the demand for turtle meat was so high that as much as three to four tons of alligator snapping turtles were harvested from the Flint River in Georgia per day (Pritchard 1989, p. 76). Significant numbers of turtles were taken from the Apalachicola and Ochlocknee Rivers, presumably to be sent to restaurants in New Orleans and other destinations (Pritchard 1989, pp. 74–75). Commercial harvest of alligator snapping turtles is now prohibited in all States within the species' range, effective from 1975 in Kentucky to as recently as 2012 in Alabama (Service 2021, Appendix B). Despite the prohibitions on commercial harvest for the species, the impacts from historical removal of large turtles continue to affect the species due to its low fecundity, low juvenile survival, long lifespan, and delayed maturity. Commercial harvest is not currently a threat to the alligator snapping turtle, but the effects of historical, large-scale removal of large turtles are ongoing.

Recreational harvest includes trapping alligator snapping turtles for personal use. Recreational harvest is prohibited in every State except for Louisiana and Mississippi. In Louisiana, harvest of one alligator snapping turtle per day, per person, per vehicle/vessel is allowed with a fishing license; however, there are no reporting or tagging requirements, so the number of turtles harvested in Louisiana is unknown. In Mississippi, recreational harvest is allowed with size and seasonal limits that include the following: (1) Limited to one turtle per year, (2) prohibited between April 1 and June 30, and (3) limited only to individuals with a straight-line carapace length of 24 in (61 cm) or larger.

Illegal Harvest (Poaching)—There is an international and domestic demand for turtles for consumption as well as from enthusiasts who collect turtle species for pets (Stanford et al. 2020, entire). The alligator snapping turtle is no exception; hatchling alligator snapping turtles may be sold for up to $100 (U.S.) per turtle (Lejeune et al. 2020, p. 8; MorphMarket 2021, unpaginated). Illegal harvest, or poaching, of alligator snapping turtle may occur anywhere within the species' range for both the pet trade and turtle meat trade. The best available information regarding potential pressure from poaching comes from a documented report by law enforcement agencies and court cases. In a 2017 case, three men were convicted of collecting 60 large alligator snapping turtles in a single year in Texas and transporting them across State lines, violating the Lacey Act (18 U.S.C. 42; 16 U.S.C. 3371–3378) (Department of Justice 2017, entire).

Aside from the local and domestic use of turtles, the global demand for pet turtles and turtle meat continues. Many species of turtles are collected from the wild as well as bred in captivity and are sold domestically and exported internationally. Many species of turtles are regularly exported out of the United States to initiate brood stock for overseas turtle farms and for turtle collectors (Stanford et al. 2020, p. R725. In 2006, *Macrochelys temminckii* was listed under the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) as an Appendix III species to allow for better monitoring of exports. According to the Service's Law Enforcement Management Information System (LEMIS), which provides reports about the legal international wildlife trade, most shipments of live alligator snapping turtles exported from 2005 to 2018 consisted of small turtles destined mostly for Hong Kong and China (Service 2018, entire). Prior to 2006, up to 23,780 *M. temminckii* per year were exported from the United States (70 FR 74700; December 16, 2005).

Impacts of Harvest—The alligator snapping turtle's life history, with delayed maturity, long generation times, and relatively low reproductive output, means that the species must maintain relatively high adult survival rates (~98 percent), especially of adult females, to sustain a stable population (Reed et al. 2002, p. 11). Adult turtles do not reach sexual maturity until 11 to 21 years of age. A mature female typically produces a single clutch per year with a mean size of 27 eggs (range 9 to 61 eggs) (Ernst and Lovich 2009, p. 145). These turtles are characterized by low survivorship in early life stages, but surviving

individuals may live many decades once they reach maturity. The life-history traits of the species (low fecundity, late age of maturity, and low survival of nests and juveniles) contribute to the population's slow response in rebounding after historical over-exploitation. Therefore, population growth rates are extremely sensitive to the harvest of adult females. Adult female survivorship of less than 98 percent per year is considered unsustainable, and a further reduction of this adult survivorship will generally result in significant local population declines (Reed et al. 2002, p. 9), although dynamics likely vary across the species' range. These data underscore how influential adult female mortality is on the ability of the species to maintain viable populations.

Although regulatory harvest restrictions have reduced the number of alligator snapping turtles taken from wild populations, the populations have not necessarily increased in response. This lag in population response is likely due to the demography of the species—specifically delayed maturity, long generation times, and relatively low reproductive output.

Poaching also is an ongoing threat to the alligator snapping turtle because removing reproductively active adult turtles from the population lowers the viability of the species by reducing reproductive potential; in addition, the species is long-lived and slow to mature, and juvenile survival is very low, making it more difficult for the historically over-harvested population to recover.

Recreational and Commercial Fishing Bycatch

Alligator snapping turtles can be killed or harmed incidentally during fishing and other recreational activities. Some of these threats from recreational and commercial fishing for other species include fishhook ingestion; drowning when hooked on trotlines (a fishing line strung across a stream with multiple hooks set at intervals), limb lines, bush hooks (single hooks hung from branches), or jug lines (line with a hook affixed to a floating jug); and injuries and drowning when entangled in various types of nets and fishing line. Hoop nets are also used to capture catfish and baitfish and are made up of a series of hoops with netting and funnels where fish enter but are unable to escape through the narrow entry point. The baited nets are left submerged and may entrap alligator snapping turtles that enter the mouth of the traps and are unable to escape. Boats and boat propeller strikes may also injure or kill alligator snapping turtles; this effect is not limited to fishing boats.

Actively used or discarded fishing line and hooks pose harm to alligator snapping turtles. The turtles can ingest baited fishhooks and the attached fishing line that may cause internal injuries; depending on where ingested hooks and line lodge in the digestive tract, they can cause harm or death (Enge et al. 2014, pp. 40–41). For example, hooks and fishing lines can cause gastrointestinal tract blockages, and the hooks can puncture the digestive organs causing deadly injuries (Enge et al. 2014, pp. 40–41). Fishhooks have been found in the gastrointestinal tracts of many radiographed congener, Suwannee alligator snapping turtles (Enge et al. 2014, entire; Thomas 2014, pp. 42–43). It is reasonable to assume fishhooks also affect alligator snapping turtles because both species only differ with minor skull and shell morphologies.

Trotlines also negatively affect alligator snapping turtles. Trotlines are a series of submerged lines with hooks off a longer line. Trotline fishing involves leaving the lines unattended for extended periods, before returning to check them. Limblines and bush hooks are similar to trot lines in that they are typically set and left unattended; however, they only use a single hook. The turtles can become entangled in the lines and drown, as well as ingest the hooks and attached lines, also causing drowning or internal injuries.

Bycatch from trotlines that resulted in mortality of alligator snapping turtles has been well documented. Dead turtles have been found on lines that had been abandoned or left without being checked for catches (Huntzinger et al. 2019, p. 73; Moore et al. 2013, p. 145). The lines and hooks may also become dislodged from their place of attachment when left unattended, becoming aquatic debris that remains in the waterway for extended periods of time and may continue to be an entanglement hazard for many species, including alligator snapping turtles. Entanglement in lines can cause injury or death as lines may ensnare limbs or wrap around the body or head restricting movement. Some types of fishing line may remain in the environment for decades and possibly centuries; however, biodegradable lines are now available that break down faster over a period of a few years. The use of biodegradable fishing line will reduce the amount of excess discarded lines remaining in the environment and is an option to further reduce the threat of entanglement in fishing lines.

Habitat Degradation and Loss

Alligator snapping turtle aquatic and nesting habitats have been altered by natural and anthropogenic disturbances. Changes in the riparian or nearshore areas affect the amount of suitable soils for nesting sites because the species constructs nests on land near the water. Riparian cover is important, as it moderates instream water temperatures and dissolved oxygen levels. In addition to affecting the distribution and abundance of alligator snapping turtle prey species, these microhabitat conditions affect the snapping turtles directly. Moderate temperatures and sufficient dissolved oxygen levels allow the turtles to remain stationary on the stream bottom for longer periods, increasing the ambush foraging opportunities. Changes in the riparian structure may affect the microclimate and conditions of the associated water body, directly affecting the foraging success of the turtles.

Activities and processes that can alter habitat include dredging, deadhead logging (removal of submerged or partially submerged snags, woody debris, and other large vegetation for wood salvage), removal of riparian cover, channelization, stream bank erosion, siltation, and land use adjacent to rivers (*e.g.,* clearing land for agriculture). These activities negatively influence habitat suitability for alligator snapping turtles. Erosion can change the stream bank structure, affecting the substrate that may be suitable for nesting or accessing nesting sites. Siltation affects water quality and may reduce the health and availability of prey species. Channelization destroys the natural benthic habitat by affecting the water depth and normal flow. Submerged obstacles may be removed during the channelization, which affects the microhabitat dynamics within the waterway and removes important structures for alligator snapping turtles to use for resting, foraging, and cover from predators. Deadhead logs and fallen riparian woody debris, where present, provide refugia during low-water periods and resting areas for all life stages and support important feeding areas for hatchlings and juveniles (Enge et al. 2014, p. 40; Ewert et al. 2006, p. 62).

Alligator snapping turtle habitat is also influenced by water availability, quantity, and quality across the species' range. Groundwater withdrawals may increase in the future due to human population growth and needs. Water withdrawals may reduce flow in some rivers and streams, effectively isolating some turtles from the rest of the

population or making immature turtles more vulnerable to predators. Additionally, reduced water levels may impact prey abundance and distribution through restricting habitat connectivity, reducing dissolved oxygen levels, and increasing water temperatures. The species is not very agile on land as it spends most of its time in water. Moving from an area where water has been depleted may be difficult for some turtles, forcing them to cross roads, resulting in increased encounters with humans or predators.

Water quality may also be a factor for alligator snapping turtles as contaminants enter the aquatic systems through runoff. Runoff from agriculture and development degrade the water quality. Agricultural practices are the main source of nitrates, which specifically come from fertilizers and in some cases from manure and other waste products. They introduce nitrates to the river and groundwater (*i.e.,* springs) through surface runoff and groundwater seepage. Groundwater seepage transports nitrates to the aquifer, which then reemerge through springs and other groundwater discharge, especially during low flow periods (Pittman et al. 1997, entire; Katz et al. 1999, entire; Thom et al. 2015, p. 2).

Water quality is also affected by runoff from development and urban areas. The increase of impervious surfaces, such as building roofs, roads, parking lots, and sidewalks, results in pulses of contaminants washed into the river systems as stormwater runoff. Some of the pollutants that may flush into the aquatic system include petroleum products, pesticides, heavy metals, organic waste from pets and other animals, along with microorganisms, including viruses and bacteria.

The direct effects of water quality and water quantity on alligator snapping turtle have not been quantified; however, as the human population that relies on water systems in the species' range continues to increase, the indirect effects across the entire range, coupled with other stressors, are likely to further reduce the species' viability. Also, more development may result in an increase in contaminated runoff and declines in water quality.

Nest Predation

Nest predation rates for alligator snapping turtles are high. Raccoons (*Procyon lotor*) are common nest predators, but nine-banded armadillos (*Dasypus novemcinctus*), Virginia opossums (*Didelphis virginiana*), bobcats (*Lynx rufus*), crows (*Corvus* spp.), coyotes (*Canis latrans*), river otters (*Lontra canadensis*), and feral pigs (*Sus scrofa*) may also depredate nests (Ernst and Lovich 2009, p. 149; Ewert et al. 2006, p. 67; Holcomb and Carr 2013, p. 482). Additional nonnative species found within the species' range that may depredate nests include invasive imported fire ants (*Solenopsis invicta* and *S. richteri*) (Pritchard 1989, p. 69). Fire ants are prevalent in many areas of the southeastern United States, and predation by fire ants was the suspected culprit in the failure of alligator snapping turtle nests in Louisiana (Holcomb 2010, p. 51). Beyond nest failure, some hatchlings endured wounds inflicted by fire ants that led to the loss of a limb or tail, which reduced their mobility and, ultimately, their chance of survival (Holcomb 2010, p. 72).

The recovery of the species from historical overharvest depends on successful reproduction and survival of young. The degree of added threat from the newer, introduced nest predators is unknown, but we can conclude that the overall threat from nest predation is greater than it was in the past because of the introduced predators and densities of subsidized (anthropogenically influenced) nest predators increase in areas where resources have been altered by humans. Subsidized nest predators include, but are not limited to, feral hogs, raccoons, and red-imported fire ants; additional nest predators may also include Virginia opossums, crows, coyotes, dogs, and river otters. Many of these predators may also take small turtles once emerged from the nest; this predation influences the survival rate of the hatchling and juvenile life stage. Coupled with other threats, predation will continue to negatively affect the species' overall viability.

Other Stressors

Other stressors that may affect alligator snapping turtles include disease, nest parasites, and the effects of climate change, but none of these stressors are having population-level impacts. These stressors may act on individuals or have highly localized impacts. While each is relatively uncommon, these stressors may exacerbate the effects of other ongoing threats.

The effects of climate change may have direct and indirect impacts to the species and its habitat. Due to the proximity of the species to the Gulf of Mexico, loss of habitat due to saltwater intrusion from sea level rise may occur for the populations near coastal areas leading to a range contraction in the southern extent of the species' range. Additionally, increasing temperatures may lead to drought conditions and variable water availability, and physiological impacts on sex determination. In the southeastern United States, temperatures are predicted to warm by 4 to 8 °F (2.2 to 4.4 °C) by 2100 (Carter et al. 2014, p. 399). In the southern Great Plains (*e.g.,* Texas and Oklahoma), increased temperatures and longer dry spells are predicted (Shafer et al. 2014, p. 445). In the Midwest, the northernmost portion of the alligator snapping turtle's range, models predict warming of 5.6 to 8.5 °F (3.1 to 4.7 °C) by 2100, increased spring precipitation, and decreased summer precipitation (Pryor et al. 2014, pp. 420, 424).

Alligator snapping turtles exhibit temperature-dependent sex determination, whereby temperature influences sex determination of the developing embryos. Male-biased sex ratios are associated with cool nests, and warmer temperatures produce female-biased sex ratios (Ewert and Jackson 1994, entire). In addition to temperature effects on sex ratio, temperature has been associated with nest viability, with greatest success in nests with intermediate sex ratios (produced at intermediate temperatures) and lowest in nests with female-biased sex ratios (produced at warmer temperatures) (Ewert and Jackson 1994, p. 28–29). Thus, alligator snapping turtle nests with strongly female-biased sex ratios and declining viability may result from warming temperatures in the future.

Climate conditions also appear to limit the distribution of alligator snapping turtles. Their distribution appears to be limited by low precipitation on the western edge of the range, and by temperature along the northern edge of the range (Thompson et al. 2016, pp. 431–432). At these northern limits of the range, adult alligator snapping turtles can survive, but they face constraints on reproduction imposed by the influence of temperature on embryonic development (Thompson et al. 2016, pp. 431–432). Warmer conditions may shift the suitable range of the species farther north as northern latitudes become able to meet the incubation temperature ranges for viable nests.

Additional information on these stressors acting on the species, including a more detailed discussion of the historical and current threats that have caused and are causing a decline in the species' viability, is available in the species' SSA report under ''Factors Influencing Viability'' (Service 2021, pp.

17–27). The primary threats currently acting on the species include harvest/collection, nest predation, habitat loss and degradation, and bycatch (hook ingestion, entanglement, and drowning) due to recreational and commercial fishing. These primary threats are not only affecting the species now but are expected to continue impacting the species and are included in the species' future condition projections in the SSA (Service 2021, pp. 59–84).

Regulatory Protections

Several local, State, and Federal regulatory mechanisms offer some protections to the alligator snapping turtle and its habitat.

Federal Protections

Federal Lands—The species' range encompasses areas of public land. Many Federal lands are protected from future development and degradation. Many sites are managed for species conservation and preservation of habitat. Some of the Federal lands that fall within the species' range are managed by the Department of Agriculture (U.S. Forest Service), Department of Interior (National Park Service (NPS) and U.S. Fish and Wildlife Service), Department of Defense (U.S. Army, U.S. Navy, U.S. Air Force, and U.S. Army Corps of Engineers), and National Aeronautics and Space Administration (NASA).

