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Presidential Documents

Title 3—

The President

Memorandum of July 26, 2016

Delegation of Authority Under Section 1247 of the National Defense Authorization Act for Fiscal Year 2016

Memorandum for the Secretary of State

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 301 of title 3, United States Code, I hereby order as follows:

I hereby delegate the functions and authorities vested in the President by section 1247 of the National Defense Authorization Act for Fiscal Year 2016 (Public Law 114–92) (the ''Act'') to the Secretary of State.

Any reference in this memorandum to the Act shall be deemed to be a reference to any future act that is the same or substantially the same as such provision.

You are authorized and directed to publish this memorandum in the *Federal Register.*

THE WHITE HOUSE,
Washington, July 26, 2016

[FR Doc. 2016–18760
Filed 8–4–16; 8:45 am]
Billing code 4710–10–P

Rules and Regulations

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OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 630

RIN 3206–AN31

Disabled Veteran Leave and Other Miscellaneous Changes

AGENCY: Office of Personnel Management.

ACTION: Final rule.

SUMMARY: The Office of Personnel Management is issuing final regulations to implement the Wounded Warriors Federal Leave Act of 2015, which establishes a separate new leave category, to be known as ''disabled veteran leave,'' available during a 12-month period beginning on the first day of employment to be used by an employee who is a veteran with a service-connected disability rated at 30 percent or more for purposes of undergoing medical treatment for such disability. We are also rescinding two obsolete leave-related regulations.

DATES: This final rule is effective on November 5, 2016.

FOR FURTHER INFORMATION CONTACT: Doris Rippey by telephone at (202) 606–2858 or by email at *pay-leave-policy@opm.gov.*

SUPPLEMENTARY INFORMATION: On June 6, 2016, the Office of Personnel Management (OPM) published proposed regulations (81 FR 36186) to add a new subpart M, Disabled Veteran Leave, in part 630 (Absence and Leave) of title 5, Code of Federal Regulations, and rescind two obsolete regulations. These final regulations implement the Wounded Warriors Federal Leave Act of 2015 (Pub. L. 114–75, November 5, 2015) (hereafter referred to as ''the Act''). The Act adds section 6329 to title 5, United States Code, which establishes a separate new leave category, to be known as ''disabled veteran leave.'' This new leave category entitles any employee who is a veteran with a qualifying service-connected disability to use disabled veteran leave during a 12-month period beginning on the first day of employment for the purposes of undergoing medical treatment for such disability.

Disabled veteran leave available to an eligible employee may not exceed 104 hours for a regular full-time employee. Disabled veteran leave not used during the established 12-month period may not be carried over to subsequent years and will be forfeited. By law, disabled veteran leave is available only to covered employees who are hired (as defined at § 630.1303) on or after November 5, 2016.

The 30-day comment period for the proposed regulations ended on July 6, 2016. We received comments from 12 individuals, 1 agency, and 1 Federal labor organization. This **Federal Register** notice provides general information regarding the regulation, addresses the comments received, and issues final regulations that reflect three changes to the proposed regulations in §§ 630.1301, 630.1303, and 630.1307(b).

Comments on Proposed Regulations

We organized our responses to comments by the affected regulatory section number. We did not receive comments on all regulatory sections. Therefore, not all sections are discussed within this Supplementary Information.

We received comments expressing general support for the new type of leave for disabled veterans. A Federal labor organization expressed that ''disabled veteran leave is an excellent way to help mitigate the adverse effects of military service and prevent veterans from experiencing unnecessary personal hardships as they transition into the civilian workforce.'' The labor organization stated that having the new 104-hour leave entitlement available during the initial 12-month period of employment ''will greatly contribute to assisting veterans in making a more seamless transition to civilian duty by affording them the flexibility they need to undergo medical treatment.''

Comments from individuals reflected that veterans often have multiple appointments necessary to treat their service-connected disabilities and may not have sufficient accrued sick or annual leave to attend those appointments. The comments expressed that the new leave category will make it possible for veterans to obtain necessary medical treatment for their service-connected disabilities (during the 12-month eligibility period) without having to take leave without pay, use accrued sick or annual leave, or become indebted for advanced sick or annual leave.

Contrary to Law

We received several comments from individuals suggesting changes that would be contrary to the statutory requirements in law. These comments fell into three general categories: (1) The requirement that the disabled veteran leave benefit is applicable only to those hired on or after November 5, 2016, (2) the amount of disabled veteran leave provided (up to 104 hours), and (3) the 12-month period in which to use disabled veteran leave (*i.e.,* that disabled veteran leave is a one-time entitlement rather than a recurring annual entitlement). Changes in these three categories would require a change in law; therefore, no changes were made to the regulations based on these comments.

Required Documentation for Eligibility

A labor organization provided a comment on a section of the Supplementary Information of the proposed regulations related to § 630.1304 (Eligibility) (81 FR 36189). In that section, we stated it is important that agencies be able to identify as soon as possible whether an employee is entitled to the benefit since the disabled veteran leave is only available during the first 12 months after the first day of employment. However, we also noted that employees have a responsibility to provide proper documentation/certification from the Veterans Benefits Administration (VBA), a subcomponent of the Department of Veterans Affairs (VA) to enable agencies to make determinations about eligibility for disabled veteran leave. The labor organization stated that the proposed regulations place the burden on veteran employees to provide the necessary documentation upon being employed to gain access to this benefit. The labor organization stated that our proposed regulations are silent on how employees will be notified of the existence of this benefit when they become employed and recommended that agencies provide

notice to veterans upon employment by including literature on disabled veteran leave in their new hire packets. Additionally, the labor organization urged that VBA notify employees of this benefit upon certifying their status as a veteran with a qualifying service-connected disability. The labor organization acknowledged that the regulations contain a retroactivity provision at § 630.1304(c), which addresses delayed employee submissions of VBA ratings; however, it asserted that having VBA provide notice of this new leave category would maximize the possibility of veterans taking advantage of the statutory entitlement to disabled veteran leave within the fixed 12-month eligibility period.

We agree that agencies should strive to make employees aware of the disabled veteran leave benefit. While we do not believe it is necessary to incorporate a formal notice requirement in regulations, we will encourage agencies through other means to educate and notify employees regarding the disabled veteran leave benefit. We have also informed VBA of the labor organization's recommendation that it notify veterans of this Federal employee leave benefit when it certifies that they have a 30 percent service-connected disability rating.

§ 630.1302—Applicability and § 630.1303—Definitions

Commenters expressed that it was ''unfair'' to provide this leave benefit only to veterans hired on or after November 5, 2016, and expressed the need for the new leave category to apply to all veterans with a 30 percent or more service-connected disability rating.

Section 2(c) of the Act specifically provides that disabled veteran leave is available to veterans with a 30 percent or more service-connected disability rating who are hired on or after November 5, 2016. Thus, comments received regarding the application of the disabled veteran leave benefit only to those hired on or after November 5, 2016, are outside the scope of OPM's authority and regulations. OPM cannot prescribe regulations that are contrary to statutory requirements.

While current Federal employees who were hired before November 5, 2016, are not eligible for disabled veteran leave, the Federal Government offers a wide range of leave options and workplace flexibilities available to assist employees who need to be away from the workplace, including veterans who must take time off from work to receive medical treatment for their service-connected disabilities. These options include advanced annual leave or advanced sick leave, alternative work schedules, earned credit hours under a flexible work schedule, and earned compensatory time off. Depending on an employee's particular circumstances, leave without pay under the Family and Medical Leave Act (FMLA) or donated leave under the voluntary leave transfer program or voluntary leave bank program may also be options for employees needing time away from work for the treatment of their service-connected disabilities. (See also the discussion of leave rights under Executive Order 5396 at the end of this Supplementary Information.)

Since the term ''hired'' is not defined in the statute, we define the term ''hired'' within these regulations to be broader than merely an employee's first appointment with the Federal Government. As discussed in the Supplementary Information of the proposed regulations, although the legislative history of the Act indicates that Congress was focused on the most common scenario—addressing veterans with 30 percent or more service-connected disabilities who are ''new'' employees and begin their Federal careers with zero hours of sick leave (see House Report 114–180 and Senate Report 114–89)—the law itself does not exclude those with previous Federal civilian service.

Therefore, we provide in these regulations that employees also will be considered to have a hiring event that may qualify them for disabled veteran leave (assuming they meet all other eligibility requirements) if, on or after November 5, 2016, they are (1) reappointed with at least a 90-day break in service or (2) return to civilian duty following a break in civilian duty (with continuous civilian leave status) to perform military service. (See definition of the term *hired* in § 630.1303.)

One commenter expressed concern that some employees may wait until after they are hired to file a claim for VA disability benefits, which would ''leave little or no time to make this process work,'' given the delays in the VA process for making disability determinations.

This comment appeared to reflect a misunderstanding of when the 12-month eligibility period begins. The 12-month eligibility period begins on the *first day of employment,* which is defined to mean the later of (1) the date the employee is first hired (in qualifying employment) or (2) the effective date of the employee's qualifying service-connected disability. The hiring date is the later date when an employee is hired after the effective date of the employee's qualifying service-connected disability. The effective date of the disability determination is the later date if the employee has already been hired. Thus, it is possible for the 12-month eligibility period to begin after an employee's hiring date. Because of comments indicating confusion about this matter, we are revising the definition of *first day of employment* to more clearly state the rule. We are also making a corresponding clarification in § 630.1301 (Purpose and authority), which relies on the clarified definition of *first day of employment.*

As discussed in the Supplementary Information for the proposed regulations, the effective date of a service-connected disability is generally either the day after the date of military discharge (if the person filed a disability claim within 1 year of discharge date) or the date the claim was filed. Thus, a delay in a determination by VBA can prevent an employee from using disabled veteran leave during the earlier portion of the 12-month eligibility period that may be retroactively established for certain employees. However, the regulations in § 630.1306(c) address this situation by allowing such employees to retroactively substitute disabled veteran leave for other leave they may have taken for covered medical treatment.

§ 630.1304—Eligibility

We received one comment regarding the requirement in proposed § 630.1304(b) that, ''[i]n order to be eligible for disabled veteran leave, an employee must provide to the agency documentation from the Veterans Benefits Administration certifying that the employee has a qualifying service-connected disability.'' The commenter expressed concerns about the VBA's ability ''to provide timely decisions'' and suggested that, in addition to the VBA rating, we also consider using the following documentation as a proof of a service-connected disability rated at 30 percent or more: A Report of Separation showing medically retired (30 percent) or Temporary Disability Retired List (TDRL) and/or a Medical Evaluation Board (MEB)/Physical Evaluation Board (PEB) evaluation from the service department concerned.

The commenter also expressed concerns that ''while many veterans will seamlessly transition from active duty to VA care, there will be those who do not immediately file a claim with VBA.'' The commenter stated that ''for those who wait to file until after they are hired there may be little or no time to make this process work,'' and ''[i]f the veteran does not have the decision in

hand when hired, the veteran has no ability to push the process within the first year and only a limited ability for after the fact adjustments.'' The same commenter mentioned that there are other problematic issues that can delay a rating from VBA.

The Act requires a formal finding by VA under title 38 that an employee is a veteran with a service-connected disability rated at 30 percent or more. (The Act relies on the title 38 definitions of terms ''veteran'' and ''service-connected.'' Only VA issues service-connected disability ratings to veterans under title 38.) The regulations already provide that a temporary disability rating by VA under 38 U.S.C. 1156 is considered a valid rating as long as it is in effect. (See definition of the term *qualifying service-connected disability* in § 630.1303.) Accordingly, we are not making any changes to the regulations in response to the commenter's suggestions to use other forms of documentation as a basis for providing disabled veteran leave. As already noted, in the event that VA delays prevent an employee from using disabled veteran leave during a portion of the 12-month eligibility period, the regulations allow the employee to retroactively substitute disabled veteran leave for other leave used for attending medical treatment of the qualifying service connected-disability. (See § 630.1306(c).)

For example, assume a veteran is discharged from the military in July 2014 and is hired to fill a qualifying Federal civilian position on December 1, 2016, but has not filed a claim for veteran disability benefits. The agency cannot credit the employee with the disabled veteran leave at the time of hire because the employee's eligibility for the benefit has not been established by VA. Subsequently, on March 4, 2017, the employee files a claim and on June 5, 2017, VBA issues a decision that the employee has a service-connected disability rating of 30 percent. In this case, the disability rating is effective on the date the employee filed the claim, March 4, 2017. After the employee provides the employing agency with documentation, the agency establishes March 4, 2017, as the ''first day of employment'' (as a veteran with a service-connected disability of 30 percent or more) and as the beginning date of the employee's 12-month eligibility period, and credits the employee with disabled veteran leave. The employee will have a 12-month period starting on March 4, 2017, and ending on March 3, 2018, in which to use the leave.

While the disability may have existed as the employee awaited the VBA determination, the Act provides that disabled veteran leave may be provided only to an employee who actually has a service-connected disability rating of 30 percent or more in effect. VBA provides disability ratings to veterans in order to determine compensation benefits related to the veteran's service-connected disability.

In the example scenario, the employee was retroactively determined to be eligible for disabled veteran leave starting on March 4, 2017; however, the determination was not made until June 5, 2017. Thus, the employee was not allowed to use disabled veteran leave during the March 4–June 4 period; however, as provided by § 630.1306(c), the agency must allow the employee to substitute disabled veteran leave retroactively for a qualifying period of absence during the March 4–June 4 period (including leave without pay, sick leave, annual leave, compensatory time off, or other paid time off, but excluding periods of suspension or absence without leave (AWOL)).

§ 630.1305—Crediting Disabled Veteran Leave

We received three comments regarding the crediting of 104 hours of disabled veteran leave on a one-time basis. One commenter thought 104 hours was too much and recommended the regulations be changed to provide a maximum of 80 hours. The commenter also suggested that those 80 hours be provided on an annual basis and recommended changing the effective date from November 5, 2016, to January 1, 2017, to avoid providing the leave benefit twice to an employee in a short amount of time.

This comment is misdirected, as it appears that the commenter believes that disabled veteran leave is provided to qualified employees on a recurring annual basis. As the law clearly provides—and as stated in the proposed and final regulations—employees who otherwise qualify are provided disabled veteran leave only once during their Federal careers. The intent of the Act is to allow qualifying veterans access to this special category of leave during a single 12-month eligibility period that commences on the employee's ''first day of employment.'' The focus of Congress was to address the problem of new Federal employees who have a zero balance of sick leave when initially appointed. In subsequent years, employees can use accrued sick and annual leave balances to receive medical treatment for their service-connected disabilities. Also, contrary to the commenter's assumption, disabled veteran leave is granted for an individualized 12-month eligibility period, not on a calendar year or leave year basis.

Another commenter also recommended that the benefit be provided on an annual basis if the employee has a need for it and if the employee continues to have the service-connected disability.