Department of Agriculture—National Forests are managed by the U.S. Forest Service with the mission to sustain the health, diversity, and productivity of the nation's forests and grasslands to meet the needs of present and future generations. Several National Forest lands are within the range of the alligator snapping turtle. Forestry activities on National Forests within the range of the alligator snapping turtle, including timber harvest and activities that may increase sedimentation or erosion when not following best management practices, could have adverse impacts on the species; however, when conducting any forestry activities, the U.S. Forest Service applies best management practices that reduce impacts to the species' aquatic and riparian habitats. The U.S. Forest Service also cooperates with State and local governments, forest industries, other private landowners and forest users in the management, protection, and development of forest land in non-Federal ownership. Activities include cooperation in urban interface fire management and urban forestry.

Department of Interior (National Park Service)—Alligator snapping turtle habitat extends across many NPS units in the Midwest, Intermountain, and Southeast regions. The species may occur in up to the following 11 units of the NPS or be found adjacent to those areas: Arkansas Post National Memorial, Big Thicket National Preserve, Buffalo National River, Cane River Creole National Historical Park, Gulf Islands National Seashore, Hot Springs National Park, Jean Lafitte National Historical Park and Preserve, Natchez Trace Parkway, Ozark National Scenic Riverways, Shiloh National Military Park, and Vicksburg National Military Park. Under the NPS' Organic Act (54 U.S.C. 100101 *et seq.*), the NPS promotes and regulates the use of Federal areas known as national parks, monuments, and reservations to conserve the scenery and the natural and historic objects and the wildlife and to provide for the enjoyment of future generations. The land within the NPS units is protected from future development and provides a level of protection to the species and its habitat.

Department of Interior (U.S. Fish and Wildlife Service)—National Wildlife Refuges are units managed by the Service's National Wildlife Refuge System (NWRS). The mission of the NWRS is to administer a national network of lands and waters for the conservation, management and, where appropriate, restoration of the fish, wildlife and plant resources and their habitats within the United States for the benefit of present and future generations of Americans. Each refuge is established to serve a statutory purpose that targets the conservation of native species dependent on its lands and waters. All activities on those acres are reviewed for compatibility with this statutory purpose.

There may be up to 50 National Wildlife Refuges with alligator snapping turtle occurrences. These lands are managed according to the designated purpose of the refuge and include conservation actions that reduce impacts from habitat loss, invasive species, pesticides and other contaminants, and climate change. These Federal lands are protected from future development and will continue contributing to the support of viable populations of alligator snapping turtles.

Department of Defense Lands—Alligator snapping turtles are found on many Department of Defense (DOD) military installations and lands across the species' range. The Sikes Act (16 U.S.C. 670 *et seq.*) requires DOD installations to conserve and protect the natural resources within their boundaries. Integrated natural resources management plans (INRMPs) are planning documents that outline how each military installation with significant natural resources will manage those resources, while ensuring no net loss in the capability of an installation to support its military testing and training mission for national security. While most INRMPs do not specifically manage for the alligator snapping turtle, some examples of management that provide for the conservation of the species on installations include INRMPs that incorporate guidance provided by the State wildlife action plan (*e.g.,* Ft. Chaffee Maneuver Training Center (Arkansas) INRMP, p. 12), direction to implement project design considering State-listed species with best management practices for all activities (*e.g.,* Red River Army Depot (Texas) INRMP, p. 48), and identifying alligator snapping turtle as a species of concern, with direction to apply management consistent with maintenance of reference stream conditions or offer direct measures to enhance habitat for this and other rare species (*e.g.,* Ft. Benning (Georgia) INRMP, pp. 28, 209–210).

Federal Laws

Clean Water Act (33 U.S.C. 1251 et seq.*)*—Section 401 of the Federal Clean Water Act (CWA) requires that an applicant for a Federal license or permit provide a certification that any discharges from the facility will not degrade water quality or violate water-quality standards, including State-established water quality standard requirements. Section 404 of the CWA establishes programs to regulate the discharge of dredged and fill material into waters of the United States.

Permits to fill wetlands; to install, replace, or remove culverts; to install, repair, replace, or remove bridges; or to realign streams or water features that are issued by the State or U.S. Army Corps of Engineers under nationwide, regional general permits or individual permits include:

- Nationwide permits for ''minor'' impacts to streams and wetlands that do not require an intense review process. The impacts allowed under nationwide permits usually include projects affecting stream reaches less than 150 ft (45.72 m) in length, and wetland fill projects up to 0.50 acres (ac) (0.2 hectare (ha)). Mitigation is usually provided for the same type of wetland or stream impacted and is usually at a 2:1 ratio to offset losses.
- Regional general permits for various specific types of impacts that are common to a particular region. These

permits will vary based on location in a certain region/State.

• Individual permits for larger, higher impact, and more complex projects. These require a complex permit process with multi-agency input and involvement. Impacts in these types of permits are reviewed individually, and the compensatory mitigation chosen may vary depending on the project and types of impacts.

CWA regulations ensure proper mitigation measures are applied to minimize the impact of activities occurring in streams and wetlands where the species occurs. These regulations contribute to the conservation of the species by minimizing or mitigating the effects of certain activities on alligator snapping turtles and their habitat.

Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)—The alligator snapping turtle is included in the CITES Appendix III species list (70 FR 74700; December 16, 2005). CITES requirements include permits for exports of Appendix III species, as well as annual reporting; annual reports must include the number of exported individuals of listed species. These requirements help control and document legal, international trade. Thus, Appendix-III listings lend additional support to State wildlife agencies in their efforts to regulate and manage these species, improve data gathering to increase knowledge of trade in the species, and strengthen State and Federal wildlife enforcement activities to prevent poaching and illegal trade.

While CITES reporting indicates the number of turtles exported with other relevant data, the information required for the export reports does not always accurately identify the source stock of the exported turtle(s). Most alligator snapping turtles that were exported between 2005 and 2018 were identified as ''wild'' individuals; however, there is uncertainty regarding whether the source of the turtles was farmed parental stock or wild-caught (Service 2018, entire). The discrepancy in reporting the actual source of the internationally exported turtles does not allow us to easily evaluate the impact of export on the alligator snapping turtle. Additionally, there are no reporting requirements to track domestically traded alligator snapping turtles, which are not included in CITES reporting.

State Protections

The alligator snapping turtle has regulatory protections in all States where the species occurs. The species is listed as a threatened species in Florida, Georgia, Kentucky, and Texas, and as an endangered species in Illinois and Indiana. Alabama identifies the species as a ''species of concern''; Kansas and Oklahoma list the species as a ''species of greatest conservation need''; Missouri lists the species as an ''imperiled species''; Tennessee lists the species as ''rare to very rare and imperiled.'' Louisiana lists the species as a species of conservation concern and allows legal take of up to one turtle per day, per person, per vehicle/vessel with a fishing license. Arkansas does not have a State list of protected species; however, it provides protections through the State's aquatic turtle regulations. Mississippi allows legal take; however, it restricts the take to one alligator snapping turtle no smaller than 24 in (61 cm) carapace length in a single year. Despite the likely extirpation of the species in Kansas, the species was originally listed as a threatened species in the State in 1978; then, due to lack of information on the species, the status was changed to ''species of greatest conservation need'' in 1987, when the species was still found in low numbers (Shipman et al. 1995, pp. 83–84). Although we have no information as to the effectiveness of these State regulations as they pertain to the conservation of the alligator snapping turtle, one benefit of being State-listed is to bring heightened public awareness of the species' need for protection.

Conservation Measures

Below, we describe conservation measures in place for the alligator snapping turtle. While many efforts are directed to *Macrochelys* in general, we describe those that affect only the alligator snapping turtle.

Surveys

Many State agencies are conducting surveys for alligator snapping turtles to better understand the species' status. Additionally, other organizations and universities are conducting monitoring and research projects that are ongoing or planned.

Captive Rearing and Release/Head-Starting

A captive breeding program at Tishomingo National Fish Hatchery in Oklahoma was initiated in 1999, to produce head-started alligator snapping turtles for reintroduction (Riedle et al. 2008a, p. 25). The program rears and releases small turtles to contribute to the conservation of the species by raising hatchling turtles to an age that increases their chance of survival. This program has successfully released alligator snapping turtles since 2002 to the present in areas where populations have been lost or are declining. Many of the turtles are monitored after release to provide information about the life history of the species. From 2008 to 2010, 246 head-started juveniles (3 to 7 years old) were released in the Caney River in northeastern Oklahoma and were monitored until 2012; 59 percent of released turtles survived (Anthony et al. 2015, pp. 44–47).

In 2007, 249 adult turtles (confiscated from a turtle farm in violation of its permits) and 16 juveniles (from Tishomingo National Fish Hatchery) were released into seven sites in southern Oklahoma, and follow-up monitoring occurred during May through August in 2007 and 2008 (Moore et al. 2013, p. 141). There were only seven confirmed instances of mortality, all within the first year after release, resulting from drowning on trotlines, a gunshot wound, and other suspicious circumstances (Moore et al. 2013, p. 144). When viable nests were found during follow-up surveys, they were covered with a mesh predator exclusion device. Only one viable nest was found during 2007 or 2008, while 25 depredated nests were found, which nevertheless indicates that released adults survived and were reproducing (Moore et al. 2013, p. 144). Mean annual survivorship post-release was estimated to be 59 percent, 70 percent, and 100 percent for turtles aged 3, 4, and 5 at release, respectively (older turtles were not included in analysis due to low sample sizes) (Anthony et al. 2015, p. 46).

Head-starting, reintroduction, and monitoring of alligator snapping turtles were conducted between 2014 and 2016 in Illinois, Louisiana, and Oklahoma (Dreslik et al. 2017, entire). Released turtles included head-started juveniles, confiscations by law enforcement, classroom turtle-rearing programs, and other captive breeding programs (Dreslik et al. 2017, pp. 6, 13). Across three States (one site each in Oklahoma and Illinois, two sites in Louisiana), 548 turtles were released, the majority of which (465) were head-started at the Tishomingo National Fish Hatchery in Tishomingo, Oklahoma, and 372 of these were tracked using radiotelemetry (Dreslik et al. 2017, p. 22). Between 21.7 percent and 28.8 percent of released juveniles were confirmed dead within the first year, primarily from predation by raccoons, while 35.6 percent to 54.2 percent experienced radio transmitter failures and could not successfully be tracked (Dreslik et al. 2017, p. 19). The greatest predictors of survival for released juveniles were size at release, age, and time of year. Larger, older

turtles had higher survival rates than smaller, younger turtles, and survival was lower over winter than other seasons (Dreslik et al. 2017, pp. 22–25).

Repatriation Efforts

Repatriation of wild turtles serves to return illegally poached turtles to wild populations from the areas of origin. In July 2021, 30 alligator snapping turtles that were confiscated in a law enforcement case were released into their river basins of origin in eastern Texas. The turtles were illegally poached from Texas and transported to Louisiana. Texas Game Wardens and the Service's Office of Law Enforcement investigated the poaching and seized the turtles in 2016. This release was a collaborative effort including many organizations and agencies including the Service, Texas Parks and Wildlife Department, Stephen F. Austin State University, Sabine River Authority, Northeast Texas Municipal Water District, the U.S. Army Corps of Engineers, Houston Zoo, and the Turtle Survival Alliance, among others. Repatriation efforts like this one not only provide for the survival of the confiscated turtles, but also contribute to public awareness of the species and its threats.

Farming

Alligator snapping turtles are bred and raised in farming facilities for the purpose of supplying small turtles to collectors in the United States and abroad. The farming operations are permitted and regulated by States. Export of turtles is regulated through CITES Appendix III, requiring information such as the source of the turtles and other relevant information. Farm-raised turtles supplement the demand for domestic pet trade and international trade (*i.e.,* turtle meat for consumption and the pet trade), which may alleviate harvest pressure on wild individuals.

State and Federal Stream Protections

Structural features within the water are important components of the habitat for alligator snapping turtles. Submerged and partially submerged vegetation provide feeding and sheltering areas for all age classes. The structural diversity and channel stabilization created by instream woody debris provides essential habitat for spawning and rearing aquatic species (Bilby 1984, p. 609; Bisson et al. 1987, p. 143). Snag or woody habitat was reported as the major stable substrate in southeastern Coastal Plain sandy-bottom streams and a site of high invertebrate diversity and productivity (Wallace and Benke 1984, p. 1651). Wood enhances the ability of a river or stream ecosystem to use the nutrient and energy inputs and has a major influence on the hydrodynamic behavior of the river (Wallace and Benke 1984, p. 1643). One component of this woody habitat is deadhead logs, which are sunken timbers from historical logging operations. Deadhead logging is the removal of submerged cut timber from a river or creek bed and banks. However, some State regulations minimize the impact of deadhead logging on alligator snapping turtle; for example, some States regulate deadhead logging and allow it with a permit with variable conditions (*e.g.,* Alabama, Florida, and Louisiana). The removal of submerged logs is costly, complicated, and impacted by the complexity of the permitting process; thus, the rate at which deadhead logging occurs is variable.

Buffers and Permits—A buffer such as a strip of trees, plants, or grass along a stream or wetland naturally filters out dirt and pollution from rainwater runoff before it enters rivers, streams, wetlands, and marshes. This vegetation not only serves as a filter for the aquatic system, but the riparian cover influences microhabitat conditions such as instream water temperature and dissolved oxygen levels. These habitat conditions influence the distribution and abundance of alligator snapping turtle prey species and also directly affect alligator snapping turtles. Moderate temperatures and sufficient dissolved oxygen levels allow the turtles to remain stationary on the stream bottom for longer periods, increasing their ambush foraging opportunities. Loss of riparian vegetation and canopy cover result in increased solar radiation, elevation of stream temperatures, loss of allochthonous (organic material originating from outside the channel) food material, and removal of submerged root systems that provide habitat for alligator snapping turtle prey species (Allan 2004, pp. 266–267).

Some State regulations provide protections against impacts to the aquatic environment, and additional activities may implement recommended best management practices (BMPs) to reduce impacts. For example, forestry BMPs are effective with a high compliance rate (often 90 percent or better) across many of the States within the species' range that provide protections for buffer zones and riparian areas (Cristan et al. 2016, p. 4). Another example includes nutrient-reduction strategies to improve water quality (Louisiana Nutrient Reduction and Management Strategy 2020, entire).

Regulatory and Analytical Framework

Regulatory Framework

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the procedures for determining whether a species is an endangered species or a threatened species. The Act defines an ''endangered species'' as a species that is in danger of extinction throughout all or a significant portion of its range, and a ''threatened species'' as a species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The Act requires that we determine whether any species is an endangered species or a threatened species because of any of the following 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.

These factors represent broad categories of natural or human-caused actions or conditions that could influence a species' continued existence. In evaluating these actions and conditions, we look for those that may have a negative effect on individuals of the species, as well as other actions or conditions that may ameliorate any negative effects or may have positive effects.

We use the term ''threat'' to refer in general to actions or conditions that are known to or are reasonably likely to negatively affect individuals of a species. The term ''threat'' includes actions or conditions that have a direct impact on individuals (direct impacts), as well as those that affect individuals through alteration of their habitat or required resources (stressors). The term ''threat'' may encompass—either together or separately—the source of the action or condition or the action or condition itself.

However, the mere identification of any threat(s) does not necessarily mean that the species meets the statutory definition of an ''endangered species'' or a ''threatened species.'' In determining whether a species meets either definition, we must evaluate all identified threats by considering the expected response by the species, and the effects of the threats—in light of those actions and conditions that will ameliorate the threats—on an

individual, population, and species level. We evaluate each threat and its expected effects on the species, then analyze the cumulative effect of all the threats acting on the species. We also consider the cumulative effect of the threats as well as those actions and conditions that will have positive effects on the species, such as any existing regulatory mechanisms or conservation efforts. The Secretary determines whether the species meets the definition of an ''endangered species'' or a ''threatened species'' only after conducting this cumulative analysis and describing the expected effect on the species now and in the foreseeable future.

The Act does not define the term ''foreseeable future,'' which appears in the statutory definition of ''threatened species.'' Our implementing regulations at 50 CFR 424.11(d) set forth a framework for evaluating the foreseeable future on a case-by-case basis. The term foreseeable future extends only so far into the future as the Service can reasonably determine that both the future threats and the species' responses to those threats are likely. In other words, the foreseeable future is the period of time in which we can make reliable predictions. ''Reliable'' does not mean ''certain''; it means sufficient to provide a reasonable degree of confidence in the prediction. Thus, a prediction is reliable if it is reasonable to depend on it when making decisions.