A third commenter stated that 104 hours was not enough time to cover the various medical appointments veterans with service-connected disabilities rated at 30 percent or more have. The commenter also stated that the location and operating hours of VA medical centers should have been taken into account when determining the amount of hours of disabled veteran leave to provide to an employee. The commenter suggested that VA medical appointments should be authorized as ''company time.'' The commenter did not feel he should have to supplement disabled veteran leave by using his own accrued sick leave to attend VA medical appointments.

The comments received regarding the amount of leave to credit under the new leave category and how often this leave is made available are outside the scope of OPM's authority and regulations; therefore, no changes were made to the regulations based on these comments. Under section 6329(b)(1), the amount of disabled leave credited to an employee may not exceed 104 hours. The Act provides a one-time benefit of up to 104 hours of disabled veteran leave to an eligible veteran to be used during the12-month period beginning on the first day of employment.

§ 630.1306—Requesting and Using Disabled Veteran Leave

One commenter expressed concern that the retroactive substitution provisions at § 630.1306(c) are too complex. These provisions allow an employee to substitute disabled veteran leave retroactively for other leave or paid time off used for the medical treatment of a qualifying service-connected disability during the employee's established 12-month eligibility.

We disagree and do not view these provisions as too complex to implement. In addition, the provisions allowing for retroactive substitution are necessary to assist employees who have not yet received their disability determination rating of 30 percent or more from the VBA. Therefore, we are not adopting any changes to this portion of the rule.

§ 630.1307—Medical Certification

We received one agency comment regarding this section. The agency recommended that, in the final rule, § 630.1307(b)(1) be changed from ''A statement by the health care provider that the medical treatment is for one or more service-connected disabilities of the employee rated at 30 percent or more'' to read as ''A statement by the health care provider that the medical treatment is for one or more service-connected disabilities of the employee that resulted in 30 percent or more disability rating'' or other similar statement. The agency stated that the proposed section could be interpreted to mean that only individual disabilities rated at 30% or higher are eligible when in reality the leave may be used for any of the disabilities listed in the veteran's disability rating determination that were combined to reach a total disability rating of 30 percent or more. The agency acknowledges that the intent of this section is covered elsewhere in the proposed rule, but expressed concern that this particular verbiage could be misunderstood.

We agree with the comment and are adopting the recommended language for § 630.1307(b)(1) in the final rule.

The same agency also commented on the proposed language regarding the time limits within which an employee must provide any required written medical certification to the agency after the agency requests it. In § 630.1307(c)(1) of the proposed rule, the employee must provide the requested medical certification no later than 15 calendar days after the date the agency requests it.

However, § 630.1307(c)(2) provides that if it is not practicable under the particular circumstances to provide the requested medical certification within 15 calendar days after the date requested by the agency despite the employee's diligent, good faith efforts, the employee must provide the medical certification within a reasonable period of time under the circumstances involved, but no later than 30 calendar days after the date the agency requests such documentation.

The agency recommended removing the phrase ''diligent, good faith effort'' from the final regulations stating that ''good faith'' is not further clarified or defined in the proposed rule and agencies will have difficulty defending determinations that an employee did not meet ''diligent and good faith efforts.''

While we understand the commenter's concerns, we are not adopting a change to the final regulations. We recognize there may be circumstances in which the employee cannot provide the requested documentation within this prescribed time period; therefore, we provide a limited extended time period for the employee. The employee should make every effort to meet the initial 15 calendar days. However, if more time is needed by the employee, the agency should allow for additional days. The employee bears the responsibility for the required medical certification, and part of his or her effort should be periodic updates to the agency on the status of the required medical certification. The employee must provide the required medical certification no later than 30 days after the agency's initial request for such documentation.

Analogous language regarding an employee's ''diligent, good faith efforts'' is also included in the medical certification provisions of both the sick leave regulations at § 630.405(b) and the Family and Medical Leave Act (FMLA) regulations at § 630.1208(h). We included parallel provisions in these regulations, so that agencies have one standard to administer regarding the timeframes for employees to provide supporting medical documentation to them. Additionally, we have not had any feedback from agencies expressing any difficulty in administering the sick leave and FMLA provisions based upon the ''diligent, good faith efforts'' language included under those regulations.

Miscellaneous Comment(s)

We received one comment regarding Executive Order (E.O.) 5396 issued on July 17, 1930. E.O. 5396 provides a basic entitlement for any veteran to use annual leave, sick leave, or leave without pay when absent from work for medical treatment of a service-connected disability (regardless of the disability rating). The commenter questioned why E.O. 5396 is not mentioned in the proposed rule. The commenter stated that ''the will of Congress was to expand the intent of the E.O. by actually paying the disabled Vet for some of the leave without pay (LWOP) that they were granted in the 1930 E.O. and that this E.O. is still in effect.'' The commenter further recommended that the final rule provide that E.O. 5396 be the first choice after disabled veteran leave has been exhausted.

While we agree that E.O. 5396 is still in effect and valid, we did not mention it in the proposed rule because the rights provided by the Executive order and benefits under the disabled veteran leave law are two separate entitlements. OPM is authorized to issue regulations on disabled veteran leave under section 2(d) of Public Law 114–75. OPM has no authority to issue regulations regarding E.O. 5396. These disabled veteran leave regulations do not change an employee's entitlement under E.O. 5396 to use annual leave, sick leave, or leave without pay for medical treatment of the employee's service-connected disability.

The commenter was also concerned that the term AWOL (absent without leave) was mentioned several times within the proposed rule and expressed concerns that ''management would be quick to build up reasons to fire an individual.''

The regulations include two references to AWOL. The first reference to AWOL in the proposed rule simply states that disabled veteran leave cannot be applied retroactively to time charged as AWOL, but may be applied retroactively to time initially charged as leave without pay (LWOP). The second instance permits an employee to be charged as AWOL if he or she fails to produce the medical documentation required by the agency. See § 630.1306 and 630.1307. We have no reason to believe agencies will abuse this authority. Therefore, no change was made to the regulations based on this comment.

Executive Order 13563 and Executive Order 12866

The Office of Management and Budget has reviewed this rule in accordance with E.O. 13563 and 12866.

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities because it will apply only to Federal agencies and employees.

List of Subjects in 5 CFR Part 630

Government employees.

Office of Personnel Management.

Beth F. Cobert,

Acting Director.

Accordingly, OPM is amending part 630 of title 5 of the Code of Federal Regulations as follows:

PART 630—ABSENCE AND LEAVE

■ 1. Revise the authority citation for part 630 to read as follows:

Authority: 5 U.S.C. 6311; § 630.205 also issued under Pub. L. 108–411, 118 Stat 2312; § 630.301 also issued under Pub. L. 103–356, 108 Stat. 3410 and Pub. L. 108–411, 118 Stat 2312; § 630.303 also issued under 5 U.S.C. 6133(a); §§ 630.306 and 630.308 also issued under 5 U.S.C. 6304(d)(3), Pub. L. 102–484,

106 Stat. 2722, and Pub. L. 103–337, 108 Stat. 2663; subpart D also issued under Pub. L. 103–329, 108 Stat. 2423; § 630.501 and subpart F also issued under E.O. 11228, 30 FR 7739, 3 CFR, 1974 Comp., p. 163; subpart G also issued under 5 U.S.C. 6305; subpart H also issued under 5 U.S.C. 6326; subpart I also issued under 5 U.S.C. 6332, Pub. L. 100–566, 102 Stat. 2834, and Pub. L. 103–103, 107 Stat. 1022; subpart J also issued under 5 U.S.C. 6362, Pub. L 100–566, and Pub. L. 103–103; subpart K also issued under Pub. L. 105–18, 111 Stat. 158; subpart L also issued under 5 U.S.C. 6387 and Pub. L. 103–3, 107 Stat. 23; and subpart M also issued under section 2(d) of Pub. L. 114–75, 129 Stat. 640.

§ 630.310 [Removed and Reserved]

■ 2. Remove and reserve § 630.310.

■ 3. Revise subpart M to read as follows:

Subpart M—Disabled Veteran Leave

Sec.

Subpart M—Disabled Veteran Leave

§ 630.1301 Purpose and authority.

This subpart implements 5 U.S.C. 6329, which establishes a leave category, to be known as ''disabled veteran leave,'' for an eligible employee who is a veteran with a service-connected disability rated at 30 percent or more. Such an employee is entitled to this leave for purposes of undergoing medical treatment for such disability. Disabled veteran leave must be used during the 12-month period beginning on the first day of employment. OPM's authority to regulate section 6329 is found in section 2(d) of Public Law 114–75.

§ 630.1302 Applicability.

This subpart applies to an employee who is a veteran with a service-connected disability rated at 30 percent or more, subject to the conditions specified in this subpart. This subpart does not apply to employees of the United States Postal Service or the Postal Regulatory Commission who are subject to regulations issued by the Postmaster General under section 2(d)(2) of Public Law 114–75. This subpart applies only to an employee who is hired on or after November 5, 2016.

§ 630.1303 Definitions.

In this subpart:

12-month eligibility period means the continuous 12-month period that begins on the first day of employment. For an employee who was eligible (or later determined to have been eligible) for disabled veteran leave as an employee of the United States Postal Service or the Postal Regulatory Commission and who subsequently commences employment covered by this subpart, the 12-month eligibility period is the period that began on the first day of employment with the United States Postal Service or the Postal Regulatory Commission (as determined under regulations issued by the Postmaster General to implement 5 U.S.C. 6329).

Agency means an agency of the Federal Government. In the case of an agency in the Executive branch, it means an Executive agency as defined in 5 U.S.C. 105. When the term ''agency'' is used in the context of an agency making determinations or taking actions, it means management officials of the agency who are authorized by the agency head to make the given determination or take the given action.

Employee has the meaning given that term in 5 U.S.C. 2105.

Employment means service as an employee during which the employee is covered by a leave system under which leave is charged for periods of absence. This excludes service in a position in which the employee is not covered by 5 U.S.C. 6329 due to application of another statutory authority.

First day of employment means the first day of service that qualifies as employment that occurs on the later of—

(1) The earliest date an employee is hired after the effective date of the employee's qualifying service-connected disability, as determined by the Veterans Benefits Administration; or

(2) The effective date of the employee's qualifying service-connected disability, as determined by the Veterans Benefits Administration.

Health care provider has the meaning given that term in § 630.1202.

Hired means the action of—

(1) Receiving an initial appointment to a civilian position in the Federal Government in which the service qualifies as employment under this subpart;

(2) Receiving a qualifying reappointment to a civilian position in the Federal Government in which the service qualifies as employment under this subpart; or

(3) Returning to duty status in a civilian position in the Federal Government in which the service qualifies as employment under this subpart, when such return immediately followed a break in civilian duty (with the employee in continuous civilian leave status) to perform military service.

Medical certificate means a written statement signed by a health care provider certifying to the treatment of a veteran's qualifying service-connected disability.

Medical treatment means any activity carried out or prescribed by a health care provider to treat a veteran's qualifying service-connected disability.

Military service means ''active military, naval, or air service'' as that term is defined in 38 U.S.C. 101(24).

Qualifying reappointment means an appointment of a former employee of the Federal Government following a break in employment of at least 90 calendar days.

Qualifying service-connected disability means a veteran's service-connected disability rated at 30 percent or more by the Veteran Benefits Administration, including a combined degree of disability of 30 percent or more that reflects the combined effect of multiple individual disabilities, which resulted in the award of disability compensation under title 38, United States Code. A temporary disability rating under 38 U.S.C. 1156 is considered a valid rating in applying this definition for as long as it is in effect.

Service-connected has the meaning given such term in 38 U.S.C. 101(16).

Veteran has the meaning given such term in 38 U.S.C. 101(2).

Veterans Benefits Administration means the Veterans Benefits Administration of the Department of Veterans Affairs.

§ 630.1304 Eligibility.

(a) An employee who is a veteran with a qualifying service-connected disability is entitled to disabled veteran leave under this subpart, which will be available for use during the 12-month eligibility period beginning on the first day of employment. For each employee, there is a single first day of employment.

(b) In order to be eligible for disabled veteran leave, an employee must provide to the agency documentation from the Veterans Benefits Administration certifying that the employee has a qualifying service-connected disability. The documentation should be provided to the agency—

(1) Upon the first day of employment, if the employee has already received such certifying documentation; or

(2) For an employee who has not yet received such certifying documentation from the Veterans Benefit

Administration, as soon as practicable after the employee receives the certifying documentation.

(c) Notwithstanding paragraph (b) of this section, an employee may submit certifying documentation at a later time, including after a period of absence for medical treatment, as described in § 630.1306(c). The 12-month eligibility period is fixed based on the first day of employment and is not affected by the timing of when certifying documentation is provided.

(d) If an employee's service-connected disability rating is decreased or discontinued during the 12-month eligibility period such that the employee no longer has a qualifying service-connected disability—

(1) The employee must notify the agency of the effective date of the change in the disability rating; and

(2) The employee is no longer eligible for disabled veteran leave as of the effective date of the rating change.

§ 630.1305 Crediting disabled veteran leave.

(a) Upon receipt of the certifying documentation under § 630.1304, an agency must credit 104 hours of disabled veteran leave to a full-time, nonseasonal employee or a proportionally equivalent amount for employees with part-time, seasonal, or uncommon tours of duty, except as otherwise provided in this section.

(b) The proportional equivalent of 104 hours for a full-time employee is determined for employees with other schedules as follows:

(1) For an employee with a part-time work schedule, the 104 hours is prorated based on the number of hours in the part-time schedule (as established for leave charging purposes) relative to a full-time schedule (*e.g.,* 52 hours for a half-time schedule);

(2) For an employee with a seasonal work schedule, the 104 hours is prorated based on the total projected hours to be worked in an annual period of 52 weeks (based on the seasonal employee's seasonal work periods and full-time or part-time schedule during those periods) relative to a full-time work year of 2,080 hours (*e.g.,* 52 hours for a seasonal employee who works full-time for half a year); and

(3) For an employee with an uncommon tour of duty (as defined in § 630.201 and described in § 630.210), 104 hours is proportionally increased based on the number of hours in the uncommon tour relative to the hours in a regular full-time tour (*e.g.,* 187 hours for an employee with a 72-hour weekly uncommon tour of duty.)

(c) When an employee is converted to a different tour of duty for leave purposes, the employee's balance of unused disabled veteran leave must be converted to the proper number of hours based on the proportion of hours in the new tour of duty compared to the former tour of duty. For seasonal employees, hours must be annualized in determining the proportion.

(d) The amount of disabled veteran leave initially credited to an employee under paragraphs (a) and (b) of this section must be offset by the number of hours of sick leave an employee has credited to his or her account as of the first day of employment. For example, if an employee is being reappointed and having sick leave recredited upon such reappointment, the amount of disabled veteran leave must be reduced by the amount of such recredited sick leave. Similarly, if an employee is returning to civilian duty status after a period of leave for military service, that employee may have a balance of sick leave, which must be used to offset the disabled veteran leave.

(e)(1) An employee who was previously employed by an agency whose employees were not subject to 5 U.S.C. 6329 must certify, at the time the employee is hired in a position subject to 5 U.S.C. 6329, whether or not that former agency provided entitlement to an equivalent disabled veteran leave benefit to be used in connection with the medical treatment of a service-connected disability rated at 30 percent or more. The employee must certify the date he or she commenced the period of eligibility to use disabled veteran leave in the former agency.

(2) If 12 months have elapsed since the commencing date referenced in paragraph (e)(1) of this section, the employee will be considered to have received the full amount of an equivalent benefit and no benefit may be provided under this subpart.

(3) If the employee is still within the 12-month period that began on the commencing date referenced in paragraph (e)(1) of this section, the employee must certify the number of hours of disabled veteran leave used at the former agency. The gaining agency must offset the number of hours of disabled veteran leave to be credited to the employee by the number of such hours used by the employee at such agency, while making no offset under paragraph (d) of this section. If the employee had a different type of work schedule at the former agency, the hours used at the former agency must be converted before applying the offset, consistent with § 630.1305(c).

§ 630.1306 Requesting and using disabled veteran leave.

(a) An employee may use disabled veteran leave only for the medical treatment of a qualifying service-connected disability. The medical treatment may include a period of rest, but only if such period of rest is specifically ordered by the health care provider as part of a prescribed course of treatment for the qualifying service-connected disability.

(b)(1) An employee must file an application—written, oral, or electronic, as required by the agency—to use disabled veteran leave. The application must include a personal self-certification by the employee that the requested leave will be (or was) used for purposes of being furnished medical treatment for a qualifying service-connected disability. The application must also include the specific days and hours of absence required for the treatment. The application must be submitted within such time limits as the agency may require.

(2) An employee must request approval to use disabled veteran leave in advance unless the need for leave is critical and not foreseeable—*e.g.,* due to a medical emergency or the unexpected availability of an appointment for surgery or other critical treatment. The employee must provide notice within a reasonable period of time appropriate to the circumstances involved. If the agency determines that the need for leave is critical and not foreseeable and that the employee is unable to provide advance notice of his or her need for leave, the leave may not be delayed or denied.

(c)(1) When an employee did not provide the agency with certification of a qualifying service-connected disability before having a period of absence for treatment of such disability, the employee is entitled to substitute approved disabled veteran leave retroactively for such period of absence (excluding periods of suspension or absence without leave (AWOL), but including leave without pay, sick leave, annual leave, compensatory time off, or other paid time off) in the 12-month eligibility period. Such retroactive substitution cancels the use of the original leave or paid time off and requires appropriate adjustments. In the case of retroactive substitution for a period when an employee used advanced annual leave or advanced sick leave, the adjustment is a liquidation of the leave indebtedness covered by the substitution.

(2) An agency may require an employee to submit the medical certification described in § 630.1307(a)

before approving such retroactive substitution.

§ 630.1307 Medical certification.

(a) In addition to the employee's self-certification required under § 630.1306(b)(1), an agency may additionally require that the use of disabled veteran leave be supported by a signed written medical certification issued by a health care provider.

(b) When an agency requires a signed written medical certification by a health care provider, the agency may specify that the certification include—

(1) A statement by the health care provider that the medical treatment is for one or more service-connected disabilities of the employee that resulted in 30 percent or more disability rating;

(2) The date or dates of treatment or, if the treatment extends over several days, the beginning and ending dates of the treatment;

(3) If the leave was not requested in advance, a statement that the treatment required was of an urgent nature or there were other circumstances that made advanced scheduling not possible; and

(4) Any additional information that is essential to verify the employee's eligibility.

(c)(1) An employee must provide any required written medical certification no later than 15 calendar days after the date the agency requests such medical certification, except as otherwise allowed under paragraph (c)(2) of this section.

(2) If the agency determines it is not practicable under the particular circumstances for the employee to provide the requested medical certification within 15 calendar days after the date requested by the agency despite the employee's diligent, good faith efforts, the employee must provide the medical certification within a reasonable period of time under the circumstances involved, but no later than 30 calendar days after the date the agency requests such documentation.

(3) An employee who does not provide the required evidence or medical certification within the specified time period is not entitled to use disabled veteran leave, and the agency may, as appropriate and consistent with applicable laws and regulations—

(i) Charge the employee as absent without leave (AWOL); or

(ii) Allow the employee to request that the absence be charged to leave without pay, sick leave, annual leave, or other forms of paid time off.

§ 630.1308 Disabled veteran leave forfeiture, transfer, reinstatement.

(a) Disabled veteran leave not used during the 12-month eligibility period may not be carried over to subsequent years and must be forfeited.

(b) If a change in the employee's disability rating during the 12-month eligibility period causes the employee to no longer have a qualifying service-connected disability (as described in § 630.1304(d)), any unused disabled veteran leave to the employee's credit as of the effective date of the rating change must be forfeited.

(c) When an employee with a positive disabled veteran leave balance transfers between positions in different agencies, or transfers from the United States Postal Service or Postal Regulatory Commission to a position in another agency, during the 12-month eligibility period, the agency from which the employee transfers must certify the number of unused disabled veteran leave hours available for credit by the gaining agency. The losing agency must also certify the expiration date of the employee's 12-month eligibility period to the gaining agency. Any unused disabled veteran leave will be forfeited at the end of that eligibility period. For the purpose of this paragraph, the term ''transfers'' means movement from a position in one agency (or the United States Postal Service or Postal Regulatory Commission) to a position in another agency without a break in employment of 1 workday or more in circumstances where service in both positions qualifies as employment under this subpart.

(d)(1) An employee covered by this subpart, or an employee of the United States Postal Service or Postal Regulatory Commission, with a balance of unused disabled veteran leave who has a break in employment of at least 1 workday during the employee's 12-month eligibility period, and later recommences employment covered by 5 U.S.C. 6329 within that same eligibility period, is entitled to a recredit of the unused balance.

(2) When an employee has a break in employment as described in paragraph (d)(1) of this section, the losing agency must certify the number of unused disabled veteran leave hours available for recredit by the gaining agency. The losing agency must also certify the expiration date of the employee's 12-month eligibility period. Any unused disabled veteran leave must be forfeited at the end of that eligibility period.

(3) In the absence of the certification described in paragraph (d)(2) of this section, the recredit of disabled veteran leave may also be supported by written documentation available to the employing agency in its official personnel records concerning the employee, the official records of the employee's former employing agency, copies of contemporaneous earnings and leave statement(s) provided by the employee, or copies of other contemporaneous written documentation acceptable to the agency.

(e) An employee may not receive a lump-sum payment for any unused disabled veteran leave under any circumstance.

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1205

[Doc. #AMS–CN–16–0012]

Cotton Board Rules and Regulations: Adjusting Supplemental Assessment on Imports (2016 Amendments)

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Direct final rule.

SUMMARY: The Agricultural Marketing Service (AMS) is amending the Cotton Board Rules and Regulations, decreasing the value assigned to imported cotton for the purposes of calculating supplemental assessments collected for use by the Cotton Research and Promotion Program. This amendment is required each year to ensure that assessments collected on imported cotton and the cotton content of imported products will be the same as those paid on domestically produced cotton.

DATES: This direct rule is effective October 4, 2016, without further action or notice, unless significant adverse comment is received by September 6, 2016. If significant adverse comment is received, AMS will publish a timely withdrawal of the amendment in the **Federal Register**.

ADDRESSES: Written comments may be submitted to the addresses specified below. All comments will be made available to the public. Please do not include personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publically disclosed. All comments may be posted on the Internet and can be retrieved by most Internet search engines. Comments may be submitted anonymously.

Comments, identified by AMS–CN–16–0012, may be submitted electronically through the *Federal eRulemaking Portal at http://www.regulations.gov*. Please follow the instructions for submitting comments. In addition, comments may be submitted by *mail or hand delivery to* Cotton Research and Promotion, Cotton and Tobacco Program, AMS, USDA, 100 Riverside Parkway, Suite 101, Fredericksburg, Virginia 22406. Comments should be submitted in triplicate. All comments received will be made available for public inspection at Cotton and Tobacco Program, AMS, USDA, 100 Riverside Parkway, Suite 101, Fredericksburg, Virginia 22406. A copy of this document may be found at: *www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Shethir M. Riva, Director, Research and Promotion, Cotton and Tobacco Program, AMS, USDA, 100 Riverside Parkway, Suite 101, Fredericksburg, Virginia 22406, telephone (540) 361–2726, facsimile (540) 361–1199, or email at *Shethir.Riva@ams.usda.gov*.

SUPPLEMENTARY INFORMATION:

A. Background

Amendments to the Cotton Research and Promotion Act (7 U.S.C. 2101–2118) (Act) were enacted by Congress under Subtitle G of Title XIX of the Food, Agriculture, Conservation, and Trade Act of 1990 (Pub. L. 101–624, 104 Stat. 3909, November 28, 1990). These amendments contained two provisions that authorize changes in the funding procedures for the Cotton Research and Promotion Program. These provisions provide for: (1) The assessment of imported cotton and cotton products; and (2) termination of refunds to cotton producers. (Prior to the 1990 amendments to the Act, producers could request assessment refunds.)

As amended, the Cotton Research and Promotion Order (7 CFR part 1205) (Order) was approved by producers and importers voting in a referendum held July 17–26, 1991, and the amended Order was published in the **Federal Register** on December 10, 1991, (56 FR 64470). A proposed rule implementing the amended Order was published in the **Federal Register** on December 17, 1991, (56 FR 65450). Implementing rules were published on July 1 and 2, 1992, (57 FR 29181) and (57 FR 29431), respectively.

This direct final rule would amend the value assigned to imported cotton in the Cotton Board Rules and Regulations (7 CFR 1205.510(b)(2)) that is used to determine the Cotton Research and Promotion assessment on imported cotton and cotton products. The total value of assessment levied on cotton imports is the sum of two parts. The first part of the assessment is based on the weight of cotton imported—levied at a rate of $1 per bale of cotton, which is equivalent to 500 pounds, or $1 per 226.8 kilograms of cotton. The second part of the import assessment (referred to as the supplemental assessment) is based on the value of imported cotton lint or the cotton contained in imported cotton products—levied at a rate of five-tenths of one percent of the value of domestically produced cotton.

Section 1205.510(b)(2) of the Cotton Research and Promotion Rules and Regulations provides for assigning the calendar year weighted average price received by U.S. farmers for Upland cotton to represent the value of imported cotton. This is so that the assessment on domestically produced cotton and the assessment on imported cotton and the cotton content of imported products is the same. The source for the average price statistic is *Agricultural Prices,* a publication of the National Agricultural Statistics Service (NASS) of the Department of Agriculture. Use of the weighted average price figure in the calculation of supplemental assessments on imported cotton and the cotton content of imported products will yield an assessment that is the same as assessments paid on domestically produced cotton.

The current value of imported cotton as published in 2015 in the **Federal Register** (80 FR 53243) for the purpose of calculating assessments on imported cotton is $0.012013 per kilogram. Using the Average Weighted Price received by U.S. farmers for Upland cotton for the calendar year 2015, this direct final rule would amend the new value of imported cotton to $0.011012 per kilogram to reflect the price paid by U.S. farmers for Upland cotton during 2015.

An example of the complete assessment formula and how the figures are obtained is as follows:

One bale is equal to 500 pounds.

One kilogram equals 2.2046 pounds.

One pound equals 0.453597 kilograms.

One Dollar per Bale Assessment Converted to Kilograms

A 500-pound bale equals 226.8 kg. (500×0.453597).

$1 per bale assessment equals $0.002000 per pound or $0.2000 cents per pound (1/500) or $0.004409 per kg or $0.4409 cents per kg. (1/226.8).

Supplemental Assessment of 5/10 of One Percent of the Value of the Cotton Converted to Kilograms

The 2015 calendar year weighted average price received by producers for Upland cotton is $0.599 per pound or $1.321 per kg. ($0.599 \times 2.2046$).

Five tenths of one percent of the average price equals $0.006603 per kg. ($1.321 \times 0.005$).

Total Assessment

The total assessment per kilogram of raw cotton is obtained by adding the $1 per bale equivalent assessment of $0.004409 per kg. and the supplemental assessment $0.006603 per kg., which equals $0.011012 per kg.

The current assessment on imported cotton is $0.012013 per kilogram of imported cotton. The revised assessment in this direct final rule is $0.011012, a decrease of $0.001001 per kilogram. This decrease reflects the decrease in the average weighted price of Upland cotton received by U.S. farmers during the period January through December 2015.

Import Assessment Table in section 1205.510(b)(3) indicates the total assessment rate ($ per kilogram) due for each Harmonized Tariff Schedule (HTS) number that is subject to assessment. This table must be revised each year to reflect changes in supplemental assessment rates and any changes to the HTS numbers. In this direct final rule, AMS is amending the Import Assessment Table.

AMS believes that these amendments are necessary to ensure that assessments collected on imported cotton and the cotton content of imported products are the same as those paid on domestically produced cotton. Accordingly, changes reflected in this rule should be adopted and implemented as soon as possible since it is required by regulation.

B. Good Cause Finding That Proposed Rulemaking Is Unnecessary

Rulemaking under section 553 of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*) ordinarily involves publication of a notice of proposed rulemaking in the **Federal Register** and the public is given an opportunity to comment on the proposed rule; however, an agency may issue a rule without prior notice and comment procedures if it determines for good cause that public notice and comment procedures are impracticable, unnecessary, or contrary to the public interest for such rule, and incorporates a statement of the finding with the underlying reasons in the final rule issued.

As described in this **Federal Register** document, the amendment to the value used to determine the Cotton Research and Promotion Program importer assessment will be updated to reflect the assessment already paid by U.S. farmers. For the reasons mentioned in section A of this preamble, AMS finds that publishing a proposed rule and seeking public comment is unnecessary because the change is required annually by regulation in 7 CFR 1205.510.

Also, this direct-final rulemaking furthers the objectives of Executive Order 13563, which requires that the regulatory process ''promote predictability and reduce uncertainty'' and ''identify and use the best, most innovative, and least burdensome tools for achieving regulatory ends.''

AMS has used the direct rule rulemaking process since 2013 and has not received any adverse comments; however, if AMS does receives significant adverse comment during the comment period, it will publish, in a timely manner, a document in the **Federal Register** withdrawing this direct final rule. AMS will then address public comments in a subsequent proposed rule and final rule based on the proposed rule.

C. Regulatory Impact Analysis

Executive Order 13175

This action has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation would not have substantial and direct effects on Tribal governments and would not have significant Tribal implications.