It is not always possible or necessary to define foreseeable future as a particular number of years. Analysis of the foreseeable future uses the best scientific and commercial data available and should consider the timeframes applicable to the relevant threats and to the species' likely responses to those threats in view of its life-history characteristics. Data that are typically relevant to assessing the species' biological response include species-specific factors such as lifespan, reproductive rates or productivity, certain behaviors, and other demographic factors.

Analytical Framework

The SSA report documents the results of our comprehensive biological review of the best scientific and commercial data regarding the status of the species, including an assessment of the potential threats to the species (Service 2021, entire). The SSA report does not represent a decision by the Service on whether the species should be proposed for listing as an endangered or threatened species under the Act. However, it does provide the scientific basis that informs our regulatory decisions, which involve the further application of standards within the Act and its implementing regulations and policies. The following is a summary of the key results and conclusions from the SSA report; the full SSA report can be found at Docket FWS–R4–ES–2021–0115 on *https://www.regulations.gov.*

To assess the alligator snapping turtle's viability, we use the three conservation biology principles of resiliency, redundancy, and representation (Shaffer and Stein 2000, pp. 306–310). Briefly, resiliency supports the ability of the species to withstand environmental and demographic stochasticity (for example, wet or dry, warm or cold years), redundancy supports the ability of the species to withstand catastrophic events (for example, droughts, large pollution events), and representation supports the ability of the species to adapt over time to long-term changes in the environment. In general, the more resilient populations there are that are spread across the range, the more redundancy it provides to the species. The more representation it has, the more likely it is to sustain populations over time, even under changing environmental conditions. Using these principles, we identify the species' ecological requirements for survival and reproduction at the individual, population, and species levels, and describe the beneficial and risk factors influencing the species' viability.

The SSA process can be categorized into three sequential stages. During the first stage, we evaluate an individual species' life-history needs. The next stage involves an assessment of the historical and current condition of the species' demographics and habitat characteristics, including an explanation of how the species arrived at its current condition. The final stage of the SSA involves making predictions about the species' responses to positive and negative environmental and anthropogenic influences. Throughout all of these stages, we used the best available information to characterize viability as the ability of a species to sustain populations in the wild over time. We use this information to inform our regulatory decisions.

Current Condition

To describe the species' current condition, we apply the conservation principles of resiliency, redundancy, and representation. Resiliency is measured at the population level to describe the ability to withstand stochastic disturbances. Delineating biological populations of the alligator snapping turtle is not feasible because of the large spatial extent of the geographic range and the patchy availability of relevant information across the entire range. In our analysis, we delineate the range of the species into seven individual analysis units as proxies for populations to describe variation in the resiliency component over time across the range for each unit. The seven analysis units are Alabama, Apalachicola, Northern Mississippi-East, Northern Mississippi-West, Southern Mississippi-East, Southern Mississippi-West, and Western.

The Alabama unit encompasses eastern Mississippi, western Alabama, and small parts of Louisiana and Florida. The main water bodies that currently support or historically supported alligator snapping turtles include, but are not limited to, the Alabama River, Pascagoula River, Pearl River, Jourdan River, Escambia River, and Perdido River.

The Apalachicola unit encompasses parts of the Florida panhandle, southeastern Alabama, and Georgia. The main water bodies that currently support or historically supported alligator snapping turtles include the Apalachicola River, Chipola River, Ochlockonee River, Flint River, Chattahoochee River, Choctawhatchee River, and associated permanent freshwater habitats.

Northern Mississippi-East unit encompasses parts of Missouri, Illinois, Indiana, Kentucky, and Tennessee. The main water bodies that currently support or historically supported alligator snapping turtles include the Mississippi River, Ohio River, Illinois River, and Tennessee River.

Northern Mississippi-West unit encompasses parts of Kansas, Oklahoma, Arkansas, and Missouri. The main water bodies that currently support or historically supported alligator snapping turtles include the Neosho River and Verdigris River.

The Southern Mississippi-East unit encompasses parts of Louisiana, Arkansas, Mississippi, Alabama, Tennessee, and Missouri. The main water bodies that currently support or historically supported alligator snapping turtles include the Mississippi River, Atchafalaya River, Red River, Ouachita River, Tensas River, Amite River, Tangipahoa River, and their affluents in Louisiana.

The Southern Mississippi-West unit encompasses parts of northeastern Texas, Oklahoma, Kansas, Missouri, Arkansas, and northwestern Louisiana. The main water bodies that currently support or historically supported alligator snapping turtles include the Arkansas River, Red River, Canadian

River, East Fork Cadron Creek, Black Lake Bayou, Cheechee Bay, Saline Bayou, Black Lake, Clear Lake, Saline Lake, Cane River Canal, Black River, Boggy Bayou, Grand Bayou, Crichton Lake, Coushatta Bayou, Smith Island Lake, Loggy Bayou, Bayou Pierre, Wallace Lake, Smithport Lake, and Bayou Lumbra.

The Western unit encompasses parts of eastern Texas and western Louisiana. The main water bodies that currently support or historically supported alligator snapping turtles include the Neches River, Red River, Sabine River, San Jacinto River, and Trinity River.

In analyzing the alligator snapping turtle's current condition, we evaluated the current abundance within each analysis unit as a measure for current resilience, along with information about current threats, conservation actions, and distribution serving as auxiliary information about the causes and effects of current versus historical abundances (Service 2021, pp. 32–59). In our efforts to obtain the best available scientific and commercial information for the SSA, we consulted species experts about current abundance, current threats, and a comparison of the current and historical distribution regarding areas for which they have knowledge and expertise. Despite the large amount of expertise in the expert team we queried, the responses indicate a high degree of uncertainty about current abundances in each analysis unit. The methods for collecting the information from the species' experts is provided in more detail in the SSA report (Service 2021, p. 32 and Appendix C).

The abundances, estimated densities, substantial threats, and distribution over time as depicted by range contraction are provided in Table 1, below.

TABLE 1—ALLIGATOR SNAPPING TURTLE ANALYSIS UNIT CURRENT RESILIENCY AS DESCRIBED BY ESTIMATED ABUNDANCE, PERCENTAGE OF ESTIMATED ABUNDANCE IN EACH UNIT, DENSITY EXPRESSED AS ESTIMATED ABUNDANCE PER 1,000 HECTARES OF OPEN WATER IN EACH UNIT, THREATS, AND STATES WITH RANGE CONTRACTION

Analysis unit	Estimated abundance (% total)	Density	Threats	Range contraction
Alabama	200,000 (55.37)	616.9	1. Adult harvest (legal and illegal)*. 2. Nest predation*. 3. Bycatch: Incidental hooking/hook ingestion*. 4. Habitat alteration.	
Apalachicola	45,000 (12.46)	281.3	1. Nest predation*. 2. Bycatch: Incidental hooking. 3. Habitat alteration. 4. Harvest (illegal).	
Northern Mississippi-East	212.5 (0.06)	1.0	1. Nest predation* 2. Habitat alteration.	Illinois, Tennessee, Kentucky, Missouri.
Northern Mississippi-West	500 (0.14)	4.7	1. Bycatch: Incidental hooking/hook ingestion* 2. Nest predation. 3. Habitat fragmentation. 4. Harvest (illegal).	Kansas.
Southern Mississippi-East	50,000 (13.84)	55.3	1. Harvest (legal and illegal)* 2. Nest predation*. 3. Bycatch: incidental hooking and drowning in nets. 4. Habitat fragmentation.	Tennessee.
Southern Mississippi-West	15,000 (4.15)	30.2	1. Bycatch: incidental hooking/hook ingestion* 2. Nest predation 3. Habitat fragmentation 4. Harvest (legal and illegal)*	Kansas, possibly Oklahoma.
Western	50,500 (13.98)	139.3	1. Nest predation*. 2. Bycatch: incidental hooking. 3. Habitat alteration. 4. Adult harvest (legal and illegal)*.	

*Denotes ''substantial'' threats, which refer to those threats estimated to reduce survival rates of an age class by 8 percent or more; legal and illegal harvest reduce adult survival, and nest predation reduces nest survival. To be considered substantial, the threat impacts more than 50 percent of the alligator snapping turtles in the unit. All information in the table was provided by experts with knowledge of the species and the area associated within the unit(s).

Our assessment of the current condition for alligator snapping turtle considers the current abundance, current threats, and conservation actions in the context of what is known about the species' historical range. To determine species-specific population and habitat factors along with threats and conservation actions acting on the species, data were available for some populations, and demographic parameters (*e.g.,* clutch size, survival of specific life stages) and threats from previous studies. Where data were unavailable to inform the model, species experts provided relevant information related to the analysis units for which each is familiar. To describe alligator snapping turtle's viability, we evaluated the ability of the populations within each unit to respond to stochastic events (resiliency) in each of the seven analysis units and the ability of the species to respond to catastrophic events (redundancy) and the adaptive capacity (representation) of the species as a whole.

We describe the species' resiliency of each analysis unit using the estimated abundances, distribution, and threats acting on the species (see Table 1, above). The abundance estimates presented were obtained from species experts with knowledge of the species in particular geographic areas; due to the wide range of the species and compiling information across the seven analysis units, there is a level of uncertainty with the precision of the estimates provided. Rangewide, the abundance of alligator snapping turtles is estimated to be between 68,154 and 1,436,825 (a range of 1,368,671 individuals). This enormous range in the estimated abundance illustrates the

high degree of uncertainty in abundances at local sites and the ability to extrapolate local abundance estimates to a much broader spatial scale. Within these bounds, the most likely estimate of rangewide alligator snapping turtle abundance is 361,213 turtles, with 55 percent of the turtles occurring in the Alabama analysis unit (Service 2021, pp. 47–48).

Just as the data to estimate current abundances are scarce, there is little information with which to make rigorous comparisons between current and historical abundances. Dramatic population depletions occurred in Louisiana, Alabama, Georgia, the Florida panhandle, and elsewhere in the range during the 1960s and 1970s, with information on the magnitude of changes coming from anecdotal observations by trappers (Pritchard 1989, pp. 74, 76, 80, 83). Since that time, commercial and recreational harvest has been banned in a large portion of the species' range (all States except Louisiana and Mississippi, where recreational harvest still occurs). There are limited data available describing how populations have responded to reduced harvest pressure. Population dynamics in Georgia, Arkansas, and Oklahoma suggest that the population in East Fork Cadron Creek, Arkansas (Howey et al. 2013, entire), and Big Vian Creek, Oklahoma (East et al. 2013, entire), are still in decline. Twenty-two years after commercial harvest ended, surveys conducted during 2014 and 2015 in Georgia's Flint River reveal no significant change in abundance since 1989 surveys (King et al. 2016, p. 583). A similar study in Missouri and Arkansas detected population declines between the initial survey period in 1993–1994 and repeated surveys in 2009, over a decade after State-level protections were implemented (Lescher et al. 2013, pp. 163–164). At Sequoyah National Wildlife Refuge in Oklahoma, an alligator snapping turtle population declined between 1997–2001 and 2010–2011 (Ligon et al. 2012, p. 40). However, an additional study in Arkansas spanning 20 years documents an increase in abundance of both adult male and female alligator snapping turtles within Salado Creek (Trauth et al. 2016, p. 242).

Because the size and amount of suitable habitat within each unit vary greatly, density is calculated using the estimated abundance and the area of open water within each analysis unit; this calculation results in the estimated number of turtles per 1,000 ha (2,471 ac) of open water in the unit (as delineated by the 2016 National Land Cover Database; Yang et al. 2018, entire) (see Table 1, above).

Note that these are rough densities meant only to correct abundances for analysis unit size so that units can be more appropriately compared relative to each other; they are not intended to serve as actual estimates of density in alligator snapping turtle habitat. Because of the variation in analysis unit size and limitations in calculating true densities of alligator snapping turtles within units, we refrained from leaning heavily on comparisons of abundance or density between analysis units to summarize resilience other than to highlight general patterns. Resilience inherently increases with abundance and density; where there are more individuals, populations will have a greater ability to withstand stochastic demographic and environmental changes. Thus, in terms of the density as a demographic factor, resilience is highest in the core of the species' range, and lowest in the northernmost analysis units at the edge of the range. The southern portion of the species range within the Alabama, Apalachicola, Southern Mississippi- East, and Western units constitute the core areas for the species according to the percentage of the species' estimated abundance (Table 1).

We also consider the threats acting on the species within each unit. The current major threats acting on the alligator snapping turtle include fishing bycatch (including incidental hooking, hook ingestion, and drowning), harvest/collection, habitat loss and degradation, and nest predation. Other stressors acting on the species include disease, nest parasites, and the effects of climate change. Experts were consulted regarding information about the prevalence of negative and positive influences on viability in each analysis unit and were asked to provide an extent of occupied area in each analysis unit where alligator snapping turtles may be exposed to incidental hooking on trot and limb lines, commercial fishing bycatch, legal collection or harvest, illegal collection or harvest (poaching), and nest predation by subsidized or nonnative predators. Experts also provided the best available information regarding the spatial extent of the different threats. This includes the effects that commercial fishing bycatch, incidental hooking, hook ingestion, legal harvest, illegal harvest, and nest predation have on the survival of relevant life stages (adults, juveniles, hatchings, nests) in areas where the threat occurs.

The historical, large-scale removal of large, reproductive turtles from the population for commercial harvest continues to affect the species and its ability to rebound. Therefore, due to the historical and current threats, as described above, the species currently has the highest resiliency at the core of the species' range, where there are higher abundances of turtles. Harvest, both legal and illegal, is estimated to have the highest impact on adult survival rates, with harvest causing reductions in survival of 18 percent (most likely estimate) in some units. Commercial and recreational bycatch and hook ingestion are estimated to have lower impacts on adult survival, with most likely reductions in survival of 7 to 9 percent. The estimated impacts of threats on juvenile survival are lower than impacts to adult survival with most likely impacts of a 6 to 8 percent reduction in survival where commercial bycatch, incidental hooking, and hook ingestion occur, and a 6 to 7 percent reduction in survival from legal and illegal harvest where they occur. Hatchlings are not estimated to be heavily impacted by any of the threats we explored. Nest survival is estimated to be heavily impacted by nest predation by subsidized or nonnative predators (*e.g.,* raccoons, fire ants), with a most likely estimate of 58 percent reduction in survival.

Another resiliency factor informing the species' current condition is the comparison between the historical range and the current range (year 2000 to 2019). We compared the historical and current ranges of alligator snapping turtles by querying State biologists or those with access to the State's natural heritage program data. For each county or parish in their State, we asked for the current and historical status, and the date of the last confirmed record of alligator snapping turtles. Due to historical overharvest, habitat degradation and loss, and other threats in some areas of the species' range, the range has contracted in Illinois, Kansas, Kentucky, Missouri, Tennessee, and possibly in Oklahoma. These States are all on the fringe of the range, where conditions are likely marginal and more dynamic. The units affected include Northern Mississippi-East, Northern Mississippi-West, Southern Mississippi-East, and Southern Mississippi-West. Additional information regarding current condition descriptions and methodology used in the analysis are included in the SSA report (Service 2021, pp. 32–59).

Redundancy refers to the number and distribution of sufficiently resilient populations across a species' range, which provides protection for the species against catastrophic events that

impact entire populations. Due to the wide range of the species, it is unlikely that a catastrophic event would affect the entire species. When considering changes from historical conditions to current conditions, none of the seven analysis units across the species' range that we identified has been lost. All units remain extant and provide the ability to withstand catastrophic events.

Although the number of analysis units has not changed, redundancy for alligator snapping turtles has been reduced in terms of the distribution within analysis units, with range contractions in the northern portions of the species' range (Oklahoma, Kansas, Missouri, Illinois, Kentucky, and Tennessee). Within the core of the species' range, however, alligator snapping turtles still seem to be widely distributed, although there are many gaps in the spatial extent of surveys. While the distribution of the species encompasses much of its historical range, resilience within that range has decreased, largely from historical harvest pressures. With the range contractions and decreases in abundance, the Northern Mississippi-East analysis unit has decreased in resilience such that it is not a robust contributor to redundancy (only 212.5 estimated abundance of turtles, influenced largely by introductions).

Representation refers to the breadth of diversity within and among populations of a species, which allow it to adapt to changing environmental conditions. Because of this mismatch in scale between analysis units and biological populations, representation is described in terms of representative units and the resiliency units within each, under the assumption that representative units with higher abundances will be more able to contribute to future adaptation than those with lower abundances.

No representative units have been lost compared to the historical distribution. The Northern Mississippi representative unit, which adds diversity in life-history strategies within the species, currently has very low abundance within its two constituent analysis units relative to the other representative units, with an estimated 712.5 alligator snapping turtles total and a shrinking range. However, alligator snapping turtles in Illinois have been introduced from Southern Mississippi breeding stock, diluting the presence of unique genetic characteristics in the Northern Mississippi representative unit.

In summary, the overall current condition of the species' viability is affected by the residual effects of historical overharvest, historical and ongoing impacts from incidental limb line/bush hook and recreational fishing bycatch and/or hook ingestion, harvest, nest predation, and the species' life history (*i.e.,* low annual recruitment and delayed sexual maturity). Because of these threats, and particularly the legacy effects of historical harvest, the overall current condition of the species is based on the resiliency of each analysis unit, the redundancy of these units across the range, and the representation across the range. Due to the variation in analysis unit size and limitations in calculating true densities of alligator snapping turtles within units, we refrain from leaning heavily on comparisons of abundance or density between analysis units to summarize resilience other than to highlight general patterns. Resilience increases with abundance and density; where there are more individuals, populations will have a greater ability to withstand stochastic demographic and environmental events. Thus, resilience is highest in the core of the species' range and lowest in the northernmost analysis units at the edge of the range. The trend in resiliency from historical to current conditions is declining because of the loss of reproductive females and the species' life history (long-lived, late age to sexual maturity, low intrinsic growth rate). With the reduction in available habitat in some areas of the range, redundancy has declined compared to historical conditions as the species has been extirpated in some counties or parishes. However, no representative units have been lost compared to the historical distribution, as the genetic lineages across the representative units are still represented across the species' range.

Future Condition

To evaluate the species' future viability, we constructed a stage-structured matrix population model to project the population dynamics into the future and incorporated information from the literature, as well as information elicited on current abundance and the threats acting on the species (described above). In that model, we apply six plausible scenarios that factor in the estimated abundance and threats acting on the species to project the future resiliency of the species. Three scenarios consider conservation actions to be implemented, while the remaining three scenarios project conditions with no conservation actions. No specific endpoint for modeling was chosen at the outset; rather, the endpoint was selected after trajectories were generated, and it became clear that extending the projection further was unnecessary because the species is extirpated under all scenarios at a certain point.

In developing the future conditions scenarios described above, we used the best available information from the literature to parameterize a population matrix and elicited data from species experts to quantify stage-specific initial abundance, the spatial extent of threats, and threat-specific percent reductions to survival. To account for potential uncertainty in the effects of each threat, the six future scenarios are divided along a spectrum: Threat-induced reductions to survival are decreased by 25 percent, are unaltered, or are increased by 25 percent. To simulate conservation actions, the spatial extent of each threat is either left the same or reduced by 25 percent. We used a fully stochastic projection model that accounted for uncertainty in demographic parameters to predict future conditions of the alligator snapping turtle units under the six different scenarios. We derived a series of summary statistics to evaluate population trends and identify potential variation among analysis units and alternative scenarios. We define an extirpation event as the total population (juveniles + adults) declining to zero individuals, whereas a decline to less than 5 percent of the starting population size is considered quasi-extirpation. We applied 5 percent because it accounts for the effects of small population size and it also represents the result of a potential catastrophic population decline (Service 2021, p. 163).

Experts provided information regarding the following threat-related quantities: Percent reduction to stage-specific survival rates attributed to each threat and the spatial extent of each threat within their analysis unit(s) of expertise. Thus, reductions in survival rates attributed to each threat are assumed to be the same across all analysis units, although the spatial extent of each threat (*i.e.,* the proportion of the alligator snapping turtles exposed to the threat) varies among analysis units. For example, ingesting a fishing hook would be expected to produce the same percent reduction in survival across the entire range, although the probability that an individual alligator snapping turtle encounters that threat would vary among analysis units. However, we determined that legal collection likely violated this assumption, as regulations for legal alligator snapping turtle collection differ among States (LDWF 2019a, unpaginated; MFWP 2019, unpaginated). Therefore, we decided to model the effects of legal collection as a direct reduction in juvenile and adult

abundances (Service 2021, Appendix E) that varied across analysis units, rather than a reduction to demographic parameters. For each analysis unit, we calculated threat-adjusted survival rates, accounting for reductions in stage-specific survival rates resulting from the percent reduction in survival expected from a given threat multiplied by the spatial extent of the threat, for each threat occurring in a given analysis unit. Lastly, to reflect spatial heterogeneity in threat occurrence and overlap within each analysis unit, we calculated a weighted average of each survival parameter, based on the probable occurrence and overlap of all possible threat combinations (Service 2021, Appendix E).

We built scenarios around the potential uncertainty regarding: (a) The magnitude of the impact of threats on survival rates, and (b) the presence or absence of conservation actions. To capture the variability in the potential input for each threat, uncertainty is considered and applied directly to the model. First, we define three different ''threat levels'' by adjusting the demographic effect of each threat (percent reduction in stage-specific survival) up and down 25 percent relative to the compiled expert elicitation responses. In addition to legal collection (as mentioned above), the only exceptions to this structure are subsidized nest predators, in which the percent reduction to nest survival remains the same across all threat levels. These three levels reflect that there is a great deal of uncertainty in the impact that each threat has on survival rates and allows us to explore what the future condition might be if the mean estimates of threat magnitude either underestimate or overestimate the true impacts by 25 percent.

Next, we defined conservation action either as absent or present in the future. Where present, conservation action is modeled to reduce the spatial extent of threats (proportion of analysis unit exposed to threat) by 25 percent. This led to six different scenarios of expert-elicited threats, decreased threats, or high threats, with conservation action absent or present. The conservation scenarios reduce the spatial extent of threats rather than their magnitude. For example, the ''Decreased Threats +'' scenario takes into consideration reduced survival rate impacts by 25 percent and also the spatial extent of threats decreasing by 25 percent compared to the conservation-absent scenario of each analysis unit, relative to the mean expert-elicited quantities. Also note that only the means for survival rate impacts and spatial extent of threats, and not the standard deviations, are adjusted across the different scenarios.

Conservation actions that could decrease the spatial extent of threats include, but are not limited to, increased enforcement or law enforcement presence to reduce poaching or bycatch on illegally set trot or limb lines, increasing the size of protected areas that prohibit recreational fishing or certain gear (*e.g.,* trotlines, hoopnets), additional harvest restrictions in some areas, and management actions that reduce the densities of nest predators. The actual amount that any of these actions would influence the prevalence of threats will depend on factors like the time, money, personnel, and conservation partners available, but we selected a 25 percent reduction in the spatial extent of threats to explore how much a change of that amount affected future population dynamics. Conservation scenario outcomes show us that conservation actions (if applied) do not alter the basic trajectory of the declines.

Note that the threat level scenarios (expert-elicited, decreased, increased) vary in the magnitude of the impact of threats on survival where they occur, reflecting uncertainty in their true values. Conversely, the conservation scenarios (absent or present) vary in the spatial extent (the proportion of the population within the analysis unit exposed to the threat) of threats rather than their magnitude. For example, in either ''Expert-Elicited Threats'' scenario, the survival rate where recreational bycatch occurs is expected to remain the same whether conservation actions are present or absent, but in the ''Expert-Elicited Threats +'' scenario, the spatial extent of any given analysis unit exposed to recreational bycatch is reduced by 25 percent compared to the conservation-absent scenario. Also note that only the means for survival rate impacts and spatial extent of threats, and not the standard deviations, are adjusted across the different scenarios.

Our modeling framework also incorporates three effects believed to influence alligator snapping turtle demography that are not incorporated into scenarios as described above: Legal collection, head-start and adult releases, and habitat loss. Unlike the threat-specific reductions in survival rates, these effects are consistent across all future condition scenarios, although they are subject to stochastic variation among iterations and time steps. The effects from legal collection and head-start releases are applied directly to the estimated stage-specific abundances at the beginning of each time step. Habitat loss is incorporated into the model through the adult fecundity element of the transition matrix where its effect depends on total abundance.

Legal Collection

Regulations for legal collection differ among States, which do not align with analysis units (LDFW 2019a, unpaginated; MFWP 2019, unpaginated). Therefore, we decided to model the effects of legal collection as an annual reduction in abundance that varies across analysis units, rather than a reduction in survival rates. Collection of alligator snapping turtles is legal only in Mississippi and Louisiana. Legal collection in Mississippi is not incorporated into the model because the harvest restrictions (>24 in (61 cm) carapace length) functionally exclude females, which typically do not exceed 19.7 in (50 cm) in carapace length (Folt et al. 2016, p. 24), and thus would have had no effect on our female-only population model. In Louisiana, current regulations allow for any angler with a freshwater fishing license to take one alligator snapping turtle of any size per day (LDWF 2019b, unpaginated). Within our modeling framework, we restrict the effects of legal collection to the two modeled analysis units that overlap geographically with Louisiana: Southern Mississippi-East and Alabama. The annual reduction in abundance due to legal collection in these analysis units is based on using freshwater fishing license and specialty permit sales for wire traps and hoopnets (often used to catch turtles) from 2012–2017 as an index of take (LDWF 2019b, unpaginated), and the proportion of each analysis unit that overlaps Louisiana (Service 2021, Appendix E).

Captive Breeding for Conservation/ Head-Starts and Adult Releases

Several States within the alligator snapping turtle's range have initiated head-start release programs, in which alligator snapping turtles are raised for several years in captivity and then released into the wild population as juveniles (Dreslik et al. 2017, p. 13). Similarly, States also opportunistically release adult alligator snapping turtles confiscated from illegal activities (*e.g.,* poaching) into wild populations. We include juvenile and adult releases within the model, but only for the first 10 time steps within an iteration, to avoid having alligator snapping turtle population persistence be contingent on head-start activities (*i.e.,* conservation-dependent). We parameterized the releases in the model based on statistics from Illinois (Dreslik et al. 2017, p. 13):

juvenile females: ~30 individuals/year; adult females: ~12 individuals/year. The mean number of releases does not vary among analysis units or scenarios, but because of the uncertainty and variability in the simulations, the specific value drawn for each year in each unit in each iteration varies. Specifically, for the first 10 time steps of each iteration, the number of released juveniles and adults are drawn from Poisson distributions that provide the probability of a certain event occurring over a fixed time or space.

Habitat Loss

We asked the species expert team to list habitat loss mechanisms within their analysis unit(s) of expertise. After adjusting for linguistic differences among responses (*e.g.,* ''desnagging'' and ''removal of large woody debris'' are two answers that reflect the same mechanism), we summarized the number of unique habitat loss mechanisms within each analysis unit and calculated the mean across experts. We imposed a population ceiling (*i.e.,* carrying capacity) that was annually reduced by a habitat loss rate, which equaled the mean number of unique threats in the unit, divided by 100. The initial population ceiling was determined based on the summarized expert elicitation values for the maximum possible number of alligator snapping turtles currently within the analysis unit, after adjusting for sex ratios and presence of hatchlings in the estimate. Thus, the population ceiling for each analysis unit at each time step was calculated deterministically and was not subject to stochastic variation across simulation iterations. To incorporate the effects of habitat loss on alligator snapping turtle demography within the model, we included a function that set adult fecundity to zero if total abundance (juveniles and adults) in any time step exceeded the population ceiling. While this function is included in the model, abundances are so far below population ceilings that the effect of habitat loss does not have an impact on modeling results (Service 2021, Appendix E).

Additional Model Descriptions

We must keep in mind the limitations of this model when interpreting the results. The precision and accuracy of model outputs depend heavily on the precision and accuracy of the information going into a model. In the case of the alligator snapping turtle, there is a large amount of uncertainty in the information that went into the model, including estimates of current abundance, age class proportions, impact of threats on stage-specific demographic rates, spatial extent of threats, and variability of these metrics across and within analysis units. We relied heavily on expert elicitation to obtain these values. Wherever possible, the uncertainty in these values is incorporated into the model structure itself, but others we were unable to address; for example, the assumptions we had to make that baseline demographic rates are largely uniform across the range of the species. Future modeling efforts would be greatly improved with further study into these aspects of the alligator snapping turtle's biology, demography, and response to (and prevalence of) threats, as well as how these threats vary across the range of the species.

We also acknowledge an ongoing concern raised with regard to the model used is that it does not match the published estimates of the population growth model (Folt et al. 2016, entire) and conflicts with the perceived stability of alligator snapping turtle populations from some catch-per-unit-effort studies for this species. First, Folt et al. (2016) resulted from a population without several of the threats explored in this model. In addition a few errors have been corrected since its publication which resulted in a change in the prediction of a population growing at 3% annually to one that was declining 3% annually. With regard to CPUE data, it is generally used for relative abundance and was not appropriate for use in this modeling effort. In addition, while there were published parameter estimates and data to inform survival, egg production and nest survival, modelers had to use expert elicitation to parameterize the spatial extent of threats and the effect of the threats on population demographics. However, estimates of variance for many elicited parameters are small, suggesting that the experts generally agree with each other, even though the values were elicited independently from each expert.

Below, Table 2 presents the six plausible scenarios that factored in the estimated abundance and threats acting on the alligator snapping turtle to project the future resiliency of the species. Tables 3 and 4 present the results of the model depicting the future condition of each of four analysis units; Table 3 shows conservation-absent scenarios, while Table 4 shows conservation-present scenarios. In both Tables 3 and 4, for each scenario, we calculated the probability of extirpation and quasi-extirpation as the proportion of the 500 replicates in which the total population (adults and juveniles) declined to zero or less than 5 percent of the starting population size, respectively. For only those replicates in which the population reached extirpation or quasi-extirpation, we then calculated the mean number of years until those thresholds were reached to represent the time to quasi-extirpation or time to extirpation, respectively. Mean quantities and their standard deviations are listed with the range (minimum and maximum quantity observed across all replicates) given in parentheses. An asterisk (*) indicates only a single simulation crossed the threshold, precluding a standard deviation calculation.

TABLE 2—DESCRIPTION OF SIX FUTURE SCENARIOS MODELED FOR THE ALLIGATOR SNAPPING TURTLE'S ANALYSIS UNITS

[Scenario names are given in quotation marks]

	Conservation absent	Conservation present
Decreased Threat Magnitude	''*Decreased Threats*'' Impact of threats: *Reduced 25 percent* Spatial extent of threats: *Expert-elicited.*	''*Decreased Threats +* '' Impact of threats: *Reduced 25 percent.* Spatial extent of threats: *Reduced 25 percent.*
Expert-Elicited Threat Magnitude	''*Expert-Elicited Threats*'' Impact of threats: *Expert-elicited.* Spatial extent of threats: *Expert-elicited.*	''*Expert-Elicited Threats +* '' Impact of threats: *Expert-elicited.* Spatial extent of threats: *Reduced 25 percent.*
Increased Threat Magnitude	''*Increased Threats*'' Impact of threats: *Increased 25 percent* Spatial extent of threats: *Expert-elicited.*	''*Increased Threats +* '' Impact of threats: *Increased 25 percent.* Spatial extent of threats: *Reduced 25 percent.*

TABLE 3—PROBABILITY AND TIME TO EXTIRPATION AND QUASI-EXTIRPATION FOR ALLIGATOR SNAPPING TURTLES FOR CONSERVATION-ABSENT SCENARIOS WITH THREE DIFFERENT THREAT LEVELS

(Decreased, expert-elicited, and increased)

Threat level	Probability of quasi-extirpation	Time to quasi-extirpation (years)	Probability of extirpation	Time to extirpation (years)
Conservation Absent				
Alabama Unit:				
Decreased	1	17.68 ± 2.27 (12, 29)	0.13	48.91 ± 2.09 (43, 51)
Expert-Elicited	1	14.20 ± 1.6 (10, 20)	0.846	45.64 ± 3.36 (36, 51)
Increased	1	12.11 ± 1.35 (8, 16)	1	40.19 ± 3.47 (30, 51)
Apalachicola Unit:				
Decreased	0.99	33.11 ± 6.09 (19, 51)	0.004	49.5 ± 0.71 (49, 50)
Expert-Elicited	1	26.28 ± 4.65 (16, 47)	0.124	49.02 ± 2.05 (44, 51)
Increased	1	21.21 ± 3.25	0.66	46.82 ± 3.15
Northern Mississippi-East Unit:				
Decreased	0.02	45.90 ± 4.01 (38, 51)	0	
Expert-Elicited	0.016	48.00 ± 4.11 (39, 51)	0	
Increased	0.024	45.42 ± 3.42 (41, 51)	0	
Southern Mississippi-East Unit:				
Decreased	1	17.69 ± 2.40 (11, 29)	0.434	49.45 ± 1.92 (43, 51)
Expert-Elicited	1	14.89 ± 1.75 (10, 22)	0.95	47.49 ± 2.84 (39, 51)
Increased	1	12.97 ± 1.39 (9, 18)	0.998	44.92 ± 3.87 (33, 51)