Executive Orders 12866 and 13563

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

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 12 of the Act, any person subject to an order may file with the Secretary of Agriculture (Secretary) a petition stating that the order, any provision of the plan, or any obligation imposed in connection with the order is not in accordance with law and requesting a modification of the order or to be exempted therefrom. Such person is afforded the opportunity for a hearing on the petition. After the hearing, the Secretary would rule on the petition. The Act provides that the District Court of the United States in any district in which the person is an inhabitant, or has his principal place of business, has jurisdiction to review the Secretary's ruling, provided a complaint is filed within 20 days from the date of the entry of the Secretary's ruling.

Regulatory Flexibility Act and Paperwork Reduction Act

In accordance with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), AMS has examined the economic impact of this rule on small entities. The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such action so that small businesses will not be unduly or disproportionately burdened. The Small Business Administration defines, in 13 CFR part 121, small agricultural producers as those having annual receipts of no more than $750,000 and small agricultural service firms (importers) as having receipts of no more than $7,500,000. In 2015, an estimated 20,000 importers are subject to the rules and regulations issued pursuant to the Cotton Research and Promotion Order. Most are considered small entities as defined by the Small Business Administration.

This rule would only affect importers of cotton and cotton-containing products and would lower the assessments paid by the importers under the Cotton Research and Promotion Order. The current assessment on imported cotton is $0.012013 per kilogram of imported cotton. The amended assessment would be $0.011012, which was calculated based on the 12-month weighted average of price received by U.S. cotton farmers. Section 1205.510, ''Levy of assessments'', provides ''The rate of the supplemental assessment on imported cotton will be the same as that levied on cotton produced within the United States.'' In addition, section 1205.510 provides that the 12-month weighted average of prices received by U.S. farmers will be used as the value of imported cotton for the purpose of levying the supplemental assessment on imported cotton.

Under the Cotton Research and Promotion Program, assessments are used by the Cotton Board to finance research and promotion programs designed to increase consumer demand for Upland cotton in the United States and international markets. In 2014 (the last audited year), producer assessments totaled $37.8 million and importer assessments totaled $38.3 million. According to the Cotton Board, should the volume of cotton products imported into the U.S. remain at the same level in 2016, one could expect a decrease of assessments by approximately $3,845,000.

Imported organic cotton and products may be exempt from assessment if eligible under section 1205.519 of the Order.

There are no Federal rules that duplicate, overlap, or conflict with this rule.

In compliance with Office of Management and Budget (OMB) regulations (5 CFR part 1320) which implement the Paperwork Reduction Act (PRA) (44 U.S.C. Chapter 35) the information collection requirements contained in the regulation to be amended have been previously approved by OMB and were assigned control number 0581–0093, National Research, Promotion, and Consumer Information Programs. This rule does not result in a change to the information collection and recordkeeping requirements previously approved.

A 30-day comment period is provided to comment on the changes to the Cotton Board Rules and Regulations proposed herein. This period is deemed appropriate because this rule would decrease the assessments paid by importers under the Cotton Research and Promotion Order. An amendment is required to adjust the assessments collected on imported cotton and the cotton content of imported products to be the same as those paid on domestically produced cotton. Accordingly, the change in this rule, if adopted, should be implemented as soon as possible.

List of Subjects in 7 CFR Part 1205

Advertising, Agricultural research, Cotton, Marketing agreements, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, AMS amends 7 CFR part 1205 as follows:

PART 1205—COTTON RESEARCH AND PROMOTION

■ 1. The authority citation for part 1205 continues to read as follows:

Authority: 7 U.S.C. 2101–2118.

■ 2. In § 1205.510, paragraph (b)(2) and the Import Assessment table in paragraph (b)(3) are revised to read as follows:

§ 1205.510 Levy of assessments.

* * * * *

(b) * * *

(2) The 12-month average of monthly weighted average prices received by U.S. farmers will be calculated annually. Such weighted average will be used as the value of imported cotton for the purpose of levying the supplemental assessment on imported cotton and will be expressed in kilograms. The value of imported cotton for the purpose of levying this supplemental assessment is $1.1012 cents per kilogram.

(3) * * *

IMPORT ASSESSMENT TABLE

[Raw cotton fiber]

HTS No.	CONV. factor	Cents/kg.
5007106010	0.2713	0.29875556
5007106020	0.2713	0.29875556
5007906010	0.2713	0.29875556
5007906020	0.2713	0.29875556
5112904000	0.1085	0.1194802
5112905000	0.1085	0.1194802
5112909010	0.1085	0.1194802
5112909090	0.1085	0.1194802
5201000500	1	1.1012
5201001200	1	1.1012
5201001400	1	1.1012
5201001800	1	1.1012
5201002200	1	1.1012
5201002400	1	1.1012
5201002800	1	1.1012
5201003400	1	1.1012
5201003800	1	1.1012
5204110000	1.0526	1.15912312
5204190000	0.6316	0.69551792
5204200000	1.0526	1.15912312
5205111000	1	1.1012
5205112000	1	1.1012
5205121000	1	1.1012
5205122000	1	1.1012
5205131000	1	1.1012
5205132000	1	1.1012
5205141000	1	1.1012
5205142000	1	1.1012
5205151000	1	1.1012
5205152000	1	1.1012
5205210020	1.044	1.1496528
5205210090	1.044	1.1496528
5205220020	1.044	1.1496528
5205220090	1.044	1.1496528
5205230020	1.044	1.1496528

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	CONV. factor	Cents/kg.
5205230090	1.044	1.1496528
5205240020	1.044	1.1496528
5205240090	1.044	1.1496528
5205260020	1.044	1.1496528
5205260090	1.044	1.1496528
5205270020	1.044	1.1496528
5205270090	1.044	1.1496528
5205280020	1.044	1.1496528
5205280090	1.044	1.1496528
5205310000	1	1.1012
5205320000	1	1.1012
5205330000	1	1.1012
5205340000	1	1.1012
5205350000	1	1.1012
5205410020	1.044	1.1496528
5205410090	1.044	1.1496528
5205420021	1.044	1.1496528
5205420029	1.044	1.1496528
5205420090	1.044	1.1496528
5205430021	1.044	1.1496528
5205430029	1.044	1.1496528
5205430090	1.044	1.1496528
5205440021	1.044	1.1496528
5205440029	1.044	1.1496528
5205440090	1.044	1.1496528
5205460021	1.044	1.1496528
5205460029	1.044	1.1496528
5205460090	1.044	1.1496528
5205470021	1.044	1.1496528
5205470029	1.044	1.1496528
5205470090	1.044	1.1496528
5205480020	1.044	1.1496528
5205480090	1.044	1.1496528
5206110000	0.7368	0.81136416
5206120000	0.7368	0.81136416
5206130000	0.7368	0.81136416
5206140000	0.7368	0.81136416
5206150000	0.7368	0.81136416
5206210000	0.7692	0.84704304
5206220000	0.7692	0.84704304
5206230000	0.7692	0.84704304
5206240000	0.7692	0.84704304
5206250000	0.7692	0.84704304
5206310000	0.7368	0.81136416
5206320000	0.7368	0.81136416
5206330000	0.7368	0.81136416
5206340000	0.7368	0.81136416
5206350000	0.7368	0.81136416
5206410000	0.7692	0.84704304
5206420000	0.7692	0.84704304
5206430000	0.7692	0.84704304
5206440000	0.7692	0.84704304
5206450000	0.7692	0.84704304
5207100000	0.9474	1.04327688
5207900000	0.6316	0.69551792
5208112020	1.0852	1.19502224
5208112040	1.0852	1.19502224
5208112090	1.0852	1.19502224
5208114020	1.0852	1.19502224
5208114040	1.0852	1.19502224
5208114060	1.0852	1.19502224
5208114090	1.0852	1.19502224
5208116000	1.0852	1.19502224
5208118020	1.0852	1.19502224
5208118090	1.0852	1.19502224
5208124020	1.0852	1.19502224
5208124040	1.0852	1.19502224
5208124090	1.0852	1.19502224
5208126020	1.0852	1.19502224

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	CONV. factor	Cents/kg.
5208126040	1.0852	1.19502224
5208126060	1.0852	1.19502224
5208126090	1.0852	1.19502224
5208128020	1.0852	1.19502224
5208128090	1.0852	1.19502224
5208130000	1.0852	1.19502224
5208192020	1.0852	1.19502224
5208192090	1.0852	1.19502224
5208194020	1.0852	1.19502224
5208194090	1.0852	1.19502224
5208196020	1.0852	1.19502224
5208196090	1.0852	1.19502224
5208198020	1.0852	1.19502224
5208198090	1.0852	1.19502224
5208212020	1.0852	1.19502224
5208212040	1.0852	1.19502224
5208212090	1.0852	1.19502224
5208214020	1.0852	1.19502224
5208214040	1.0852	1.19502224
5208214060	1.0852	1.19502224
5208214090	1.0852	1.19502224
5208216020	1.0852	1.19502224
5208216090	1.0852	1.19502224
5208224020	1.0852	1.19502224
5208224040	1.0852	1.19502224
5208224090	1.0852	1.19502224
5208226020	1.0852	1.19502224
5208226040	1.0852	1.19502224
5208226060	1.0852	1.19502224
5208226090	1.0852	1.19502224
5208228020	1.0852	1.19502224
5208228090	1.0852	1.19502224
5208230000	1.0852	1.19502224
5208292020	1.0852	1.19502224
5208292090	1.0852	1.19502224
5208294020	1.0852	1.19502224
5208294090	1.0852	1.19502224
5208296020	1.0852	1.19502224
5208296090	1.0852	1.19502224
5208298020	1.0852	1.19502224
5208298090	1.0852	1.19502224
5208312000	1.0852	1.19502224
5208314020	1.0852	1.19502224
5208314040	1.0852	1.19502224
5208314090	1.0852	1.19502224
5208316020	1.0852	1.19502224
5208316040	1.0852	1.19502224
5208316060	1.0852	1.19502224
5208316090	1.0852	1.19502224
5208318020	1.0852	1.19502224
5208318090	1.0852	1.19502224
5208321000	1.0852	1.19502224
5208323020	1.0852	1.19502224
5208323040	1.0852	1.19502224
5208323090	1.0852	1.19502224
5208324020	1.0852	1.19502224
5208324040	1.0852	1.19502224
5208324060	1.0852	1.19502224
5208324090	1.0852	1.19502224
5208325020	1.0852	1.19502224
5208325090	1.0852	1.19502224
5208330000	1.0852	1.19502224
5208392020	1.0852	1.19502224
5208392090	1.0852	1.19502224
5208394020	1.0852	1.19502224
5208394090	1.0852	1.19502224
5208396020	1.0852	1.19502224
5208396090	1.0852	1.19502224
5208398020	1.0852	1.19502224

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	CONV. factor	Cents/kg.
5208398090	1.0852	1.19502224
5208412000	1.0852	1.19502224
5208414000	1.0852	1.19502224
5208416000	1.0852	1.19502224
5208418000	1.0852	1.19502224
5208421000	1.0852	1.19502224
5208423000	1.0852	1.19502224
5208424000	1.0852	1.19502224
5208425000	1.0852	1.19502224
5208430000	1.0852	1.19502224
5208492000	1.0852	1.19502224
5208494010	1.0852	1.19502224
5208494020	1.0852	1.19502224
5208494090	1.0852	1.19502224
5208496010	1.0852	1.19502224
5208496020	1.0852	1.19502224
5208496030	1.0852	1.19502224
5208496090	1.0852	1.19502224
5208498020	1.0852	1.19502224
5208498090	1.0852	1.19502224
5208512000	1.0852	1.19502224
5208514020	1.0852	1.19502224
5208514040	1.0852	1.19502224
5208514090	1.0852	1.19502224
5208516020	1.0852	1.19502224
5208516040	1.0852	1.19502224
5208516060	1.0852	1.19502224
5208516090	1.0852	1.19502224
5208518020	1.0852	1.19502224
5208518090	1.0852	1.19502224
5208521000	1.0852	1.19502224
5208523020	1.0852	1.19502224
5208523035	1.0852	1.19502224
5208523045	1.0852	1.19502224
5208523090	1.0852	1.19502224
5208524020	1.0852	1.19502224
5208524035	1.0852	1.19502224
5208524045	1.0852	1.19502224
5208524055	1.0852	1.19502224
5208524065	1.0852	1.19502224
5208524090	1.0852	1.19502224
5208525020	1.0852	1.19502224
5208525090	1.0852	1.19502224
5208591000	1.0852	1.19502224
5208592015	1.0852	1.19502224
5208592025	1.0852	1.19502224
5208592085	1.0852	1.19502224
5208592095	1.0852	1.19502224
5208594020	1.0852	1.19502224
5208594090	1.0852	1.19502224
5208596020	1.0852	1.19502224
5208596090	1.0852	1.19502224
5208598020	1.0852	1.19502224
5208598090	1.0852	1.19502224
5209110020	1.0309	1.13522708
5209110025	1.0309	1.13522708
5209110035	1.0309	1.13522708
5209110050	1.0309	1.13522708
5209110090	1.0309	1.13522708
5209120020	1.0309	1.13522708
5209120040	1.0309	1.13522708
5209190020	1.0309	1.13522708
5209190040	1.0309	1.13522708
5209190060	1.0309	1.13522708
5209190090	1.0309	1.13522708
5209210020	1.0309	1.13522708
5209210025	1.0309	1.13522708
5209210035	1.0309	1.13522708
5209210050	1.0309	1.13522708

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	CONV. factor	Cents/kg.
5209210090	1.0309	1.13522708
5209220020	1.0309	1.13522708
5209220040	1.0309	1.13522708
5209290020	1.0309	1.13522708
5209290040	1.0309	1.13522708
5209290060	1.0309	1.13522708
5209290090	1.0309	1.13522708
5209313000	1.0309	1.13522708
5209316020	1.0309	1.13522708
5209316025	1.0309	1.13522708
5209316035	1.0309	1.13522708
5209316050	1.0309	1.13522708
5209316090	1.0309	1.13522708
5209320020	1.0309	1.13522708
5209320040	1.0309	1.13522708
5209390020	1.0309	1.13522708
5209390040	1.0309	1.13522708
5209390060	1.0309	1.13522708
5209390080	1.0309	1.13522708
5209390090	1.0309	1.13522708
5209413000	1.0309	1.13522708
5209416020	1.0309	1.13522708
5209416040	1.0309	1.13522708
5209420020	0.9767	1.07554204
5209420040	0.9767	1.07554204
5209420060	0.9767	1.07554204
5209420080	0.9767	1.07554204
5209430030	1.0309	1.13522708
5209430050	1.0309	1.13522708
5209490020	1.0309	1.13522708
5209490040	1.0309	1.13522708
5209490090	1.0309	1.13522708
5209513000	1.0309	1.13522708
5209516015	1.0852	1.19502224
5209516025	1.0852	1.19502224
5209516032	1.0852	1.19502224
5209516035	1.0852	1.19502224
5209516050	1.0852	1.19502224
5209516090	1.0852	1.19502224
5209520020	1.0852	1.19502224
5209520040	1.0852	1.19502224
5209590015	1.0852	1.19502224
5209590025	1.0852	1.19502224
5209590040	1.0852	1.19502224
5209590060	1.0852	1.19502224
5209590090	1.0852	1.19502224
5210114020	0.6511	0.71699132
5210114040	0.6511	0.71699132
5210114090	0.6511	0.71699132
5210116020	0.6511	0.71699132
5210116040	0.6511	0.71699132
5210116060	0.6511	0.71699132
5210116090	0.6511	0.71699132
5210118020	0.6511	0.71699132
5210118090	0.6511	0.71699132
5210191000	0.6511	0.71699132
5210192020	0.6511	0.71699132
5210192090	0.6511	0.71699132
5210194020	0.6511	0.71699132
5210194090	0.6511	0.71699132
5210196020	0.6511	0.71699132
5210196090	0.6511	0.71699132
5210198020	0.6511	0.71699132
5210198090	0.6511	0.71699132
5210214020	0.6511	0.71699132
5210214040	0.6511	0.71699132
5210214090	0.6511	0.71699132
5210216020	0.6511	0.71699132
5210216040	0.6511	0.71699132

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	CONV. factor	Cents/kg.
5210216060	0.6511	0.71699132
5210216090	0.6511	0.71699132
5210218020	0.6511	0.71699132
5210218090	0.6511	0.71699132
5210291000	0.6511	0.71699132
5210292020	0.6511	0.71699132
5210292090	0.6511	0.71699132
5210294020	0.6511	0.71699132
5210294090	0.6511	0.71699132
5210296020	0.6511	0.71699132
5210296090	0.6511	0.71699132
5210298020	0.6511	0.71699132
5210298090	0.6511	0.71699132
5210314020	0.6511	0.71699132
5210314040	0.6511	0.71699132
5210314090	0.6511	0.71699132
5210316020	0.6511	0.71699132
5210316040	0.6511	0.71699132
5210316060	0.6511	0.71699132
5210316090	0.6511	0.71699132
5210318020	0.6511	0.71699132
5210318090	0.6511	0.71699132
5210320000	0.6511	0.71699132
5210392020	0.6511	0.71699132
5210392090	0.6511	0.71699132
5210394020	0.6511	0.71699132
5210394090	0.6511	0.71699132
5210396020	0.6511	0.71699132
5210396090	0.6511	0.71699132
5210398020	0.6511	0.71699132
5210398090	0.6511	0.71699132
5210414000	0.6511	0.71699132
5210416000	0.6511	0.71699132
5210418000	0.6511	0.71699132
5210491000	0.6511	0.71699132
5210492000	0.6511	0.71699132
5210494010	0.6511	0.71699132
5210494020	0.6511	0.71699132
5210494090	0.6511	0.71699132
5210496010	0.6511	0.71699132
5210496020	0.6511	0.71699132
5210496090	0.6511	0.71699132
5210498020	0.6511	0.71699132
5210498090	0.6511	0.71699132
5210514020	0.6511	0.71699132
5210514040	0.6511	0.71699132
5210514090	0.6511	0.71699132
5210516020	0.6511	0.71699132
5210516040	0.6511	0.71699132
5210516060	0.6511	0.71699132
5210516090	0.6511	0.71699132
5210518020	0.6511	0.71699132
5210518090	0.6511	0.71699132
5210591000	0.6511	0.71699132
5210592020	0.6511	0.71699132
5210592090	0.6511	0.71699132
5210594020	0.6511	0.71699132
5210594090	0.6511	0.71699132
5210596020	0.6511	0.71699132
5210596090	0.6511	0.71699132
5210598020	0.6511	0.71699132
5210598090	0.6511	0.71699132
5211110020	0.6511	0.71699132
5211110025	0.6511	0.71699132
5211110035	0.6511	0.71699132
5211110050	0.6511	0.71699132
5211110090	0.6511	0.71699132
5211120020	0.6511	0.71699132
5211120040	0.6511	0.71699132

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	CONV. factor	Cents/kg.
5211190020	0.6511	0.71699132
5211190040	0.6511	0.71699132
5211190060	0.6511	0.71699132
5211190090	0.6511	0.71699132
5211202120	0.6511	0.71699132
5211202125	0.6511	0.71699132
5211202135	0.6511	0.71699132
5211202150	0.6511	0.71699132
5211202190	0.6511	0.71699132
5211202220	0.6511	0.71699132
5211202240	0.6511	0.71699132
5211202920	0.6511	0.71699132
5211202940	0.6511	0.71699132
5211202960	0.6511	0.71699132
5211202990	0.6511	0.71699132
5211310020	0.6511	0.71699132
5211310025	0.6511	0.71699132
5211310035	0.6511	0.71699132
5211310050	0.6511	0.71699132
5211310090	0.6511	0.71699132
5211320020	0.6511	0.71699132
5211320040	0.6511	0.71699132
5211390020	0.6511	0.71699132
5211390040	0.6511	0.71699132
5211390060	0.6511	0.71699132
5211390090	0.6511	0.71699132
5211410020	0.6511	0.71699132
5211410040	0.6511	0.71699132
5211420020	0.7054	0.77678648
5211420040	0.7054	0.77678648
5211420060	0.6511	0.71699132
5211420080	0.6511	0.71699132
5211430030	0.6511	0.71699132
5211430050	0.6511	0.71699132
5211490020	0.6511	0.71699132
5211490090	0.6511	0.71699132
5211510020	0.6511	0.71699132
5211510030	0.6511	0.71699132
5211510050	0.6511	0.71699132
5211510090	0.6511	0.71699132
5211520020	0.6511	0.71699132
5211520040	0.6511	0.71699132
5211590015	0.6511	0.71699132
5211590025	0.6511	0.71699132
5211590040	0.6511	0.71699132
5211590060	0.6511	0.71699132
5211590090	0.6511	0.71699132
5212111010	0.5845	0.6436514
5212111020	0.6231	0.68615772
5212116010	0.8681	0.95595172
5212116020	0.8681	0.95595172
5212116030	0.8681	0.95595172
5212116040	0.8681	0.95595172
5212116050	0.8681	0.95595172
5212116060	0.8681	0.95595172
5212116070	0.8681	0.95595172
5212116080	0.8681	0.95595172
5212116090	0.8681	0.95595172
5212121010	0.5845	0.6436514
5212121020	0.6231	0.68615772
5212126010	0.8681	0.95595172
5212126020	0.8681	0.95595172
5212126030	0.8681	0.95595172
5212126040	0.8681	0.95595172
5212126050	0.8681	0.95595172
5212126060	0.8681	0.95595172
5212126070	0.8681	0.95595172
5212126080	0.8681	0.95595172
5212126090	0.8681	0.95595172

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	CONV. factor	Cents/kg.
5212131010	0.5845	0.6436514
5212131020	0.6231	0.68615772
5212136010	0.8681	0.95595172
5212136020	0.8681	0.95595172
5212136030	0.8681	0.95595172
5212136040	0.8681	0.95595172
5212136050	0.8681	0.95595172
5212136060	0.8681	0.95595172
5212136070	0.8681	0.95595172
5212136080	0.8681	0.95595172
5212136090	0.8681	0.95595172
5212141010	0.5845	0.6436514
5212141020	0.6231	0.68615772
5212146010	0.8681	0.95595172
5212146020	0.8681	0.95595172
5212146030	0.8681	0.95595172
5212146090	0.8681	0.95595172
5212151010	0.5845	0.6436514
5212151020	0.6231	0.68615772
5212156010	0.8681	0.95595172
5212156020	0.8681	0.95595172
5212156030	0.8681	0.95595172
5212156040	0.8681	0.95595172
5212156050	0.8681	0.95595172
5212156060	0.8681	0.95595172
5212156070	0.8681	0.95595172
5212156080	0.8681	0.95595172
5212156090	0.8681	0.95595172
5212211010	0.5845	0.6436514
5212211020	0.6231	0.68615772
5212216010	0.8681	0.95595172
5212216020	0.8681	0.95595172
5212216030	0.8681	0.95595172
5212216040	0.8681	0.95595172
5212216050	0.8681	0.95595172
5212216060	0.8681	0.95595172
5212216090	0.8681	0.95595172
5212221010	0.5845	0.6436514
5212221020	0.6231	0.68615772
5212226010	0.8681	0.95595172
5212226020	0.8681	0.95595172
5212226030	0.8681	0.95595172
5212226040	0.8681	0.95595172
5212226050	0.8681	0.95595172
5212226060	0.8681	0.95595172
5212226090	0.8681	0.95595172
5212231010	0.5845	0.6436514
5212231020	0.6231	0.68615772
5212236010	0.8681	0.95595172
5212236020	0.8681	0.95595172
5212236030	0.8681	0.95595172
5212236040	0.8681	0.95595172
5212236050	0.8681	0.95595172
5212236060	0.8681	0.95595172
5212236090	0.8681	0.95595172
5212241010	0.5845	0.6436514
5212241020	0.6231	0.68615772
5212246010	0.8681	0.95595172
5212246020	0.7054	0.77678648
5212246030	0.8681	0.95595172
5212246040	0.8681	0.95595172
5212246090	0.8681	0.95595172
5212251010	0.5845	0.6436514
5212251020	0.6231	0.68615772
5212256010	0.8681	0.95595172
5212256020	0.8681	0.95595172
5212256030	0.8681	0.95595172
5212256040	0.8681	0.95595172
5212256050	0.8681	0.95595172

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	CONV. factor	Cents/kg.
5212256060	0.8681	0.95595172
5212256090	0.8681	0.95595172
5309213005	0.5426	0.59751112
5309213010	0.5426	0.59751112
5309213015	0.5426	0.59751112
5309213020	0.5426	0.59751112
5309214010	0.2713	0.29875556
5309214090	0.2713	0.29875556
5309293005	0.5426	0.59751112
5309293010	0.5426	0.59751112
5309293015	0.5426	0.59751112
5309293020	0.5426	0.59751112
5309294010	0.2713	0.29875556
5309294090	0.2713	0.29875556
5311003005	0.5426	0.59751112
5311003010	0.5426	0.59751112
5311003015	0.5426	0.59751112
5311003020	0.5426	0.59751112
5311004010	0.8681	0.95595172
5311004020	0.8681	0.95595172
5407810010	0.5426	0.59751112
5407810020	0.5426	0.59751112
5407810030	0.5426	0.59751112
5407810040	0.5426	0.59751112
5407810090	0.5426	0.59751112
5407820010	0.5426	0.59751112
5407820020	0.5426	0.59751112
5407820030	0.5426	0.59751112
5407820040	0.5426	0.59751112
5407820090	0.5426	0.59751112
5407830010	0.5426	0.59751112
5407830020	0.5426	0.59751112
5407830030	0.5426	0.59751112
5407830040	0.5426	0.59751112
5407830090	0.5426	0.59751112
5407840010	0.5426	0.59751112
5407840020	0.5426	0.59751112
5407840030	0.5426	0.59751112
5407840040	0.5426	0.59751112
5407840090	0.5426	0.59751112
5509210000	0.1053	0.11595636
5509220010	0.1053	0.11595636
5509220090	0.1053	0.11595636
5509530030	0.3158	0.34775896
5509530060	0.3158	0.34775896
5509620000	0.5263	0.57956156
5509920000	0.5263	0.57956156
5510300000	0.3684	0.40568208
5511200000	0.3158	0.34775896
5512110010	0.1085	0.1194802
5512110022	0.1085	0.1194802
5512110027	0.1085	0.1194802
5512110030	0.1085	0.1194802
5512110040	0.1085	0.1194802
5512110050	0.1085	0.1194802
5512110060	0.1085	0.1194802
5512110070	0.1085	0.1194802
5512110090	0.1085	0.1194802
5512190005	0.1085	0.1194802
5512190010	0.1085	0.1194802
5512190015	0.1085	0.1194802
5512190022	0.1085	0.1194802
5512190027	0.1085	0.1194802
5512190030	0.1085	0.1194802
5512190035	0.1085	0.1194802
5512190040	0.1085	0.1194802
5512190045	0.1085	0.1194802
5512190050	0.1085	0.1194802
5512190090	0.1085	0.1194802

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	CONV. factor	Cents/kg.
5512210010	0.0326	0.03589912
5512210020	0.0326	0.03589912
5512210030	0.0326	0.03589912
5512210040	0.0326	0.03589912
5512210060	0.0326	0.03589912
5512210070	0.0326	0.03589912
5512210090	0.0326	0.03589912
5512290010	0.217	0.2389604
5512910010	0.0543	0.05979516
5512990005	0.0543	0.05979516
5512990010	0.0543	0.05979516
5512990015	0.0543	0.05979516
5512990020	0.0543	0.05979516
5512990025	0.0543	0.05979516
5512990030	0.0543	0.05979516
5512990035	0.0543	0.05979516
5512990040	0.0543	0.05979516
5512990045	0.0543	0.05979516
5512990090	0.0543	0.05979516
5513110020	0.3581	0.39433972
5513110040	0.3581	0.39433972
5513110060	0.3581	0.39433972
5513110090	0.3581	0.39433972
5513120000	0.3581	0.39433972
5513130020	0.3581	0.39433972
5513130040	0.3581	0.39433972
5513130090	0.3581	0.39433972
5513190010	0.3581	0.39433972
5513190020	0.3581	0.39433972
5513190030	0.3581	0.39433972
5513190040	0.3581	0.39433972
5513190050	0.3581	0.39433972
5513190060	0.3581	0.39433972
5513190090	0.3581	0.39433972
5513210020	0.3581	0.39433972
5513210040	0.3581	0.39433972
5513210060	0.3581	0.39433972
5513210090	0.3581	0.39433972
5513230121	0.3581	0.39433972
5513230141	0.3581	0.39433972
5513230191	0.3581	0.39433972
5513290010	0.3581	0.39433972
5513290020	0.3581	0.39433972
5513290030	0.3581	0.39433972
5513290040	0.3581	0.39433972
5513290050	0.3581	0.39433972
5513290060	0.3581	0.39433972
5513290090	0.3581	0.39433972
5513310000	0.3581	0.39433972
5513390111	0.3581	0.39433972
5513390115	0.3581	0.39433972
5513390191	0.3581	0.39433972
5513410020	0.3581	0.39433972
5513410040	0.3581	0.39433972
5513410060	0.3581	0.39433972
5513410090	0.3581	0.39433972
5513491000	0.3581	0.39433972
5513492020	0.3581	0.39433972
5513492040	0.3581	0.39433972
5513492090	0.3581	0.39433972
5513499010	0.3581	0.39433972
5513499020	0.3581	0.39433972
5513499030	0.3581	0.39433972
5513499040	0.3581	0.39433972
5513499050	0.3581	0.39433972
5513499060	0.3581	0.39433972
5513499090	0.3581	0.39433972
5514110020	0.4341	0.47803092
5514110030	0.4341	0.47803092