TABLE 4—PROBABILITY AND TIME TO EXTIRPATION AND QUASI-EXTIRPATION FOR ALLIGATOR SNAPPING TURTLES FOR CONSERVATION PRESENT SCENARIOS WITH THREE DIFFERENT THREAT LEVELS

[Decreased, expert-elicited, and increased]

Threat level	Probability of quasi-extirpation	Time to quasi-extirpation (years)	Probability of extirpation	Time to extirpation (years)
Conservation Present (+)				
Alabama Unit:				
Decreased	1	22.84 ± 3.20 (14, 33)	0.002	*51 ± (51, 51)
Expert-Elicited	1	17.91 ± 2.27 (13, 26)	0.114	49.14 ± 2.23 (40, 51)
Increased	1	15.11 ± 1.72 (12, 23)	0.658	47.21 ± 2.76 (40, 51)
Apalachicola Unit:				
Decreased	0.98	32.44 ± 6.1 (20, 51)	0	
Expert-Elicited	1	32.04 ± 5.79 (18, 51)	0.006	50.67 ± 0.58 (50, 51)
Increased	1	26.22 ± 4.75	0.052	48.92 ± 1.94
Northern Mississippi-East Unit:				
Decreased	0.038	48.21 ± 2.90 (42, 51)	0	.....
Expert-Elicited	0.036	46.72 ± 3.39 (39, 51)	0.002	*51.00 ± (51, 51)
Increased	0.02	46.60 ± 2.50 (42, 50)	0	.....
Southern Mississippi-East Unit:				
Decreased	1	20.9 ± 3.34 (14, 35)	0.058	49.45 ± 1.92 (43, 51)
Expert-Elicited	1	17.74 ± 2.34 (12, 26)	0.476	47.49 ± 2.84 (39, 51)
Increased	1	15.74 ± 1.98 (11, 25)	0.856	44.92 ± 3.87 (33, 51)

Alabama Analysis Unit

The Alabama analysis unit provides habitat for more than half (55.37 percent) of the entire estimated alligator snapping turtle abundance; however, the total abundance in the Alabama analysis unit is predicted to decline over the next 50 years in all scenarios. Predicted declines are more rapid the higher the threat level and are slightly mediated by conservation actions. Compared to initial abundances, after the first 10 years of the simulation, the mean abundance within the unit is predicted to decline by 75–83 percent under decreased threat scenarios, 83–90 percent under expert-elicited threat scenarios, and 88–93 percent under increased threat scenarios (see Tables 3 and 4, above). Halfway through the simulation, after 25 years, the mean abundance is predicted to decline by 97–100 percent compared to the initial abundance across all six scenarios, with declines of 100 percent (extirpation) after 50 years (Service 2021, Appendix E).

Although abundance declined in all scenarios, the probability of extirpation within 50 years depends heavily on the threat levels and presence or absence of conservation actions. Without conservation, the species is unlikely to be extirpated in this unit within 50 years under the ''Decreased Threats'' scenario, likely to be extirpated under the ''Expert-Elicited Threats'' scenario, and virtually certain to become extirpated under the ''Increased Threats'' scenario (see Table 3, above). With conservation, the species is exceptionally unlikely to be extirpated under the ''Decreased Threats +'' scenario, unlikely to be extirpated under the ''Expert-Elicited Threats +'' scenario, and about as likely as not to be extirpated under the ''Increased Threats +'' scenario (see Table 4, above). While the likelihood that the species will become extirpated from the Alabama analysis unit varies by scenario, quasi-extirpation where abundances fell below 5 percent of current levels is virtually certain in all

scenarios. In scenarios where the probability of extirpation is about as likely as not, extirpation occurs on average after 40–51 years, with quasi-extirpation occurring much sooner in 12–23 years. Predicted time to quasi-extirpation averages 18–22 years under the decreased threats scenarios, 14–18 years under the expert-elicited threats scenarios, and 12–15 years under the increased threats scenarios, with the upper bound of each time period range predicted when conservation actions are present.

Apalachicola Analysis Unit

The Apalachicola analysis unit is included in part of the species' core area and includes around 12 percent of the entire estimated abundance of the species; however, the total abundance in the Apalachicola analysis unit is predicted to decline over the next 50 years in all scenarios. Predicted declines are more rapid the higher the threat level and are slightly mediated by conservation actions (Service 2021, Appendix E). Compared to initial abundances, after the first 10 years of the simulation, the mean abundance within the unit is predicted to decline by 55–64 percent under decreased threats scenarios, 65–74 percent under expert-elicited threats scenarios, and 72–82 percent under increased threats scenarios. Halfway through the simulation after 25 years, mean abundance is predicted to decline by 90–99 percent compared to initial abundance across all six scenarios and is predicted to decline by 99–100 percent after 50 years in all scenarios (Service 2021, Appendix E).

Although abundance declined in all scenarios, the probability of extirpation within 50 years depends heavily on the threat levels and presence or absence of conservation actions. Without conservation, the species is exceptionally unlikely to be extirpated in this unit within 50 years under the ''Decreased Threats'' scenario, unlikely to be extirpated under the ''Expert-Elicited Threats'' scenario, and likely to become extirpated under the ''Increased Threats'' scenario (see Table 3, above). With conservation, the species is exceptionally unlikely to be extirpated under the ''Decreased Threats +'' scenario and the ''Expert-Elicited Threats +'' scenario, and very unlikely to be extirpated under the ''Increased Threats +'' scenario (see Table 4, above). In scenarios where the probability of extirpation is about as likely as not, when extirpation does occur, it is on average around the 47-year mark. In the conservation-absent scenarios, quasi-extirpation is very likely to occur within 26–33 years. While the likelihood that the species will become extirpated in the Apalachicola analysis unit varies by scenario and ranges between likely to exceptionally unlikely, quasi-extirpation, where abundances fell below 5 percent of current levels, is very likely to virtually certain to occur with or without conservation actions within 50 years in all scenarios (see Tables 3 and 4, above).

Northern Mississippi-East Analysis Unit

The Northern Mississippi-East analysis unit currently supports the fewest alligator snapping turtles (0.06 percent) of any other unit across its range. Because of ongoing conservation efforts with turtle releases occurring in the Northern Mississippi-East analysis unit, alligator snapping turtle abundances in this unit are predicted to increase for the next decade because of the population augmentation efforts, but at 50 years in all scenarios, the population is predicted to decline to a mean of fewer than 51 females (Service 2021, pp. 72–74, Appendix E). Predicted declines are consistent across scenarios with and without conservation; however, the rate of decline is lower in the Northern Mississippi-East analysis unit (Service 2021, Appendix E). Compared to initial abundances, after the first 10 years of the simulation, mean abundance is predicted to increase by at least 200 percent across every scenario. By halfway through the simulation after 25 years, mean abundances are predicted to fall but remain over 32 percent higher than initial abundances. By the end of the 50-year simulation, however, abundances are predicted to decline by 47–51 percent compared to initial abundances in the scenarios without conservation actions, and 44–48 percent in the scenarios with conservation actions (Service 2021, Appendix E).

Although abundance eventually declines in all scenarios after initial increases, the species is exceptionally unlikely to very unlikely to be extirpated in this unit within 50 years under any modeled scenario (Service 2021, p. 74). Quasi-extirpation is similarly very unlikely to occur in any scenario; however, abundance continues to decline beyond 50 years.

Southern Mississippi-East Analysis Unit

The Southern Mississippi-East analysis unit includes around 14 percent of the total estimated abundance of the species; however, the total abundance in the Southern Mississippi-East analysis unit is predicted to decline over the next 50 years in all scenarios (Service 2021, pp. 70–72). Predicted declines are more rapid the higher the threat level and are slightly mediated by conservation actions (Service 2021, Appendix E). Compared to initial abundances, after the first 10 years of the simulation, mean abundance is predicted to decline by 76–82 percent under decreased threats scenarios, 83–88 percent under expert-elicited threats scenarios, and 87–92 percent under increased threats scenarios (see Tables 3 and 4, above). Halfway through the simulation, after 25 years, mean abundance is predicted to decline by 95–100 percent compared to initial abundance across all six scenarios (Service 2021, Appendix E).

Although abundance declines in all scenarios, the probability of extirpation within 50 years depends heavily on the threat levels and presence or absence of conservation actions. Without conservation, the species is unlikely to be extirpated in this unit within 50 years under the ''Decreased Threats'' scenario, likely to be extirpated under the ''Expert-Elicited Threats'' scenario, and very likely to become extirpated under the ''Increased Threats'' scenario (see Table 3, above). With conservation, the species is exceptionally unlikely to be extirpated under the ''Decreased Threats +'' scenario, very unlikely to be extirpated under the ''Expert-Elicited Threats +'' scenario, and about as likely as not to be extirpated under the ''Increased Threats +'' scenario (see Table 4, above). While the likelihood that the species will become completely extirpated within this unit varied by scenario, quasi-extirpation where abundances fell below 5 percent of current levels is virtually certain in all scenarios within the next 13–21 years. Predicted time to quasi-extirpation averages 18–21 years under the decreased threats scenarios, 15–18 years under the expert-elicited threats scenarios, and 13–16 years under the increased threats scenarios, with the lower bound of each range predicted when conservation actions are present.

The Western, Southern Mississippi-West, and Northern Mississippi-West analysis units are not included in the future simulation modeling because we do not have adequate input data. However, we have no evidence that alligator snapping turtle demographic trends in response to threats in these analysis units would behave dramatically differently from the range of analysis units that we did model. While we do not have precise abundance estimates in the future or probabilities of extirpation or quasi-extirpation, it is likely that alligator snapping turtles in these analysis units will decline along similar trajectories as

the modeled analysis units, meaning they likely face a high probability of quasi-extirpation within the next 30–50 years.

In summary, alligator snapping turtle abundance was shown to decline drastically over the next 30 to 50 years in all analysis units that are included in the model (Alabama, Apalachicola, Northern Mississippi-East, and Southern Mississippi-East) across all scenarios. The model projects out past 50 years; however, the declining abundance trends drop so low within 50 years, there was no need to project beyond that time period. The future conditions projections, which include three conservation-based scenarios, indicate a 95 percent decline in 50 years and quasi-extirpation in approximately 30 years under even the most optimistic scenario.

Resilience is expected to drastically decline across all analysis units under all scenarios. We modeled scenarios that reflected uncertainty in the impact of threats on alligator snapping turtle demography, and all threat levels (decreased, expert-elicited, and increased) produced mean growth rates (lambda) indicating population decline. Predicted abundances are likely to very likely to virtually certain to drop below 5 percent of current abundances within 12–50 years under all scenarios in the Southern Mississippi-East, Alabama, and Apalachicola analysis units (Service 2021, pp. 78–82). The only analysis unit for which quasi-extirpation is not consistently likely is the Northern Mississippi-East analysis unit. Although the risk of quasi-extirpation is lower in this analysis unit than the others, this is in part an artifact of the way that quasi-extirpation thresholds are defined, as a percentage of the initial abundance. In terms of raw abundance, the Northern Mississippi-East analysis unit is predicted on average to support fewer than 51 female alligator snapping turtles (as we used a female-only demographic model) with or without conservation actions. Thus, even though quasi-extirpation risks are lower than other analysis units, the predicted abundances for this unit still indicate that alligator snapping turtles will become very rare or disappear from this analysis unit.

Time to quasi-extirpation varies across analysis units and scenarios (conservation absent–conservation present), but in general, the first analysis unit likely to reach the quasi-extirpation threshold is the Alabama unit (12–22 years), followed by the Southern Mississippi-East unit (after an average of 14–25 years depending on the scenario), the Apalachicola unit (21–33 years), and finally the Northern Mississippi-East unit, where quasi-extirpation is not likely to occur within the 50-year time frame.

After 50 years, the mean female abundance in any given analysis unit is not predicted to exceed 133 individuals in any scenario. As we did for the current condition, we scaled future predicted abundances (after 25 years and after 50 years of the simulation) to the area of open water in each analysis unit to aid in comparing abundances among units of different sizes.

Resilience refers to the ability of populations (or, in our case, analysis units, as we are unable to delineate populations with currently available information) to withstand stochastic disturbances (*e.g.,* demographic, environmental stochasticity). Abundance is central to resilience, as small populations are more vulnerable to perturbations than larger populations. We compiled the best information available about alligator snapping turtles, their demographic rates, and threats, and the resulting simulation model predicts dramatic declines in abundance, and thus resilience, over the next 50 years across all analysis units. Abundances in nearly every analysis unit are predicted to decline by more than 95 percent, resulting in drastically lowered abilities of populations to withstand stochastic events, if alligator snapping turtle populations persist at all.

Most of the threats described in the SSA report (Service 2021, pp. 17–21) (hook ingestion, illegal collection, etc.) are factors that affect adult or juvenile survival, and so large changes in population growth and predicted future abundance are expected to occur when those effects are incorporated into the model. For example, experts indicated that hook ingestion is likely to negatively affect adult survival and could cause up to 8 percent decline in survival rate in areas where trotline and other fishing activities are allowed, dropping survival from 95 percent to 87 percent. That one threat alone changes the trajectory of the population from stable or increasing to rapidly declining, as a result of the cumulative threats.

Future representation, referring to the ability of the species to adapt to changing environmental conditions over time, is similarly predicted to decline rapidly as alligator snapping turtles in every representative unit decline in abundance to quasi-extirpation or true extirpation. The loss of alligator snapping turtles across all representative units would represent losses in genetic diversity (two broad genetic lineages), life-history diversity along a north-south gradient, and finer scale genetic differences among drainages within the larger genetic lineages.

Future redundancy, or the ability to withstand catastrophic events, for alligator snapping turtles is expected to decline drastically over the next 50 years. Our future simulation model operates at the scale of the analysis unit and is limited to the units for which data are available, so we cannot provide precise predictions about which States or counties are most likely to lose or retain alligator snapping turtle biological populations in the future. While accounting for uncertainty with the magnitude of threats at the analysis unit scale, all units are predicted to lose resiliency at such a high rate that no analysis unit will remain across the landscape to contribute to redundancy. Where alligator snapping turtles persist in the future, they are predicted to be rare and not found in adequately resilient groupings. Analysis units are predicted to reach quasi-extirpation thresholds in some cases within the next two decades, with more units becoming quasi-extirpated each decade after that. The addition of conservation actions, or different assumptions about the impact of threats on alligator snapping turtle demography, alters the time to quasi-extirpation by about a decade at most, typically less. No scenarios result in stable or increasing redundancy within representative units or rangewide. The future condition analysis for the alligator snapping turtle is described in detail in the SSA report (Service 2021, pp. 59–84).

We note that, by using the SSA framework to guide our analysis of the scientific information documented in the SSA report, we have not only analyzed individual effects on the species, but we have also analyzed their potential cumulative effects. We incorporate the cumulative effects into our SSA analysis when we characterize the current and future condition of the species. To assess the current and future condition of the species, we undertake an iterative analysis that encompasses and incorporates the threats individually and then accumulates and evaluates the effects of all the factors that may be influencing the species, including threats and conservation efforts. Because the SSA framework considers not just the presence of the factors, but to what degree they collectively influence risk to the entire species, our assessment integrates the cumulative effects of the factors and replaces a standalone cumulative effects analysis.

Determination of Alligator Snapping Turtle's Status

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the procedures for determining whether a species meets the definition of an ''endangered species'' or a ''threatened species.'' The Act defines an ''endangered species'' as a species that is in danger of extinction throughout all or a significant portion of its range, and a ''threatened species'' as a species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.

The Act requires that we determine whether a species meets the definition of ''endangered species'' or ''threatened species'' because of any of the following 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.

Status Throughout All of Its Range

When evaluating the species to determine if it is in danger of extinction throughout all of its range, we consider the threats acting on the species and the cumulative effects of those threats under the section 4(a)(1) factors. The current threats include harvest and collection (Factor B), nest predation (Factor C), habitat degradation and loss (Factor A), and hook ingestion and entanglement due to bycatch associated with freshwater fishing (Factor E). The current condition of the alligator snapping turtle, as discussed under Current Condition above, describes the species and the threats acting on the species such that it retains sufficient resiliency, redundancy, and representation to ensure the species is currently maintaining viability across its range.