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	CONV. factor	Cents/kg.
5514110050	0.4341	0.47803092
5514110090	0.4341	0.47803092
5514120020	0.4341	0.47803092
5514120040	0.4341	0.47803092
5514191020	0.4341	0.47803092
5514191040	0.4341	0.47803092
5514191090	0.4341	0.47803092
5514199010	0.4341	0.47803092
5514199020	0.4341	0.47803092
5514199030	0.4341	0.47803092
5514199040	0.4341	0.47803092
5514199090	0.4341	0.47803092
5514210020	0.4341	0.47803092
5514210030	0.4341	0.47803092
5514210050	0.4341	0.47803092
5514210090	0.4341	0.47803092
5514220020	0.4341	0.47803092
5514220040	0.4341	0.47803092
5514230020	0.4341	0.47803092
5514230040	0.4341	0.47803092
5514230090	0.4341	0.47803092
5514290010	0.4341	0.47803092
5514290020	0.4341	0.47803092
5514290030	0.4341	0.47803092
5514290040	0.4341	0.47803092
5514290090	0.4341	0.47803092
5514303100	0.4341	0.47803092
5514303210	0.4341	0.47803092
5514303215	0.4341	0.47803092
5514303280	0.4341	0.47803092
5514303310	0.4341	0.47803092
5514303390	0.4341	0.47803092
5514303910	0.4341	0.47803092
5514303920	0.4341	0.47803092
5514303990	0.4341	0.47803092
5514410020	0.4341	0.47803092
5514410030	0.4341	0.47803092
5514410050	0.4341	0.47803092
5514410090	0.4341	0.47803092
5514420020	0.4341	0.47803092
5514420040	0.4341	0.47803092
5514430020	0.4341	0.47803092
5514430040	0.4341	0.47803092
5514430090	0.4341	0.47803092
5514490010	0.4341	0.47803092
5514490020	0.4341	0.47803092
5514490030	0.4341	0.47803092
5514490040	0.4341	0.47803092
5514490090	0.4341	0.47803092
5515110005	0.1085	0.1194802
5515110010	0.1085	0.1194802
5515110015	0.1085	0.1194802
5515110020	0.1085	0.1194802
5515110025	0.1085	0.1194802
5515110030	0.1085	0.1194802
5515110035	0.1085	0.1194802
5515110040	0.1085	0.1194802
5515110045	0.1085	0.1194802
5515110090	0.1085	0.1194802
5515120010	0.1085	0.1194802
5515120022	0.1085	0.1194802
5515120027	0.1085	0.1194802
5515120030	0.1085	0.1194802
5515120040	0.1085	0.1194802
5515120090	0.1085	0.1194802
5515190005	0.1085	0.1194802
5515190010	0.1085	0.1194802
5515190015	0.1085	0.1194802
5515190020	0.1085	0.1194802

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	CONV. factor	Cents/kg.
5515190025	0.1085	0.1194802
5515190030	0.1085	0.1194802
5515190035	0.1085	0.1194802
5515190040	0.1085	0.1194802
5515190045	0.1085	0.1194802
5515190090	0.1085	0.1194802
5515290005	0.1085	0.1194802
5515290010	0.1085	0.1194802
5515290015	0.1085	0.1194802
5515290020	0.1085	0.1194802
5515290025	0.1085	0.1194802
5515290030	0.1085	0.1194802
5515290035	0.1085	0.1194802
5515290040	0.1085	0.1194802
5515290045	0.1085	0.1194802
5515290090	0.1085	0.1194802
5515999005	0.1085	0.1194802
5515999010	0.1085	0.1194802
5515999015	0.1085	0.1194802
5515999020	0.1085	0.1194802
5515999025	0.1085	0.1194802
5515999030	0.1085	0.1194802
5515999035	0.1085	0.1194802
5515999040	0.1085	0.1194802
5515999045	0.1085	0.1194802
5515999090	0.1085	0.1194802
5516210010	0.1085	0.1194802
5516210020	0.1085	0.1194802
5516210030	0.1085	0.1194802
5516210040	0.1085	0.1194802
5516210090	0.1085	0.1194802
5516220010	0.1085	0.1194802
5516220020	0.1085	0.1194802
5516220030	0.1085	0.1194802
5516220040	0.1085	0.1194802
5516220090	0.1085	0.1194802
5516230010	0.1085	0.1194802
5516230020	0.1085	0.1194802
5516230030	0.1085	0.1194802
5516230040	0.1085	0.1194802
5516230090	0.1085	0.1194802
5516240010	0.1085	0.1194802
5516240020	0.1085	0.1194802
5516240030	0.1085	0.1194802
5516240040	0.1085	0.1194802
5516240085	0.1085	0.1194802
5516240095	0.1085	0.1194802
5516410010	0.3798	0.41823576
5516410022	0.3798	0.41823576
5516410027	0.3798	0.41823576
5516410030	0.3798	0.41823576
5516410040	0.3798	0.41823576
5516410050	0.3798	0.41823576
5516410060	0.3798	0.41823576
5516410070	0.3798	0.41823576
5516410090	0.3798	0.41823576
5516420010	0.3798	0.41823576
5516420022	0.3798	0.41823576
5516420027	0.3798	0.41823576
5516420030	0.3798	0.41823576
5516420040	0.3798	0.41823576
5516420050	0.3798	0.41823576
5516420060	0.3798	0.41823576
5516420070	0.3798	0.41823576
5516420090	0.3798	0.41823576
5516430010	0.217	0.2389604
5516430015	0.3798	0.41823576
5516430020	0.3798	0.41823576
5516430035	0.3798	0.41823576

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	CONV. factor	Cents/kg.
5516430080	0.3798	0.41823576
5516440010	0.3798	0.41823576
5516440022	0.3798	0.41823576
5516440027	0.3798	0.41823576
5516440030	0.3798	0.41823576
5516440040	0.3798	0.41823576
5516440050	0.3798	0.41823576
5516440060	0.3798	0.41823576
5516440070	0.3798	0.41823576
5516440090	0.3798	0.41823576
5516910010	0.0543	0.05979516
5516910020	0.0543	0.05979516
5516910030	0.0543	0.05979516
5516910040	0.0543	0.05979516
5516910050	0.0543	0.05979516
5516910060	0.0543	0.05979516
5516910070	0.0543	0.05979516
5516910090	0.0543	0.05979516
5516920010	0.0543	0.05979516
5516920020	0.0543	0.05979516
5516920030	0.0543	0.05979516
5516920040	0.0543	0.05979516
5516920050	0.0543	0.05979516
5516920060	0.0543	0.05979516
5516920070	0.0543	0.05979516
5516920090	0.0543	0.05979516
5516930010	0.0543	0.05979516
5516930020	0.0543	0.05979516
5516930090	0.0543	0.05979516
5516940010	0.0543	0.05979516
5516940020	0.0543	0.05979516
5516940030	0.0543	0.05979516
5516940040	0.0543	0.05979516
5516940050	0.0543	0.05979516
5516940060	0.0543	0.05979516
5516940070	0.0543	0.05979516
5516940090	0.0543	0.05979516
5601210010	0.9767	1.07554204
5601210090	0.9767	1.07554204
5601220010	0.9767	1.07554204
5601220090	0.9767	1.07554204
5601300000	0.3256	0.35855072
5602101000	0.0543	0.05979516
5602109090	0.4341	0.47803092
5602290000	0.4341	0.47803092
5602909000	0.3256	0.35855072
5603143000	0.2713	0.29875556
5603910010	0.0217	0.02389604
5603910090	0.0651	0.07168812
5603920010	0.0217	0.02389604
5603920090	0.0651	0.07168812
5603930010	0.0217	0.02389604
5603930090	0.0651	0.07168812
5603941090	0.3256	0.35855072
5603943000	0.1628	0.17927536
5603949010	0.0326	0.03589912
5604100000	0.2632	0.28983584
5604909000	0.2105	0.2318026
5605009000	0.1579	0.17387948
5606000010	0.1263	0.13908156
5606000090	0.1263	0.13908156
5607502500	0.1684	0.18544208
5607909000	0.8421	0.92732052
5608902300	0.6316	0.69551792
5608902700	0.6316	0.69551792
5608903000	0.3158	0.34775896
5609001000	0.8421	0.92732052
5609004000	0.2105	0.2318026
5701101300	0.0526	0.05792312
5701101600	0.0526	0.05792312
5701104000	0.0526	0.05792312
5701109000	0.0526	0.05792312
5701901010	1	1.1012
5701901020	1	1.1012
5701901030	0.0526	0.05792312
5701901090	0.0526	0.05792312
5701902010	0.9474	1.04327688
5701902020	0.9474	1.04327688
5701902030	0.0526	0.05792312
5701902090	0.0526	0.05792312
5702101000	0.0447	0.04922364
5702109010	0.0447	0.04922364
5702109020	0.85	0.93602
5702109030	0.0447	0.04922364
5702109090	0.0447	0.04922364
5702201000	0.0447	0.04922364
5702311000	0.0447	0.04922364
5702312000	0.0895	0.0985574
5702322000	0.0895	0.0985574
5702391000	0.0895	0.0985574
5702392010	0.8053	0.88679636
5702392090	0.0447	0.04922364
5702411000	0.0447	0.04922364
5702412000	0.0447	0.04922364
5702421000	0.0895	0.0985574
5702422020	0.0895	0.0985574
5702422080	0.0895	0.0985574
5702491020	0.8947	0.98524364
5702491080	0.8947	0.98524364
5702492000	0.0895	0.0985574
5702502000	0.0895	0.0985574
5702504000	0.0447	0.04922364
5702505200	0.0895	0.0985574
5702505600	0.85	0.93602
5702912000	0.0447	0.04922364
5702913000	0.0447	0.04922364
5702914000	0.0447	0.04922364
5702921000	0.0447	0.04922364
5702929000	0.0447	0.04922364
5702990500	0.8947	0.98524364
5702991500	0.8947	0.98524364
5703201000	0.0452	0.04977424
5703202010	0.0452	0.04977424
5703302000	0.0452	0.04977424
5703900000	0.3615	0.3980838
5705001000	0.0452	0.04977424
5705002005	0.0452	0.04977424
5705002015	0.0452	0.04977424
5705002020	0.7682	0.84594184
5705002030	0.0452	0.04977424
5705002090	0.1808	0.19909696
5801210000	0.9767	1.07554204
5801221000	0.9767	1.07554204
5801229000	0.9767	1.07554204
5801230000	0.9767	1.07554204
5801260010	0.7596	0.83647152
5801260020	0.7596	0.83647152
5801271000	0.9767	1.07554204
5801275010	1.0852	1.19502224
5801275020	0.9767	1.07554204
5801310000	0.217	0.2389604
5801320000	0.217	0.2389604
5801330000	0.217	0.2389604
5801360010	0.217	0.2389604
5801360020	0.217	0.2389604
5802110000	1.0309	1.13522708
5802190000	1.0309	1.13522708
5802200020	0.1085	0.1194802
5802200090	0.3256	0.35855072
5802300030	0.4341	0.47803092
5802300090	0.1085	0.1194802
5803001000	1.0852	1.19502224
5803002000	0.8681	0.95595172
5803003000	0.8681	0.95595172
5803005000	0.3256	0.35855072
5804101000	0.4341	0.47803092
5804109090	0.2193	0.24149316
5804291000	0.8772	0.96597264
5804300020	0.3256	0.35855072
5805001000	0.1085	0.1194802
5805003000	1.0852	1.19502224
5806101000	0.8681	0.95595172
5806103090	0.217	0.2389604
5806200010	0.2577	0.28377924
5806200090	0.2577	0.28377924
5806310000	0.8681	0.95595172
5806393080	0.217	0.2389604
5806400000	0.0814	0.08963768
5807100510	0.8681	0.95595172
5807102010	0.8681	0.95595172
5807900510	0.8681	0.95595172
5807902010	0.8681	0.95595172
5808104000	0.217	0.2389604
5808107000	0.217	0.2389604
5808900010	0.4341	0.47803092
5810100000	0.3256	0.35855072
5810910010	0.7596	0.83647152
5810910020	0.7596	0.83647152
5810921000	0.217	0.2389604
5810929030	0.217	0.2389604
5810929050	0.217	0.2389604
5810929080	0.217	0.2389604
5811002000	0.8681	0.95595172
5901102000	0.5643	0.62140716
5901904000	0.8139	0.89626668
5903101000	0.4341	0.47803092
5903103000	0.1085	0.1194802
5903201000	0.4341	0.47803092
5903203090	0.1085	0.1194802
5903901000	0.4341	0.47803092
5903903090	0.1085	0.1194802
5904901000	0.0326	0.03589912
5905001000	0.1085	0.1194802
5905009000	0.1085	0.1194802
5906100000	0.4341	0.47803092
5906911000	0.4341	0.47803092
5906913000	0.1085	0.1194802
5906991000	0.4341	0.47803092
5906993000	0.1085	0.1194802
5907002500	0.3798	0.41823576
5907003500	0.3798	0.41823576
5907008090	0.3798	0.41823576
5908000000	0.7813	0.86036756
5909001000	0.6837	0.75289044
5909002000	0.4883	0.53771596
5910001010	0.3798	0.41823576
5910001020	0.3798	0.41823576
5910001030	0.3798	0.41823576
5910001060	0.3798	0.41823576
5910001070	0.3798	0.41823576
5910001090	0.6837	0.75289044
5910009000	0.5697	0.62735364
5911101000	0.1736	0.19116832
5911102000	0.0434	0.04779208
5911201000	0.4341	0.47803092
5911310010	0.4341	0.47803092
5911310020	0.4341	0.47803092

IMPORT ASSESSMENT TABLE—Continued
[Raw cotton fiber]

HTS No.	CONV. factor	Cents/kg.
5911310030	0.4341	0.47803092
5911310080	0.4341	0.47803092
5911320010	0.4341	0.47803092
5911320020	0.4341	0.47803092
5911320030	0.4341	0.47803092
5911320080	0.4341	0.47803092
5911400000	0.5426	0.59751112
5911900040	0.3158	0.34775896
5911900080	0.2105	0.2318026
6001106000	0.1096	0.12069152
6001210000	0.9868	1.08666416
6001220000	0.1096	0.12069152
6001290000	0.1096	0.12069152
6001910010	0.8772	0.96597264
6001910020	0.8772	0.96597264
6001920010	0.0548	0.06034576
6001920020	0.0548	0.06034576
6001920030	0.0548	0.06034576
6001920040	0.0548	0.06034576
6001999000	0.1096	0.12069152
6002404000	0.7401	0.81499812
6002408020	0.1974	0.21737688
6002408080	0.1974	0.21737688
6002904000	0.7895	0.8693974
6002908020	0.1974	0.21737688
6002908080	0.1974	0.21737688
6003201000	0.8772	0.96597264
6003203000	0.8772	0.96597264
6003301000	0.1096	0.12069152
6003306000	0.1096	0.12069152
6003401000	0.1096	0.12069152
6003406000	0.1096	0.12069152
6003901000	0.1096	0.12069152
6003909000	0.1096	0.12069152
6004100010	0.2961	0.32606532
6004100025	0.2961	0.32606532
6004100085	0.2961	0.32606532
6004902010	0.2961	0.32606532
6004902025	0.2961	0.32606532
6004902085	0.2961	0.32606532
6004909000	0.2961	0.32606532
6005210000	0.7127	0.78482524
6005220000	0.7127	0.78482524
6005230000	0.7127	0.78482524
6005240000	0.7127	0.78482524
6005310010	0.1096	0.12069152
6005310080	0.1096	0.12069152
6005320010	0.1096	0.12069152
6005320080	0.1096	0.12069152
6005330010	0.1096	0.12069152
6005330080	0.1096	0.12069152
6005340010	0.1096	0.12069152
6005340080	0.1096	0.12069152
6005410010	0.1096	0.12069152
6005410080	0.1096	0.12069152
6005420010	0.1096	0.12069152
6005420080	0.1096	0.12069152
6005430010	0.1096	0.12069152
6005430080	0.1096	0.12069152
6005440010	0.1096	0.12069152
6005440080	0.1096	0.12069152
6005909000	0.1096	0.12069152
6006211000	1.0965	1.2074658
6006219020	0.7675	0.845171
6006219080	0.7675	0.845171
6006221000	1.0965	1.2074658
6006229020	0.7675	0.845171
6006229080	0.7675	0.845171
6006231000	1.0965	1.2074658
6006239020	0.7675	0.845171
6006239080	0.7675	0.845171
6006241000	1.0965	1.2074658
6006249020	0.7675	0.845171
6006249080	0.7675	0.845171
6006310020	0.3289	0.36218468
6006310040	0.3289	0.36218468
6006310060	0.3289	0.36218468
6006310080	0.3289	0.36218468
6006320020	0.3289	0.36218468
6006320040	0.3289	0.36218468
6006320060	0.3289	0.36218468
6006320080	0.3289	0.36218468
6006330020	0.3289	0.36218468
6006330040	0.3289	0.36218468
6006330060	0.3289	0.36218468
6006330080	0.3289	0.36218468
6006340020	0.3289	0.36218468
6006340040	0.3289	0.36218468
6006340060	0.3289	0.36218468
6006340080	0.3289	0.36218468
6006410025	0.3289	0.36218468
6006410085	0.3289	0.36218468
6006420025	0.3289	0.36218468
6006420085	0.3289	0.36218468
6006430025	0.3289	0.36218468
6006430085	0.3289	0.36218468
6006440025	0.3289	0.36218468
6006440085	0.3289	0.36218468
6006909000	0.1096	0.12069152
6101200010	1.02	1.123224
6101200020	1.02	1.123224
6101301000	0.2072	0.22816864
6101900500	0.1912	0.21054944
6101909010	0.5737	0.63175844
6101909030	0.51	0.561612
6101909060	0.255	0.280806
6102100000	0.255	0.280806
6102200010	0.9562	1.05296744
6102200020	0.9562	1.05296744
6102300500	0.1785	0.1965642
6102909005	0.5737	0.63175844
6102909015	0.4462	0.49135544
6102909030	0.255	0.280806
6103101000	0.0637	0.07014644
6103104000	0.1218	0.13412616
6103105000	0.1218	0.13412616
6103106010	0.8528	0.93910336
6103106015	0.8528	0.93910336
6103106030	0.8528	0.93910336
6103109010	0.5482	0.60367784
6103109020	0.5482	0.60367784
6103109030	0.5482	0.60367784
6103109040	0.1218	0.13412616
6103109050	0.1218	0.13412616
6103109080	0.1827	0.20118924
6103320000	0.8722	0.96046664
6103398010	0.7476	0.82325712
6103398030	0.3738	0.41162856
6103398060	0.2492	0.27441904
6103411010	0.3576	0.39378912
6103411020	0.3576	0.39378912
6103412000	0.3576	0.39378912
6103421020	0.8343	0.91873116
6103421035	0.8343	0.91873116
6103421040	0.8343	0.91873116
6103421050	0.8343	0.91873116
6103421065	0.8343	0.91873116
6103421070	0.8343	0.91873116
6103422010	0.8343	0.91873116
6103422015	0.8343	0.91873116
6103422025	0.8343	0.91873116
6103431520	0.2384	0.26252608
6103431535	0.2384	0.26252608
6103431540	0.2384	0.26252608
6103431550	0.2384	0.26252608
6103431565	0.2384	0.26252608
6103431570	0.2384	0.26252608
6103432020	0.2384	0.26252608
6103432025	0.2384	0.26252608
6103491020	0.2437	0.26836244
6103491060	0.2437	0.26836244
6103492000	0.2437	0.26836244
6103498010	0.5482	0.60367784
6103498014	0.3655	0.4024886
6103498024	0.2437	0.26836244
6103498026	0.2437	0.26836244
6103498034	0.5482	0.60367784
6103498038	0.3655	0.4024886
6103498060	0.2437	0.26836244
6104196010	0.8722	0.96046664
6104196020	0.8722	0.96046664
6104196030	0.8722	0.96046664
6104196040	0.8722	0.96046664
6104198010	0.5607	0.61744284
6104198020	0.5607	0.61744284
6104198030	0.5607	0.61744284
6104198040	0.5607	0.61744284
6104198060	0.3738	0.41162856
6104198090	0.2492	0.27441904
6104320000	0.8722	0.96046664
6104392010	0.5607	0.61744284
6104392030	0.3738	0.41162856
6104392090	0.2492	0.27441904
6104420010	0.8528	0.93910336
6104420020	0.8528	0.93910336
6104499010	0.5482	0.60367784
6104499030	0.3655	0.4024886
6104499060	0.2437	0.26836244
6104520010	0.8822	0.97147864
6104520020	0.8822	0.97147864
6104598010	0.5672	0.62460064
6104598030	0.3781	0.41636372
6104598090	0.2521	0.27761252
6104610010	0.2384	0.26252608
6104610020	0.2384	0.26252608
6104610030	0.2384	0.26252608
6104621010	0.7509	0.82689108
6104621020	0.8343	0.91873116
6104621030	0.8343	0.91873116
6104622006	0.7151	0.78746812
6104622011	0.8343	0.91873116
6104622016	0.7151	0.78746812
6104622021	0.8343	0.91873116
6104622026	0.7151	0.78746812
6104622028	0.8343	0.91873116
6104622030	0.8343	0.91873116
6104622050	0.8343	0.91873116
6104622060	0.8343	0.91873116
6104631020	0.2384	0.26252608
6104631030	0.2384	0.26252608
6104632006	0.8343	0.91873116
6104632011	0.8343	0.91873116
6104632016	0.7151	0.78746812
6104632021	0.8343	0.91873116
6104632026	0.3576	0.39378912
6104632028	0.3576	0.39378912
6104632030	0.3576	0.39378912

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	CONV. factor	Cents/kg.
6104632050	0.7151	0.78746812
6104632060	0.3576	0.39378912
6104691000	0.3655	0.4024886
6104692030	0.3655	0.4024886
6104692060	0.3655	0.4024886
6104698010	0.5482	0.60367784
6104698014	0.3655	0.4024886
6104698020	0.2437	0.26836244
6104698022	0.5482	0.60367784
6104698026	0.3655	0.4024886
6104698038	0.2437	0.26836244
6104698040	0.2437	0.26836244
6105100010	0.9332	1.02763984
6105100020	0.9332	1.02763984
6105100030	0.9332	1.02763984
6105202010	0.2916	0.32110992
6105202020	0.2916	0.32110992
6105202030	0.2916	0.32110992
6105908010	0.5249	0.57801988
6105908030	0.3499	0.38530988
6105908060	0.2333	0.25690996
6106100010	0.9332	1.02763984
6106100020	0.9332	1.02763984
6106100030	0.9332	1.02763984
6106202010	0.2916	0.32110992
6106202020	0.4666	0.51381992
6106202030	0.2916	0.32110992
6106901500	0.0583	0.06419996
6106902510	0.5249	0.57801988
6106902530	0.3499	0.38530988
6106902550	0.2916	0.32110992
6106903010	0.5249	0.57801988
6106903030	0.3499	0.38530988
6106903040	0.2916	0.32110992
6107110010	1.0727	1.18125724
6107110020	1.0727	1.18125724
6107120010	0.4767	0.52494204
6107120020	0.4767	0.52494204
6107191000	0.1192	0.13126304
6107210010	0.8343	0.91873116
6107210020	0.7151	0.78746812
6107220010	0.3576	0.39378912
6107220015	0.1192	0.13126304
6107220025	0.2384	0.26252608
6107299000	0.1788	0.19689456
6107910030	1.1918	1.31241016
6107910040	1.1918	1.31241016
6107910090	0.9535	1.0499942
6107991030	0.3576	0.39378912
6107991040	0.3576	0.39378912
6107991090	0.3576	0.39378912
6107999000	0.1192	0.13126304
6108199010	1.0611	1.16848332
6108199030	0.2358	0.25966296
6108210010	1.179	1.2983148
6108210020	1.179	1.2983148
6108299000	0.3537	0.38949444
6108310010	1.0611	1.16848332
6108310020	1.0611	1.16848332
6108320010	0.2358	0.25966296
6108320015	0.2358	0.25966296
6108320025	0.2358	0.25966296
6108398000	0.3537	0.38949444
6108910005	1.179	1.2983148
6108910015	1.179	1.2983148
6108910025	1.179	1.2983148
6108910030	1.179	1.2983148
6108910040	1.179	1.2983148
6108920005	0.2358	0.25966296

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	CONV. factor	Cents/kg.
6108920015	0.2358	0.25966296
6108920025	0.2358	0.25966296
6108920030	0.2358	0.25966296
6108920040	0.2358	0.25966296
6108999000	0.3537	0.38949444
6109100004	1.0022	1.10362264
6109100007	1.0022	1.10362264
6109100011	1.0022	1.10362264
6109100012	1.0022	1.10362264
6109100014	1.0022	1.10362264
6109100018	1.0022	1.10362264
6109100023	1.0022	1.10362264
6109100027	1.0022	1.10362264
6109100037	1.0022	1.10362264
6109100040	1.0022	1.10362264
6109100045	1.0022	1.10362264
6109100060	1.0022	1.10362264
6109100065	1.0022	1.10362264
6109100070	1.0022	1.10362264
6109901007	0.2948	0.32463376
6109901009	0.2948	0.32463376
6109901013	0.2948	0.32463376
6109901025	0.2948	0.32463376
6109901047	0.2948	0.32463376
6109901049	0.2948	0.32463376
6109901050	0.2948	0.32463376
6109901060	0.2948	0.32463376
6109901065	0.2948	0.32463376
6109901070	0.2948	0.32463376
6109901075	0.2948	0.32463376
6109901090	0.2948	0.32463376
6109908010	0.3499	0.38530988
6109908030	0.2333	0.25690996
6110201010	0.7476	0.82325712
6110201020	0.7476	0.82325712
6110201022	0.7476	0.82325712
6110201024	0.7476	0.82325712
6110201026	0.7476	0.82325712
6110201029	0.7476	0.82325712
6110201031	0.7476	0.82325712
6110201033	0.7476	0.82325712
6110202005	1.1214	1.23488568
6110202010	1.1214	1.23488568
6110202015	1.1214	1.23488568
6110202020	1.1214	1.23488568
6110202025	1.1214	1.23488568
6110202030	1.1214	1.23488568
6110202035	1.1214	1.23488568
6110202040	1.0965	1.2074658
6110202045	1.0965	1.2074658
6110202067	1.0965	1.2074658
6110202069	1.0965	1.2074658
6110202077	1.0965	1.2074658
6110202079	1.0965	1.2074658
6110909010	0.5607	0.61744284
6110909012	0.1246	0.13720952
6110909014	0.3738	0.41162856
6110909026	0.5607	0.61744284
6110909028	0.1869	0.20581428
6110909030	0.3738	0.41162856
6110909044	0.5607	0.61744284
6110909046	0.5607	0.61744284
6110909052	0.3738	0.41162856
6110909054	0.3738	0.41162856
6110909064	0.2492	0.27441904
6110909066	0.2492	0.27441904
6110909067	0.5607	0.61744284
6110909069	0.5607	0.61744284
6110909071	0.5607	0.61744284

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	CONV. factor	Cents/kg.
6110909073	0.5607	0.61744284
6110909079	0.3738	0.41162856
6110909080	0.3738	0.41162856
6110909081	0.3738	0.41162856
6110909082	0.3738	0.41162856
6110909088	0.2492	0.27441904
6110909090	0.2492	0.27441904
6111201000	1.1918	1.31241016
6111202000	1.1918	1.31241016
6111203000	0.9535	1.0499942
6111204000	0.9535	1.0499942
6111205000	0.9535	1.0499942
6111206010	0.9535	1.0499942
6111206020	0.9535	1.0499942
6111206030	0.9535	1.0499942
6111206050	0.9535	1.0499942
6111206070	0.9535	1.0499942
6111301000	0.2384	0.26252608
6111302000	0.2384	0.26252608
6111303000	0.2384	0.26252608
6111304000	0.2384	0.26252608
6111305010	0.2384	0.26252608
6111305015	0.2384	0.26252608
6111305020	0.2384	0.26252608
6111305030	0.2384	0.26252608
6111305050	0.2384	0.26252608
6111305070	0.2384	0.26252608
6111901000	0.2384	0.26252608
6111902000	0.2384	0.26252608
6111903000	0.2384	0.26252608
6111904000	0.2384	0.26252608
6111905010	0.2384	0.26252608
6111905020	0.2384	0.26252608
6111905030	0.2384	0.26252608
6111905050	0.2384	0.26252608
6111905070	0.2384	0.26252608
6112110010	0.9535	1.0499942
6112110020	0.9535	1.0499942
6112110030	0.9535	1.0499942
6112110040	0.9535	1.0499942
6112110050	0.9535	1.0499942
6112110060	0.9535	1.0499942
6112120010	0.2384	0.26252608
6112120020	0.2384	0.26252608
6112120030	0.2384	0.26252608
6112120040	0.2384	0.26252608
6112120050	0.2384	0.26252608
6112120060	0.2384	0.26252608
6112191010	0.2492	0.27441904
6112191020	0.2492	0.27441904
6112191030	0.2492	0.27441904
6112191040	0.2492	0.27441904
6112191050	0.2492	0.27441904
6112191060	0.2492	0.27441904
6112201060	0.2492	0.27441904
6112201070	0.2492	0.27441904
6112201080	0.2492	0.27441904
6112201090	0.2492	0.27441904
6112202010	0.8722	0.96046664
6112202020	0.3738	0.41162856
6112202030	0.2492	0.27441904
6112310010	0.1192	0.13126304
6112310020	0.1192	0.13126304
6112390010	1.0727	1.18125724
6112410010	0.1192	0.13126304
6112410020	0.1192	0.13126304
6112410030	0.1192	0.13126304
6112410040	0.1192	0.13126304
6112490010	0.8939	0.98436268