The species is currently still relatively widespread, occurring throughout much of its historical range, and remains extant within all analysis units. Although some resiliency has been lost due to past and ongoing threats, sufficient resiliency remains across the seven analysis units, especially in the core of the range in the southern parts of the Alabama, Apalachicola, South Mississippi-East, and Western analysis units. There has been some range contraction in some of the fringe States, including Illinois, Kansas, Missouri, Oklahoma, and Tennessee where the species' resilience is lowest in the northernmost analysis units.

Despite the historical, large-scale commercial harvest in some areas and additional ongoing threats, the overall population across the current range is still large with an estimated 360,000 turtles (range of 68,000 to 1.4 million) (Service 2021, pp. 50). However, due to the delayed age of sexual maturity and a generation time of about 30 years, the species has been slow to recover from the historical harvest pressures. An example of the slow response is evident in a study conducted 22 years after alligator snapping turtle commercial harvest ended in Georgia; surveys conducted during 2014 and 2015 in Georgia's Flint River reveal no significant change in abundance since 1989 (King et al. 2016, entire). Thus, despite the prohibition of legal harvest of alligator snapping turtles in all States except Louisiana and Mississippi, the species has been slow to recover because it is a long-lived species with high nest predation and relatively low fecundity.

This past large-scale removal of large, adult turtles continues to affect the current demographics; however, successful reproduction is occurring. While the species is not currently impacted by commercial harvest, resiliency is lower than it was historically as a result of the loss of reproductive females, low juvenile survival, and the species' life-history traits (long-lived, late age to sexual maturity, low intrinsic growth rate). Regardless, the current estimated population size provides a sufficient contribution to the species' viability through successful reproduction that is adequate to sustain the populations across all units. Thus, after assessing the best available information, we conclude that the alligator snapping turtle is not currently in danger of extinction throughout all of its range.

To determine if the species is likely to become an endangered species within the foreseeable future throughout all of its range, we considered the threats that will affect the species in the future and the species' response to those threats. According to the description above under Future Condition, six scenarios are considered to project the threats acting on the species' viability over the next 50 years; however, the species will decline into extirpation or quasi-extirpation under all six scenarios within the next 30–50 years. We can reasonably predict the threats acting on the species and the species' response to those threats within the 30- to 50-year timeframe when extirpation within most of the analysis units is projected. Based on this information, we determined the appropriate timeframe for assessing whether this species is likely to become in danger of extinction in the foreseeable future is 30–50 years. While there is inherent uncertainty in the modeling, we have determined we can make reliable predictions as to the status of the alligator snapping turtle within this timeframe. As our framework for determining foreseeable future articulates, ''reliable'' does not mean ''certain;'' it means sufficient to provide a reasonable degree of confidence in the prediction. We have a reasonable degree of confidence in our status predictions, particularly because the species declines into extirpation or quasi-extirpation under even the most optimistic scenarios.

When evaluating the future viability of the species, we found that the threats currently acting on the species are expected to continue across its range into the future, resulting in greater reduction of the number and distribution of reproductive individuals and continued effects of subsidized nest predators on nest success and juvenile survival. This species is highly dependent upon adult female survival to maintain viability. Existing and ongoing threats affecting adult female survival are projected to reduce recruitment to an extent that the species will continue to decline in the foreseeable future. While there is uncertainty regarding the rate at which population declines will occur, the threats are projected to drive the species towards extinction unless reduced. Additionally, the resiliency of each analysis unit will continue to decline and further reduce the species' redundancy and representation into the future. The existing regulatory mechanisms are not adequate to protect the species from these threats (Factor D).

There are additional stressors including disease, nest parasites, and climate change impacts (elevated nest temperatures, increased flooding, increased water withdrawals, etc.). These secondary environmental stressors will have compounding impacts that further reduce the viability of the species in the foreseeable future.

Despite the implementation of the conservation actions described above under *Conservation Measures,* the delay in the species' response to historical over-harvesting indicates other factors may be acting on the species or additional conservation actions are needed. This is illustrated by the future conditions projections, which include three conservation-based scenarios and indicate a 95 percent decline in 50 years and quasi-extirpation in approximately

30 years under even the most optimistic scenario.

The best available information shows that the species' viability is expected to decline with projected quasi-extirpation of most units to occur within the next 30 years and within the next 50 years for the Northern Mississippi-East unit (Service 2021, pp. 78–79). Based on modeling results, which address uncertainty regarding the extent and severity of threats, resiliency is expected to decline dramatically under all scenarios. Regardless of whether the projected timeframe to quasi-extirpation is fully accurate, the projected loss of resiliency across the range of the species will place the alligator snapping turtle at risk of extinction within the foreseeable future across all of its range due to the inability of this species to effectively reproduce and maintain viability in the coming decades in light of ongoing threats.

Thus, after assessing the best available information regarding the threats acting on the species and the species' response as described in the future condition analysis (Service 2021, pp. 59–85), we conclude that the alligator snapping turtle is likely to become in danger of extinction within the foreseeable future throughout all of its range.

Status Throughout a Significant Portion of Its Range

Under the Act and our implementing regulations, a species may warrant listing if it is in danger of extirpation or likely to become so in the foreseeable future throughout all or a significant portion of its range. The court in *Center for Biological Diversity* v. *Everson,* 2020 WL 437289 (D.D.C. Jan. 28, 2020) (*Center for Biological Diversity*), vacated the aspect of the Final Policy on Interpretation of the Phrase ''Significant Portion of Its Range'' in the Endangered Species Act's Definitions of ''Endangered Species'' and ''Threatened Species'' (79 FR 37578; July 1, 2014) that provided that the Service does not undertake an analysis of significant portions of a species' range if the species warrants listing as threatened throughout all of its range. Therefore, we proceed to evaluating whether the species is endangered in a significant portion of its range—that is, whether there is any portion of the species' range for which both (1) the portion is significant; and (2) the species is in danger of extirpation in that portion. Depending on the case, it might be more efficient for us to address the ''significance'' question or the ''status'' question first. We can choose to address either question first. Regardless of which question we address first, if we reach a negative answer with respect to the first question that we address, we do not need to evaluate the other question for that portion of the species' range.

Following the court's holding in *Center for Biological Diversity,* we now consider whether there are any significant portions of the species' range where the species is in danger of extirpation now (*i.e.,* endangered). In undertaking this analysis for alligator snapping turtle, we choose to address the status question first. We consider information pertaining to the geographic distribution of both the species and the threats that the species faces to identify any portions of the range where the species is endangered.

The statutory difference between an endangered species and a threatened species is the time frame in which the species becomes in danger of extinction; an endangered species is in danger of extinction now while a threatened species is not in danger of extinction now but is likely to become so in the foreseeable future. Thus, we reviewed the best scientific and commercial data available regarding the time horizon for the threats that are driving the alligator snapping turtle to warrant listing as a threatened species throughout all of its range. We considered whether the threats are geographically concentrated in any portion of the species' range in a way that would accelerate the time horizon for the species' exposure or response to the threats. We examined the following threats: Harvest (legal and poaching), fishing bycatch (recreational and commercial), and nest predation. We also considered the cumulative effects acting on the species with additional stressors such as disease, nest parasites, and climate change.

After considering the threats acting on the species, we identified a concentration of threats in Mississippi and Louisiana due to legal harvest, albeit more limited in Mississippi. The three analysis units that overlap with these two States include the Alabama, Southern Mississippi-East, and Southern Mississippi-West units. The Alabama unit has the greatest abundance and density estimates of all seven analysis units, indicating this unit at the core of the range may be a stronghold for the species in terms of resiliency and contributing to the species' overall viability. The Alabama unit currently demonstrates high resiliency in comparison to the other units; however, due to the continued compounding effects of the threats acting on the species in the Alabama unit, resiliency will decline in the future.

The estimated abundance within the Southern Mississippi-East unit is around 50,000 individuals; the major threats acting on the species in this unit include nest predation and harvest. Legal harvest has been ongoing in the Louisiana and Mississippi portions of this unit; however, the species is not in danger of extinction now due to the high abundance of turtles and augmented populations from conservation efforts of head-start and release programs. The historical and current distribution in this unit has some shifts in county and parish occurrences with some range contraction in western Tennessee and expansion in Mississippi and Louisiana (Service 2021, p. 42). Additionally, the species has been managed through conservation efforts by supplementing the population from a captive breeding program that raises the turtle beyond the first few years and releases them into the wild. Due to the current condition of the population within this unit, it is not currently in danger of extinction; however, the ongoing threats will cause the species to decline in the future.

The Southern Mississippi-West unit has an estimated current abundance of 15,000 alligator snapping turtles, but impoundments have fragmented the habitat in this unit. About 9 percent of the unit is the upper northwestern part of Louisiana where legal harvest is still allowed. When considering the historical and current ranges, there has been some range contraction in some counties in Oklahoma; however, occurrence is unknown, meaning there have been no recent surveys or documented records in some of those counties. The species has become virtually extirpated in Kansas. The species is still found in all parishes in Louisiana with no changes in the historical distribution. In Texas, there have been changes from occupied to unknown status and vice versa, but no contractions of the species' range have been confirmed between historical and current distribution. Because the species is still widely distributed across this unit as described in the species' current condition, the population within this unit has sufficient resiliency such that the species is not currently in danger of extinction in this unit, but the ongoing threats will cause the species to decline in the future.

Although the threat of legal harvest is concentrated in the Mississippi and Louisiana areas of the Alabama, Southern Mississippi-East, and Southern Mississippi-West units, the best scientific and commercial data available do not indicate that the concentration of threats, or the species'

responses to the concentration of threats, are likely to accelerate the time horizon in which the species becomes in danger of extinction in this portion of its range. As a result, the alligator snapping turtle is not in danger of extinction now in this portion range of the species' range.

We also considered the threat of habitat degradation and loss compounded with historical overharvest that has affected the species along the fringe areas of the range as there has been some range contraction in Illinois, Kansas, Kentucky, Missouri, Tennessee, and possibly in Oklahoma likely due to changes in the habitat. These areas are all on the fringe of the range, where conditions are likely marginal and more dynamic. The species does not occur in large numbers or densities in these areas because the core areas are associated with the more southern portions of the species' range. The species' occurrence within these areas is inherently low because of the variable pressures associated with dynamic conditions. The alligator snapping turtle is not in danger of extinction now in this portion range of the species' range.

After analyzing the portions of the range where threats are concentrated, we found there are no significant portions of the range where the species is at risk of extinction and do not meet the definition of endangered. Therefore, we determine that the species is likely to become in danger of extinction within the foreseeable future throughout all of its range. This is consistent with the courts' holdings in *Desert Survivors* v. *Department of the Interior,* No. 16–cv–01165–JCS, 2018 WL 4053447 (N.D. Cal. Aug. 24, 2018), and *Center for Biological Diversity* v. *Jewell,* 248 F. Supp. 3d, 946, 959 (D. Ariz. 2017).

Determination of Status

Our review of the best scientific and commercial data available indicates that the alligator snapping turtle meets the Act's definition of a threatened species. Therefore, we propose to list the alligator snapping turtle as a threatened species in accordance with sections 3(20) and 4(a)(1) of the Act.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened species under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing results in public awareness and conservation by Federal, State, Tribal, and local agencies; private organizations; and individuals. The Act encourages cooperation with the States and other countries and calls for recovery actions to be carried out for listed species. The protection required by Federal agencies and the prohibitions against certain activities are discussed, in part, below.

The primary purpose of the Act is the conservation of endangered and threatened species and the ecosystems upon which they depend. The goal of such conservation efforts is the recovery of these listed species so that they no longer need the protective measures of the Act. Subsection 4(f) of the Act calls for the Service to develop and implement recovery plans for the conservation of endangered and threatened species. The recovery planning process involves the identification of actions that are necessary to halt or reverse the species' decline by addressing the threats to its survival and recovery. The goal of this process is to restore listed species to a point where they are secure, self-sustaining, and functioning components of their ecosystems.

Recovery planning consists of preparing draft and final recovery plans, beginning with the development of a recovery outline and making it available to the public subsequent to a final listing determination. The recovery outline guides the immediate implementation of urgent recovery actions and describes the process to be used to develop a recovery plan. The plan may be revised to address continuing or new threats to the species as new substantive information becomes available. The recovery plan also identifies recovery criteria for review of when a species may be ready for reclassification from endangered to threatened (''downlisting'') or removal from protected status (''delisting''), and methods for monitoring recovery progress. Recovery plans also establish a framework for agencies to coordinate their recovery efforts and provide estimates of the cost of implementing recovery tasks. Recovery teams (composed of species experts, Federal and State agencies, nongovernmental organizations, and stakeholders) are often established to develop recovery plans. When completed, the recovery outline, draft recovery plan, and the final recovery plan for alligator snapping turtle will be available on our website (*http://www.fws.gov/endangered*), or from our Louisiana Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Implementation of recovery actions generally requires the participation of a broad range of partners, including other Federal agencies, States, Tribes, nongovernmental organizations, businesses, and private landowners. Examples of recovery actions include habitat restoration (*e.g.,* restoration of native vegetation), research, protective regulations, adjustments to fishing techniques to reduce bycatch, captive propagation and reintroduction, and outreach and education. The recovery of many listed species cannot be accomplished solely on Federal lands because their range may occur primarily or solely on non-Federal lands. Achieving recovery of these species requires cooperative conservation efforts on private, State, and Tribal lands.

If the alligator snapping turtle is listed, funding for recovery actions will be available from a variety of sources, including Federal budgets, State programs, and cost share grants for non-Federal landowners, the academic community, and nongovernmental organizations. In addition, pursuant to section 6 of the Act, the States of Alabama, Arkansas, Florida, Georgia, Illinois, Indiana, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Oklahoma, Tennessee, and Texas would be eligible for Federal funds to implement management actions that promote the protection or recovery of the alligator snapping turtle. Information on our grant programs that are available to aid species recovery can be found at: *http://www.fws.gov/grants.*

Although the alligator snapping turtle is only proposed for listing under the Act at this time, please let us know if you are interested in participating in recovery efforts for the species. Additionally, we invite you to submit any new information on the species whenever it becomes available and any information you may have for recovery planning purposes (see **FOR FURTHER INFORMATION CONTACT**).

Section 7(a) of the Act requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as an endangered or threatened species and with respect to its critical habitat, if any is designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any action that is likely to jeopardize the continued existence of a species proposed for listing or result in destruction or adverse modification of proposed critical habitat. If a species is listed subsequently, section 7(a)(2) of the Act requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of the species or destroy or adversely modify its critical habitat. If a Federal

action may affect a listed species or its critical habitat, the responsible Federal agency must enter into consultation with the Service.

Federal agency actions within the species' habitat that may require conference, consultation, or both, as described in the preceding paragraph, may include, but are not limited to, management and any other landscape-altering activities on Federal lands administered by the U.S. Fish and Wildlife Service; U.S. Forest Service; NPS; Department of Transportation (construction and maintenance of roads or highways by the Federal Highway Administration and railroads by the Federal Railroad Administration); National Aeronautics and Space Administration; Department of Defense (DOD), including issuance of section 404 Clean Water Act permits by the U.S. Army Corps of Engineers; and Federal Energy Regulatory Commission (dams that produce hydropower).

It is our policy, as published in the **Federal Register** on July 1, 1994 (59 FR 34272), to identify to the maximum extent practicable at the time a species is listed, those activities that would or would not constitute a violation of section 9 of the Act. The intent of this policy is to increase public awareness of the effect of a proposed listing on proposed and ongoing activities within the range of the species proposed for listing. The discussion below regarding protective regulations under the Act's section 4(d) complies with our policy.

II. Proposed Rule Issued Under Section 4(d) of the Act

Background

Section 4(d) of the Act contains two sentences. The first sentence states in part that the Secretary shall issue such regulations as she deems necessary and advisable to provide for the conservation of species listed as threatened. The U.S. Supreme Court has noted that statutory language like ''necessary and advisable'' demonstrates a large degree of deference to the agency (see *Webster* v. *Doe,* 486 U.S. 592 (1988)). Conservation is defined in the Act to mean the use of all methods and procedures which are necessary to bring any endangered species or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Additionally, the second sentence of section 4(d) of the Act states in part that the Secretary may by regulation prohibit with respect to any threatened species any act prohibited under section 9(a)(1), in the case of fish or wildlife, or section 9(a)(2), in the case of plants. Thus, the combination of the two sentences of section 4(d) provides the Secretary with wide latitude of discretion to select and promulgate appropriate regulations tailored to the specific conservation needs of the threatened species. The second sentence grants particularly broad discretion to the Service when adopting the prohibitions under section 9.

The courts have recognized the extent of the Secretary's discretion under this standard to develop rules that are appropriate for the conservation of a species. For example, courts have upheld rules developed under section 4(d) as a valid exercise of agency authority where they prohibited take of threatened wildlife or include a limited taking prohibition (see *Alsea Valley Alliance* v. *Lautenbacher,* 2007 U.S. Dist. Lexis 60203 (D. Or. 2007); *Washington Environmental Council* v. *National Marine Fisheries Service,* 2002 U.S. Dist. Lexis 5432 (W.D. Wash. 2002)). Courts have also upheld 4(d) rules that do not address all of the threats a species faces (*see State of Louisiana* v. *Verity,* 853 F.2d 322 (5th Cir. 1988)). As noted in the legislative history when the Act was initially enacted, ''once an animal is on the threatened list, the Secretary has an almost infinite number of options available to [her] with regard to the permitted activities for those species. [She] may, for example, permit taking, but not importation of such species, or [she] may choose to forbid both taking and importation but allow the transportation of such species'' (H.R. Rep. No. 412, 93rd Cong., 1st Sess. 1973).

Exercising this authority under section 4(d), we have developed a proposed rule that is designed to address the alligator snapping turtle's conservation needs. Although the statute does not require us to make a ''necessary and advisable'' finding with respect to the adoption of specific prohibitions under section 9, we find that this rule as a whole satisfies the requirement in section 4(d) of the Act to issue regulations deemed necessary and advisable to provide for the conservation of the alligator snapping turtle. As discussed above under Summary of Biological Status and Threats, we have concluded that the alligator snapping turtle is likely to become in danger of extinction within the foreseeable future primarily due to harvest/collection, nest predation, habitat alteration, and bycatch (hook ingestion, entanglement, and drowning) associated with commercial and recreational fishing.

The provisions of this proposed 4(d) rule would promote conservation of the alligator snapping turtle by prohibiting harvest and encouraging implementation of best management practices for activities in freshwater wetlands and riparian areas to minimize habitat alteration to the maximum extent practicable. The provisions of this proposed rule are one of many tools that we would use to promote the conservation of the alligator snapping turtle. This proposed 4(d) rule would apply only if and when we make final the listing of the alligator snapping turtle as a threatened species.

Section 7(a)(2) of the Act requires Federal agencies, including the Service, to ensure that any action they fund, authorize, or carry out is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of designated critical habitat of such species. In addition, section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any agency action which is likely to jeopardize the continued existence of any species proposed to be listed under the Act.

If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency (action agency) must enter into consultation with us. Examples of actions that are subject to the section 7 consultation process are actions on State, Tribal, local, or private lands that require a Federal permit (such as a permit from the U.S. Army Corps of Engineers under section 404 of the Clean Water Act or a permit from the Service under section 10 of the Act) or that involve some other Federal action (such as funding from the Federal Highway Administration, Federal Aviation Administration, or the Federal Emergency Management Agency). Federal actions not affecting listed species or critical habitat—and actions on State, Tribal, local, or private lands that are not federally funded, authorized, or carried out by a Federal agency—do not require section 7 consultation.

This obligation to confer on species proposed to be listed or engage in consultation with the Service on actions that may affect listed species or their critical habitat does not change in any way for a threatened species with a species-specific 4(d) rule. Actions that result in a determination by a Federal agency of ''not likely to adversely affect'' continue to require the Service's written concurrence and actions that are ''likely to adversely affect'' a species require formal consultation and the formulation of a biological opinion.

Provisions of the Proposed 4(d) Rule

This proposed 4(d) rule would provide for the conservation of the alligator snapping turtle by prohibiting the following activities, except as otherwise authorized or permitted: Importing or exporting; take (as set forth at 50 CFR 17.21(c)(1) with exceptions as discussed below); possessing, selling, delivering, carrying, transporting, or shipping of unlawfully taken specimens from any source; delivering, receiving, transporting, or shipping in interstate or foreign commerce in the course of commercial activity; and selling or offering for sale in interstate or foreign commerce. We also include several exceptions to these prohibitions, which along with the prohibitions are set forth under Proposed Regulation Promulgation, below.

Under the Act, ''take'' means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct. Some of these provisions have been further defined in regulation at 50 CFR 17.3. Take can result knowingly or otherwise, by direct and indirect impacts, intentionally or incidentally. This proposed 4(d) rule would provide for the conservation of alligator snapping turtle by prohibiting intentional and incidental take, except as otherwise authorized or permitted. Prohibiting take of the species resulting from activities, including, but not limited to, harvest (legal and poaching), hook ingestions and entanglement due to bycatch associated with commercial and recreational fishing practices for freshwater fish (particularly as a result of unlawful activities and/or abandonment of equipment), and habitat alteration, will provide for the conservation of the species. Regulating take associated with these activities under a 4(d) rule would prevent continued declines in population abundance and decrease synergistic, negative effects from other threats; this regulatory approach will provide for the conservation of the species by improving resiliency within all seven analysis units.

Prohibitions

Due to the life-history characteristics of the alligator snapping turtle, specifically delayed maturity, long generation times, and relatively low reproductive output, this species cannot sustain significant collection from the wild, especially of adult females (Reed et al. 2002, pp. 8–12). An adult female harvest rate of more than 2 percent per year is considered unsustainable, and harvest of this magnitude or greater will result in significant local population declines (Reed et al. 2002, p. 9). Louisiana and Mississippi allow recreational harvest of alligator snapping turtles; all other States within the species' range prohibit commercial and recreational harvest of the species. Due to the species' demography, however, the overall population has not recovered from prior extensive loss of individuals from past over-exploitation. While current recruitment is sufficient to maintain viability, continued harvest, combined with other stressors, will eventually result in quasi-extinction. Therefore, this proposed 4(d) rule would prohibit collection and harvest (with some exceptions as described below).

Habitat alteration is also a concern for the alligator snapping turtle, as the species is endemic to river systems that drain into the Gulf of Mexico, including tributary waterbodies and associated wetland habitats (*e.g.,* swamps, lakes, reservoirs, etc.), where structure (*e.g.,* tree root masses, stumps, submerged trees, etc.) and a high percentage of canopy cover is more often selected over open water (Howey and Dinkelacker 2009, p. 589). Alligator snapping turtles spend the majority of their time in aquatic habitat; overland movements are generally restricted to nesting females and juveniles moving from the nest to water (Reed at al. 2002, p. 5). The primary causes for habitat alteration include actions that change hydrologic conditions to the extent that dispersal and genetic interchange are impeded.

Activities that may alter the habitat include dredging, deadhead logging, clearing and snagging, removal of riparian cover, channelization, instream activities that result in stream bank erosion and siltation (*e.g.,* stream crossings, bridge replacements, flood control structures, etc.), and changes in land use within the riparian zone of waterbodies (*e.g.,* clearing land for agriculture). Deadhead logs and fallen riparian woody debris provide refugia during low-water periods (Enge et al. 2014, p. 40), resting areas for all life stages (Ewert et al. 2006, p. 62), and important feeding areas for hatchlings and juveniles. The species' habitat needs concentrate around a freshwater ecosystem that supplies both shallower water for hatchlings and juveniles and deeper water for adults, with associated forested habitat that is free from inundation for nesting and provides structure within the waterbody. The species can tolerate some brackish conditions; however, freshwater provides higher quality habitat.

Exceptions to the Prohibitions

The exceptions to the prohibitions set forth in this proposed 4(d) rule include activities conducted as authorized by a permit issued under 50 CFR 17.32 for threatened species, as well as certain actions taken by an employee or agent of the Service, of the National Marine Fisheries Service, or of a State conservation agency that is operating a conservation program in accordance with 50 CFR 17.31(b), as discussed later in this document. In addition, this proposed 4(d) rule includes some of the general exceptions allowed for take of endangered wildlife as set forth at 50 CFR 17.21 (see the rule portion of this document) and certain other specific activities that we propose for exception, as described below.

We are proposing to except certain activities involving specimens originating from captive breeding operations, for conservation or commercial purposes, if the captive breeding operations meet the necessary requirements. We are also proposing to except take incidental to construction, operation, and maintenance activities using appropriate BMPs; pesticide and herbicide use; silviculture practices and forestry activities that implement industry and/or State-approved BMPs accordingly; and maintenance dredging that affects previously disturbed portions of the maintained channel.

Captive breeding for conservation—The Service recognizes that captive breeding provides for the species' conservation (*i.e.,* captive rearing, head-starting, and reintroductions) by supplementing depleted populations and reintroducing turtles to areas where the species has been extirpated. This includes head-starting programs, where turtles are bred and raised beyond the hatchling phase to improve survival, then released into the wild. Captive rearing for the purposes of head-starting hatchlings to release back into the wild can help mitigate losses from nest predation and parasitic insects, as well as provide individuals for reintroduction into areas with depleted turtle numbers. Such activities can help bolster population numbers by improving overall juvenile survival and may also increase genetic diversity. When brood stock is legally acquired and permitted, with proper pedigree management and disease surveillance, Federal and State agencies can implement head-start programs without putting undue stress on the wild population.

All captive production programs for the purpose of reintroducing alligator snapping turtles to the wild must also

develop a controlled propagation plan in accordance with the Service's Policy Regarding Controlled Propagation of Species Listed under the Endangered Species Act (65 FR 56916; September 20, 2000). In addition, captive breeding for conservation purposes should apply kinship-based pedigree management to avoid consequences of inbreeding or inadvertently introducing turtles with deleterious alleles into the wild population. Thus, incidental take associated with Federal and State captive-breeding programs to support conservation efforts for wild populations (*i.e.,* head-starting) would be excepted from the prohibitions when conducted using permitted brood stock and following approved turtle husbandry practices in accordance with State regulations and U.S. Fish and Wildlife Service policy.

State-authorized farming/captive breeding programs—The Service recognizes that turtle farming can alleviate harvest of wild stock and provides a means to serve international markets without affecting wild populations in the future. Therefore, existing State-authorized farming operations using captive brood stock or otherwise legally acquired turtles prior to the listing of the species would be excepted. We will work with States to ensure an appropriate mechanism for identifying, marking, and tracking captive brood stock to differentiate them from wild stock. Without a system to identify alligator snapping turtles that have originated from these operations, we will not be able to finalize such an exception, as there will not be a way to distinguish captive-bred from wild-caught alligator snapping turtles.

This 4(d) rule would allow individuals to take; deliver, receive, carry, transport or ship in interstate commerce, in the course of a commercial activity; or sell or offer for sale in interstate commerce alligator snapping turtle specimens that meet the definitions of ''captive-bred'' or ''bred in captivity'' in 50 CFR 17.3 and the definitions and requirements in 50 CFR part 23 (see 50 CFR 23.5 and 23.24) if the specimen originated in a State-approved facility. It also allows individuals to import; export; deliver, receive, carry, transport, or ship in foreign commerce and in the course of a commercial activity; or sell or offer to sell in foreign commerce dead specimens of alligator snapping turtle that are otherwise lawfully taken. We are not currently proposing to allow foreign commerce and foreign trade of live specimens, in an effort to further ensure that wild specimens are not laundered through the black market and international trade. However, we seek public comment on whether such an exception may be appropriate if a mechanism is developed for identifying captive-bred specimens.

Any person wishing to exercise this exception would have to maintain documentation to demonstrate that the specimen was legally acquired and held in captivity prior to the effective date of the final rule listing the alligator snapping turtle. Such documentation may include a bill of sale or other receipts, including the State permit information for the source facility; record of pedigree of pit-tagged or uniquely identified, marked turtles with State permit from the source facility; accession records; CITES documents; or wildlife declaration forms dated prior to the specified dates. Also, the activity must not be prohibited by either the State or Tribe where the taking occurs or by the State or Tribe where the specimen is sold or otherwise transferred. Finally, the specimens held by a person claiming the benefit of this exception would have to be managed in a manner that prevents hybridization of the species or subspecies and in a manner that maintains genetic diversity.

Best management practices for implementing actions that occur near or in a stream—Implementing best management practices to avoid and/or minimize the effects of habitat alterations in areas that support alligator snapping turtles would provide additional measures for conserving the species by reducing direct and indirect effects to the species. We considered that certain construction, forestry, and pesticide/herbicide management activities that occur near and in a stream may result in removal of riparian cover or forested habitat, changes in land use within the riparian zone, or stream bank erosion and/or siltation. These actions andactivities may have some minimal leveloftake of the alligator snapping turtle, but any such take isexpected to be rare and insignificant, and is not expected to negatively impact the species' conservation and recovery efforts.

Construction, operation, and maintenance activities, such as installation of stream crossings, replacement of existing instream structures (*e.g.,* bridges, culverts, water control structures, boat launches, etc.), operation and maintenance of existing flood control features (or other existing structures), and directional boring, when implemented with industry and State-approved standard best management practices, will have minimal impacts to alligator snapping turtles and their habitat. In addition, we recognize that silvicultural operations are widely implemented in accordance with State-approved BMPs (Cristan et al. 2018, entire), and the adherence to these BMPs broadly preserves water quality standards, particularly related to sedimentation (Cristan et al. 2016, entire; Warrington et al. 2017, entire), to an extent that does not impair the species' conservation. Lastly, invasive species removal activities, particularly through pesticide and herbicide application, are considered beneficial to the native ecosystem and are likely to improve habitat conditions for the species; therefore, pesticide and herbicide application that follow the chemical label and appropriate application rates would not impair the species' conservation. These activities should have minimal impacts to alligator snapping turtles if industry and/or State-approved BMPs are implemented. These activities and management practices should be carried out in accordance with any existing regulations, permit and label requirements, and best management practices to avoid or minimize impacts to the species and its habitat.

Thus, under this proposed 4(d) rule, incidental take associated with the following best management practiced and activities would be excepted:

(1) Construction, operation, and maintenance activities that occur near and in a stream, such as installation of stream crossings, replacement of existing instream structures (*e.g.,* bridges, culverts, water control structures, boat launches, etc.), operation and maintenance of existing flood control features (or other existing structures), and directional boring, when implemented with industry and/or State-approved BMPs for construction.

(2) Pesticide and herbicide application that follows the chemical label and appropriate application rates.

(3) Silviculture practices and forest management activities that use State-approved BMPs to protect water and sediment quality and stream and riparian habitat.

Maintenance dredging of navigable waterways—We considered that maintenance dredging activities generally disturb the same area of the waterbody in each cycle; thus, there is less likelihood that suitable turtle habitat (*e.g.,* submerged logs, cover, etc.) occurs in the maintained portion of the channel. Accordingly, incidental take associated with maintenance dredging activities that occur within the previously disturbed portion of the navigable waterway would be excepted from the prohibitions as long as these

activities do not encroach upon suitable turtle habitat outside the maintained portion of the channel and provide for the conservation of the species.

Tribal employees—Under the exceptions in this proposed 4(d) rule, when acting in the course of their official duties, Tribal employees designated by the Tribe for such purposes, working in the range of the species, would be able to take alligator snapping turtles for the following purposes:

(A) Aiding or euthanizing sick or injured alligator snapping turtles;

(B) Disposing of a dead specimen; and

(C) Salvaging a dead specimen that may be used for scientific study.

Such take would have to be reported to the local Service field office within 72 hours, and specimens would have to be retained or disposed of only in accordance with directions from the Service.

State-licensed wildlife rehabilitation facilities—Under the exceptions in this proposed 4(d) rule, when acting in the course of their official duties, State-licensed wildlife rehabilitation facilities would be able to take alligator snapping turtles for the purpose of aiding or euthanizing sick or injured alligator snapping turtles. Such take would have to be reported to the local Service field office within 72 hours, and specimens would have to be retained and disposed of only in accordance with directions from the Service.

We are also considering an exception for incidental take of the alligator snapping turtle associated with bycatch from otherwise lawful recreational and commercial fishing. We note that alligator snapping turtle bycatch from recreational and commercial fishing with hoop nets and trot lines (and varieties including jug lines, bush hooks, and limb lines) is a concern for the conservation of the species due to its effects on species abundance, particularly in light of the species' life-history traits. However, there is limited information on the magnitude and on the temporal and spatial distribution of this threat across the species' range. It is important to ensure that fishing activities take into consideration the need to prevent accidental turtle deaths from the use of such fishing gear, and we will work with the States to identify measures and revisions to existing regulations to reduce bycatch of alligator snapping turtle. If we conclude that the measures and/or revisions to existing regulations would provide for the conservation of the species, we may include a provision in the final 4(d) rule excepting incidental take associated with legal recreational or commercial fishing activities for other targeted species, in compliance with State regulations, if such an exception is appropriate in light of comments and new information we receive during the comment period on this proposed rule (see **DATES**, above).

Also, to better understand threats associated with bycatch related to otherwise lawful fishing, we are considering adding a provision to the 4(d) rule that would require reporting within 72 hours of all injured or dead alligator snapping turtles resulting from bycatch from recreational or commercial fishing (for other targeted species) in accordance with State regulations and the relevant information provided to the Service. We specifically request comments on the additional 4(d) rule exception and provision that we are considering.

Future conservation efforts may be possible through advances in fishing gear technology that implement effective turtle escape or exclusion devices for hoop nets or modified trot lines (including limb lines and jug lines) that would reduce or eliminate turtle bycatch. Thus, we are requesting information from the public regarding new technology, design of a turtle escape, or exclusion device and modified trot line techniques that would effectively eliminate or significantly reduce bycatch of alligator snapping turtles from recreational fishing. We would particularly appreciate input from the commercial and recreational fishing communities. Our intent is to allow exceptions to incidental take for recreational and commercial fishing bycatch pending new technologies and regulations that may be applied to reduce the threat to the species; we are relying on input during the public comment period to further address bycatch incidental take.

We may issue permits to carry out otherwise prohibited activities, including those described above, involving threatened wildlife under certain circumstances. Regulations governing permits are codified at 50 CFR 17.32. With regard to threatened wildlife, a permit may be issued for the following purposes: For scientific purposes, to enhance propagation or survival, for economic hardship, for zoological exhibition, for educational purposes, for incidental taking, or for special purposes consistent with the purposes of the Act. The statue also contains certain exemptions from the prohibitions, which are found in sections 9 and 10 of the Act.

We recognize the special and unique relationship with our State natural resource agency partners in contributing to conservation of listed species. State agencies often possess scientific data and valuable expertise on the status and distribution of endangered, threatened, and candidate species of wildlife and plants. State agencies, because of their authorities and their close working relationships with local governments and landowners, are in a unique position to assist the Service in implementing all aspects of the Act. In this regard, section 6 of the Act provides that the Service shall cooperate to the maximum extent practicable with the States in carrying out programs authorized by the Act. Therefore, any qualified employee or agent of a State conservation agency that is a party to a cooperative agreement with the Service in accordance with section 6(c) of the Act, who is designated by his, her, or their agency for such purposes, would be able to conduct activities designed to conserve alligator snapping turtle that may result in otherwise prohibited take without additional authorization.

Nothing in this proposed 4(d) rule would change in any way the recovery planning provisions of section 4(f) of the Act, the consultation requirements under section 7 of the Act, or the ability of the Service to enter into partnerships for the management and protection of the alligator snapping turtle. However, interagency cooperation may be further streamlined through planned programmatic consultations for the species between Federal agencies and the Service, where appropriate. We ask the public, particularly State agencies, Tribes, and other interested stakeholders that may be affected by the proposed 4(d) rule, to provide comments and suggestions regarding additional guidance and methods that the Service could provide or use, respectively, to streamline the implementation of this proposed 4(d) rule (see Information Requested, above).

III. Critical Habitat

Background

Critical habitat is defined in section 3 of the Act as:

(1) The specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the Act, on which are found those physical or biological features

(a) Essential to the conservation of the species, and

(b) Which may require special management considerations or protection; and

(2) Specific areas outside the geographical area occupied by the species at the time it is listed, upon a

determination that such areas are essential for the conservation of the species.

Our regulations at 50 CFR 424.02 define the geographical area occupied by the species as an area that may generally be delineated around species' occurrences, as determined by the Secretary (*i.e.,* range). Such areas may include those areas used throughout all or part of the species' life cycle, even if not used on a regular basis (*e.g.,* migratory corridors, seasonal habitats, and habitats used periodically, but not solely by vagrant individuals).

Conservation, as defined under section 3 of the Act, means to use and the use of all methods and procedures that are necessary to bring an endangered or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Such methods and procedures include, but are not limited to, all activities associated with scientific resources management such as research, census, law enforcement, habitat acquisition and maintenance, propagation, live trapping, and transplantation, and, in the extraordinary case where population pressures within a given ecosystem cannot be otherwise relieved, may include regulated taking.

Section 4 of the Act requires that we designate critical habitat on the basis of the best scientific data available. Further, our Policy on Information Standards Under the Endangered Species Act (published in the **Federal Register** on July 1, 1994 (59 FR 34271)), the Information Quality Act (section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106–554; H.R. 5658)), and our associated Information Quality Guidelines provide criteria, establish procedures, and provide guidance to ensure that our decisions are based on the best scientific data available. They require our biologists, to the extent consistent with the Act and with the use of the best scientific data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat.

Prudency Determination

Section 4(a)(3) of the Act, as amended, and implementing regulations (50 CFR 424.12), require that, to the maximum extent prudent and determinable, the Secretary shall designate critical habitat at the time the species is determined to be an endangered or threatened species. Our regulations (50 CFR 424.12(a)(1)) state that the Secretary may, but is not required to, determine that a designation would not be prudent in the following circumstances:

(i) The species is threatened by taking or other human activity and identification of critical habitat can be expected to increase the degree of such threat to the species;

(ii) The present or threatened destruction, modification, or curtailment of a species' habitat or range is not a threat to the species, or threats to the species' habitat stem solely from causes that cannot be addressed through management actions resulting from consultations under section 7(a)(2) of the Act;

(iii) Areas within the jurisdiction of the United States provide no more than negligible conservation value, if any, for a species occurring primarily outside the jurisdiction of the United States;

(iv) No areas meet the definition of critical habitat; or

(v) The Secretary otherwise determines that designation of critical habitat would not be prudent based on the best scientific data available.

In our SSA and proposed listing determination for the alligator snapping turtle, we determined that the present or threatened destruction, modification, or curtailment of habitat or range is a threat to the species and that those threats in some way can be addressed by section 7(a)(2) consultation measures. The species occurs wholly in the jurisdiction of the United States, and we are able to identify areas that meet the definition of critical habitat.

However, as discussed earlier in this document, collection and/or vandalism has been identified as a threat to this species. The alligator snapping turtle is declining throughout its range as a consequence of factors including collection of live adult turtles from the wild for human consumption and for the pet trade. Adult alligator snapping turtles are harvested for local human consumption and for use in the specialty meat trade both domestically and internationally.

It is unclear, however, whether identification and mapping of critical habitat would increase the degree of such threat to the alligator snapping turtle. Accordingly, we seek comment on whether the designation of critical habitat may not be prudent because it would more widely announce the exact locations of alligator snapping turtles and their highly suitable habitat which could facilitate poaching, thereby exacerbating the threat of collection and contributing to further declines of the species' viability.

Therefore, because we are seeking comment on whether the identification of critical habitat can be expected to increase the degree of taking as a result of human activity, but we find that none of the other circumstances enumerated in our regulations at 50 CFR 424.12(a)(1) have been met, we determine that the designation of critical habitat may be prudent for the alligator snapping turtle.

Critical Habitat Determinability

Having determined that critical habitat may be prudent, under section 4(a)(3) of the Act we consider whether critical habitat for the alligator snapping turtle is determinable. Our regulations at 50 CFR 424.12(a)(2) state that critical habitat is not determinable when one or both of the following situations exist:

(i) Data sufficient to perform required analyses are lacking, or

(ii) The biological needs of the species are not sufficiently well known to identify any area that meets the definition of ''critical habitat.''

For the alligator snapping turtle, the species' needs are sufficiently well known. However, information sufficient to perform the required analyses are lacking because we have not determined the extent to which critical habitat may be prudent. Therefore, we find designation of critical habitat for the alligator snapping turtle is not determinable at this time. The Act allows the Service an additional year to publish a critical habitat designation that is not determinable at the time of listing (16 U.S.C. 1533(b)(6)(C)(ii)).

Required Determinations

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(1) Be logically organized;

(2) Use the active voice to address readers directly;

(3) Use clear language rather than jargon;

(4) Be divided into short sections and sentences; and

(5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in **ADDRESSES**. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

We have determined that environmental assessments and environmental impact statements, as defined under the authority of the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*), need not be prepared in connection with regulations adopted pursuant to section 4(a) of the Endangered Species Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This position was upheld by the U.S. Court of Appeals for the Ninth Circuit (*Douglas County* v. *Babbitt,* 48 F.3d 1495 (9th Cir. 1995), cert. denied 516 U.S. 1042 (1996)).

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951), Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with Tribes in developing programs for healthy ecosystems, to acknowledge that Tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to Tribes.

Upon the initiation of the SSA process, we contacted Tribes within the range of the alligator snapping turtle and additional Tribes of interest to inform them of our intent to complete an SSA for the species that would inform the species' 12-month finding. In addition, as described above under *Tribal employees,* the proposed 4(d) rule would authorize certain take by Tribes. As we move forward with this listing process, we will continue to consult with Tribes on a government-to-government basis as necessary.

References Cited

A complete list of references cited in this rulemaking is available on the internet at *http://www.regulations.gov* in Docket No. FWS–R4–ES–2021–0115 and by mailed request from the Louisiana Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this proposed rule are the staff members of the Service's Species Assessment Team and the Louisiana Ecological Services Field Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

■ 2. Amend § 17.11(h) by adding an entry for ''Turtle, alligator snapping'' to the List of Endangered and Threatened Wildlife in alphabetical order under Reptiles to read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
*	*	*	*	* * *
REPTILES				
*	*	*	*	* * *
Turtle, alligator snapping	*Macrochelys temminckii*	Wherever found	T	[**Federal Register** CITATION OF THE FINAL RULE]; 50 CFR 17.42(o).[4d]
*	*	*	*	* * *

■ 3. As proposed to be amended at 85 FR 61700 (September 30, 2020) and 86 FR 18014 (April 7, 2021), § 17.42 is further amended by adding paragraph (o) to read as follows:

§ 17.42 Special rules—reptiles.

* * * * *

(o) Alligator snapping turtle (*Macrochelys temminckii*).

(1) *Prohibitions.* The following prohibitions that apply to endangered wildlife also apply to alligator snapping turtle. Except as provided under paragraphs (o)(2) and (3) of this section and §§ 17.4 and 17.5, it is unlawful for any person subject to the jurisdiction of the United States to commit, to attempt to commit, to solicit another to commit, or cause to be committed, any of the following acts in regard to this species:

(i) Import or export, as set forth at § 17.21(b) for endangered wildlife.

(ii) Take, as set forth at § 17.21(c)(1) for endangered wildlife.

(iii) Possession and other acts with unlawfully taken specimens, as set forth at § 17.21(d)(1) for endangered wildlife.

(iv) Interstate or foreign commerce in the course of commercial activity, as set forth at § 17.21(e) for endangered wildlife.

(v) Sale or offer for sale, as set forth at § 17.21(f) for endangered wildlife.

(2) *General exceptions from prohibitions.* In regard to this species, you may:

(i) Conduct activities as authorized by a permit under § 17.32.

(ii) Take, as set forth at § 17.21(c)(2) through (c)(4) for endangered wildlife.

(iii) Take as set forth at § 17.31(b).

(iv) Possess and engage in other acts with unlawfully taken wildlife, as set forth at § 17.21(d)(2) for endangered wildlife.

(v) Federal and State captive-breeding programs to support conservation efforts for wild populations that use permitted brood stock and approved turtle husbandry practices in accordance with

State regulations and U.S. Fish and Wildlife Service policy.

(vi) Take; export; import; delivery, receipt, carrying, transport, or shipment in interstate or foreign commerce, in the course of a commercial activity; or sale or offer for sale in interstate or foreign commerce specimens that meet the definition of ''captive-bred'' or ''bred in captivity'' at § 17.3 and the definitions and requirements in 50 CFR part 23 for Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) source codes ''C'' (Bred-in-captivity) or ''F'' (Captive-bred) (see 50 CFR 23.5 and 23.24), if they originated in a State-approved captive breeding facility and provided that all of the following requirements are met:

(A) Take is authorized in accordance with the laws and regulations of the State or Tribe where the taking occurs.

(B) Delivery, receipt, carrying, transport, or shipment in interstate commerce and in the course of a commercial activity, or sale or offer for sale in interstate commerce, is only authorized if the activity is conducted in accordance with the laws and regulations of the State or Tribe in which the taking occurs and the State or Tribe in which the sale or transfer occurs. The activity must not be prohibited by either the State or Tribe where the taking occurs or the State or Tribe where the specimen is sold or otherwise transferred.

(C) Import; export; delivery, receipt, carrying, transport, or shipment in foreign commerce and in the course of a commercial activity; or sale or offer for sale in foreign commerce is only authorized with dead specimens taken in accordance with paragraph (o)(2)(vi)(A) of this section, and only if trade in the specimen meets the requirements of parts 13, 14, and 23 of this chapter. This exception does not apply to gametes, eggs, or live alligator snapping turtles.

(D) Any specimens that do not qualify as ''captive-bred'' or ''bred in captivity'' (*e.g.,* any specimens taken from the wild) may only be used by captive breeding operations as parental stock (or broodstock), and only if the specimens were legally acquired and held in captivity prior to the effective date of the final rule. You must maintain documentation to demonstrate that the specimen was legally acquired and held in captivity prior to the effective date of the final rule. Such documentation may include a bill of sale or other receipt that includes the State permit information for the source facility, record of pedigree of pit-tagged or uniquely identified, marked turtles with State permit from the source facility, accession records, CITES documents, or wildlife declaration forms that must be dated prior to the specified dates.

(E) All gametes, eggs, and live specimens of the species held by a person claiming the benefit of an exception under this paragraph (o)(2)(vi) of this section must be managed in a manner that prevents hybridization of the species or subspecies and in a manner that maintains genetic diversity.

(F) Each person claiming the benefit of an exception under this paragraph (o)(2)(vi) of this section must maintain accurate written records of activities, including of any birth, death, take, possession, transportation, sale, purchase, barter, exportation, importation, and any other transfers of specimens. Any person claiming the benefit of an exception in paragraph (o)(2)(vi)(C) of this section must also maintain accurate written records as are otherwise required to be maintained by all import/export licensees under part 14 of this subchapter. Such records shall be maintained as in the normal course of business, reproducible in the English language, and retained for a minimum of 5 years from the date of each transaction. Subject to applicable limitations of law, duly authorized officers at all reasonable times shall be afforded access to inspect any wildlife or plant held or to inspect, audit, or copy any permits, books, or records required to be kept by regulations of this subchapter B.

(vii) When acting in the course of their official duties, Tribal employees designated by the Tribe for such purposes may take alligator snapping turtle for the following purposes:

(A) Aiding or euthanizing sick or injured alligator snapping turtles;

(B) Disposing of a dead specimen; and

(C) Salvaging a dead specimen that may be used for scientific study.

(viii) State-licensed wildlife rehabilitation facilities, when acting in the course of their official duties, may take alligator snapping turtle for the purpose of aiding or euthanizing sick or injured alligator snapping turtles.

(ix) Take carried out under paragraphs (o)(2)(vii) and (viii) of this section must be reported to the local Service field office within 72 hours, and specimens may be retained or disposed of only in accordance with directions from the Service.

(3) *Exceptions from prohibitions for specific types of incidental take.* You may take alligator snapping turtle while carrying out the following legally conducted activities in accordance with this paragraph (o)(3):

(i) Construction, operation, and maintenance activities that occur near and in a stream, such as installation of stream crossings, replacement of existing instream structures (*e.g.,* bridges, culverts, water control structures, boat launches, etc.), operation and maintenance of existing flood control features (or other existing structures), and directional boring, when implemented with industry and/or State-approved best management practices for construction.

(ii) Pesticide and herbicide application that follows the chemical label and appropriate application rates.

(iii) Silviculture practices and forest management activities that use State-approved best management practices to protect water and sediment quality and stream and riparian habitat.

(iv) Maintenance dredging activities that remain in the previously disturbed portion of a maintained channel.

Martha Williams,

Principal Deputy Director, Exercising the Delegated Authority of the Director, U.S. Fish and Wildlife Service.

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LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

Last List November 3, 2021

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