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	CONV. factor	Cents/kg.
6113001005	0.1246	0.13720952
6113001010	0.1246	0.13720952
6113001012	0.1246	0.13720952
6113009015	0.3489	0.38420868
6113009020	0.3489	0.38420868
6113009038	0.3489	0.38420868
6113009042	0.3489	0.38420868
6113009055	0.3489	0.38420868
6113009060	0.3489	0.38420868
6113009074	0.3489	0.38420868
6113009082	0.3489	0.38420868
6114200005	0.9747	1.07333964
6114200010	0.9747	1.07333964
6114200015	0.8528	0.93910336
6114200020	0.8528	0.93910336
6114200035	0.8528	0.93910336
6114200040	0.8528	0.93910336
6114200042	0.3655	0.4024886
6114200044	0.8528	0.93910336
6114200046	0.8528	0.93910336
6114200048	0.8528	0.93910336
6114200052	0.8528	0.93910336
6114200055	0.8528	0.93910336
6114200060	0.8528	0.93910336
6114301010	0.2437	0.26836244
6114301020	0.2437	0.26836244
6114302060	0.1218	0.13412616
6114303014	0.2437	0.26836244
6114303020	0.2437	0.26836244
6114303030	0.2437	0.26836244
6114303042	0.2437	0.26836244
6114303044	0.2437	0.26836244
6114303052	0.2437	0.26836244
6114303054	0.2437	0.26836244
6114303060	0.2437	0.26836244
6114303070	0.2437	0.26836244
6114909045	0.5482	0.60367784
6114909055	0.3655	0.4024886
6114909070	0.3655	0.4024886
6115100500	0.4386	0.48298632
6115101510	1.0965	1.2074658
6115103000	0.9868	1.08666416
6115106000	0.1096	0.12069152
6115298010	1.0965	1.2074658
6115309030	0.7675	0.845171
6115956000	0.9868	1.08666416
6115959000	0.9868	1.08666416
6115966020	0.2193	0.24149316
6115991420	0.2193	0.24149316
6115991920	0.2193	0.24149316
6115999000	0.1096	0.12069152
6116101300	0.3463	0.38134556
6116101720	0.8079	0.88965948
6116104810	0.4444	0.48937328
6116105510	0.6464	0.71181568
6116107510	0.6464	0.71181568
6116109500	0.1616	0.17795392
6116920500	0.8079	0.88965948
6116920800	0.8079	0.88965948
6116926410	1.0388	1.14392656
6116926420	1.0388	1.14392656
6116926430	1.1542	1.27100504
6116926440	1.0388	1.14392656
6116927450	1.0388	1.14392656
6116927460	1.1542	1.27100504
6116927470	1.0388	1.14392656
6116928800	1.0388	1.14392656
6116929400	1.0388	1.14392656
6116938800	0.1154	0.12707848

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	CONV. factor	Cents/kg.
6116939400	0.1154	0.12707848
6116994800	0.1154	0.12707848
6116995400	0.1154	0.12707848
6116999510	0.4617	0.50842404
6116999530	0.3463	0.38134556
6117106010	0.9234	1.01684808
6117106020	0.2308	0.25415696
6117808500	0.9234	1.01684808
6117808710	1.1542	1.27100504
6117808770	0.1731	0.19061772
6117809510	0.9234	1.01684808
6117809540	0.3463	0.38134556
6117809570	0.1731	0.19061772
6117909003	1.1542	1.27100504
6117909015	0.2308	0.25415696
6117909020	1.1542	1.27100504
6117909040	1.1542	1.27100504
6117909060	1.1542	1.27100504
6117909080	1.1542	1.27100504
6201121000	0.8981	0.98898772
6201122010	0.8482	0.93403784
6201122020	0.8482	0.93403784
6201122025	0.9979	1.09888748
6201122035	0.9979	1.09888748
6201122050	0.6486	0.71423832
6201122060	0.6486	0.71423832
6201134015	0.1996	0.21979952
6201134020	0.1996	0.21979952
6201134030	0.2495	0.2747494
6201134040	0.2495	0.2747494
6201199010	0.5613	0.61810356
6201199030	0.3742	0.41206904
6201199060	0.3742	0.41206904
6201921000	0.8779	0.96674348
6201921500	1.0974	1.20845688
6201922005	0.9754	1.07411048
6201922010	0.9754	1.07411048
6201922021	1.2193	1.34269316
6201922031	1.2193	1.34269316
6201922041	1.2193	1.34269316
6201922051	0.9754	1.07411048
6201922061	0.9754	1.07411048
6201931000	0.2926	0.32221112
6201932010	0.2439	0.26858268
6201932020	0.2439	0.26858268
6201933511	0.2439	0.26858268
6201933521	0.2439	0.26858268
6201999010	0.5487	0.60422844
6201999030	0.3658	0.40281896
6201999060	0.2439	0.26858268
6202121000	0.8879	0.97775548
6202122010	1.0482	1.15427784
6202122020	1.0482	1.15427784
6202122025	1.2332	1.35799984
6202122035	1.2332	1.35799984
6202122050	0.8016	0.88272192
6202122060	0.8016	0.88272192
6202134005	0.2524	0.27794288
6202134010	0.2524	0.27794288
6202134020	0.3155	0.3474286
6202134030	0.3155	0.3474286
6202199010	0.5678	0.62526136
6202199030	0.3786	0.41691432
6202199060	0.2524	0.27794288
6202921000	0.9865	1.0863338
6202921500	0.9865	1.0863338
6202922010	0.9865	1.0863338
6202922020	0.9865	1.0863338
6202922026	1.2332	1.35799984

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	CONV. factor	Cents/kg.
6202922031	1.2332	1.35799984
6202922061	0.9865	1.0863338
6202922071	0.9865	1.0863338
6202931000	0.296	0.3259552
6202932010	0.2466	0.27155592
6202932020	0.2466	0.27155592
6202935011	0.2466	0.27155592
6202935021	0.2466	0.27155592
6202999011	0.5549	0.61105588
6202999031	0.37	0.407444
6202999061	0.2466	0.27155592
6203122010	0.1233	0.13577796
6203122020	0.1233	0.13577796
6203191010	0.9865	1.0863338
6203191020	0.9865	1.0863338
6203191030	0.9865	1.0863338
6203199010	0.5549	0.61105588
6203199020	0.5549	0.61105588
6203199030	0.5549	0.61105588
6203199050	0.37	0.407444
6203199080	0.2466	0.27155592
6203221000	1.2332	1.35799984
6203321000	0.6782	0.74683384
6203322010	1.1715	1.2900558
6203322020	1.1715	1.2900558
6203322030	1.1715	1.2900558
6203322040	1.1715	1.2900558
6203322050	1.1715	1.2900558
6203332010	0.1233	0.13577796
6203332020	0.1233	0.13577796
6203392010	0.1233	0.13577796
6203392020	0.1233	0.13577796
6203399010	0.5549	0.61105588
6203399030	0.37	0.407444
6203399060	0.2466	0.27155592
6203421000	1.0616	1.16903392
6203422005	0.7077	0.77931924
6203422010	0.9436	1.03909232
6203422025	0.9436	1.03909232
6203422050	0.9436	1.03909232
6203422090	0.9436	1.03909232
6203424003	1.0616	1.16903392
6203424006	1.1796	1.29897552
6203424011	1.1796	1.29897552
6203424016	0.9436	1.03909232
6203424021	1.1796	1.29897552
6203424026	1.1796	1.29897552
6203424031	1.1796	1.29897552
6203424036	1.1796	1.29897552
6203424041	0.9436	1.03909232
6203424046	0.9436	1.03909232
6203424051	0.8752	0.96377024
6203424056	0.8752	0.96377024
6203424061	0.8752	0.96377024
6203431000	0.1887	0.20779644
6203431500	0.118	0.1299416
6203432005	0.118	0.1299416
6203432010	0.2359	0.25977308
6203432025	0.2359	0.25977308
6203432050	0.2359	0.25977308
6203432090	0.2359	0.25977308
6203432500	0.4128	0.45457536
6203433510	0.059	0.0649708
6203433590	0.059	0.0649708
6203434010	0.1167	0.12851004
6203434015	0.1167	0.12851004
6203434020	0.1167	0.12851004
6203434030	0.1167	0.12851004
6203434035	0.1167	0.12851004

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	CONV. factor	Cents/kg.
6203434040	0.1167	0.12851004
6203491005	0.118	0.1299416
6203491010	0.2359	0.25977308
6203491025	0.2359	0.25977308
6203491050	0.2359	0.25977308
6203491090	0.2359	0.25977308
6203491500	0.4128	0.45457536
6203492015	0.2359	0.25977308
6203492020	0.2359	0.25977308
6203492030	0.118	0.1299416
6203492045	0.118	0.1299416
6203492050	0.118	0.1299416
6203492060	0.118	0.1299416
6203498020	0.5308	0.58451696
6203498030	0.3539	0.38971468
6203498045	0.2359	0.25977308
6204110000	0.0617	0.06794404
6204120010	0.9865	1.0863338
6204120020	0.9865	1.0863338
6204120030	0.9865	1.0863338
6204120040	0.9865	1.0863338
6204132010	0.1233	0.13577796
6204132020	0.1233	0.13577796
6204192000	0.1233	0.13577796
6204198010	0.5549	0.61105588
6204198020	0.5549	0.61105588
6204198030	0.5549	0.61105588
6204198040	0.5549	0.61105588
6204198060	0.3083	0.33949996
6204198090	0.2466	0.27155592
6204221000	1.2332	1.35799984
6204321000	0.6782	0.74683384
6204322010	1.1715	1.2900558
6204322020	1.1715	1.2900558
6204322030	0.9865	1.0863338
6204322040	0.9865	1.0863338
6204398010	0.5549	0.61105588
6204398030	0.3083	0.33949996
6204412010	0.0603	0.06640236
6204412020	0.0603	0.06640236
6204421000	1.2058	1.32782696
6204422000	0.6632	0.73031584
6204423010	1.2058	1.32782696
6204423020	1.2058	1.32782696
6204423030	0.9043	0.99581516
6204423040	0.9043	0.99581516
6204423050	0.9043	0.99581516
6204423060	0.9043	0.99581516
6204431000	0.4823	0.53110876
6204432000	0.0603	0.06640236
6204442000	0.4316	0.47527792
6204495010	0.5549	0.61105588
6204495030	0.2466	0.27155592
6204510010	0.0631	0.06948572
6204510020	0.0631	0.06948572
6204521000	1.2618	1.38949416
6204522010	1.1988	1.32011856
6204522020	1.1988	1.32011856
6204522030	1.1988	1.32011856
6204522040	1.1988	1.32011856
6204522070	1.0095	1.1116614
6204522080	1.0095	1.1116614
6204531000	0.4416	0.48628992
6204532010	0.0631	0.06948572
6204532020	0.0631	0.06948572
6204533010	0.2524	0.27794288
6204533020	0.2524	0.27794288
6204591000	0.4416	0.48628992
6204594010	0.5678	0.62526136

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	CONV. factor	Cents/kg.
6204594030	0.2524	0.27794288
6204594060	0.2524	0.27794288
6204611010	0.059	0.0649708
6204611020	0.059	0.0649708
6204619010	0.059	0.0649708
6204619020	0.059	0.0649708
6204619030	0.059	0.0649708
6204619040	0.118	0.1299416
6204621000	0.8681	0.95595172
6204622005	0.7077	0.77931924
6204622010	0.9436	1.03909232
6204622025	0.9436	1.03909232
6204622050	0.9436	1.03909232
6204623000	1.1796	1.29897552
6204624003	1.0616	1.16903392
6204624006	1.1796	1.29897552
6204624011	1.1796	1.29897552
6204624021	0.9436	1.03909232
6204624026	1.1796	1.29897552
6204624031	1.1796	1.29897552
6204624036	1.1796	1.29897552
6204624041	1.1796	1.29897552
6204624046	0.9436	1.03909232
6204624051	0.9436	1.03909232
6204624056	0.9335	1.0279702
6204624061	0.9335	1.0279702
6204624066	0.9335	1.0279702
6204631000	0.2019	0.22233228
6204631200	0.118	0.1299416
6204631505	0.118	0.1299416
6204631510	0.2359	0.25977308
6204631525	0.2359	0.25977308
6204631550	0.2359	0.25977308
6204632000	0.4718	0.51954616
6204632510	0.059	0.0649708
6204632520	0.059	0.0649708
6204633010	0.0603	0.06640236
6204633090	0.0603	0.06640236
6204633510	0.2412	0.26560944
6204633525	0.2412	0.26560944
6204633530	0.2412	0.26560944
6204633532	0.2309	0.25426708
6204633535	0.2309	0.25426708
6204633540	0.2309	0.25426708
6204691005	0.118	0.1299416
6204691010	0.2359	0.25977308
6204691025	0.2359	0.25977308
6204691050	0.2359	0.25977308
6204692010	0.059	0.0649708
6204692020	0.059	0.0649708
6204692030	0.059	0.0649708
6204692510	0.2359	0.25977308
6204692520	0.2359	0.25977308
6204692530	0.2359	0.25977308
6204692540	0.2309	0.25426708
6204692550	0.2309	0.25426708
6204692560	0.2309	0.25426708
6204696010	0.5308	0.58451696
6204696030	0.2359	0.25977308
6204696070	0.3539	0.38971468
6204699010	0.5308	0.58451696
6204699030	0.2359	0.25977308
6204699044	0.2359	0.25977308
6204699046	0.2359	0.25977308
6204699050	0.3539	0.38971468
6205201000	1.1796	1.29897552
6205202003	0.9436	1.03909232
6205202016	0.9436	1.03909232
6205202021	0.9436	1.03909232

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	CONV. factor	Cents/kg.
6205202026	0.9436	1.03909232
6205202031	0.9436	1.03909232
6205202036	1.0616	1.16903392
6205202041	1.0616	1.16903392
6205202044	1.0616	1.16903392
6205202047	0.9436	1.03909232
6205202051	0.9436	1.03909232
6205202056	0.9436	1.03909232
6205202061	0.9436	1.03909232
6205202066	0.9436	1.03909232
6205202071	0.9436	1.03909232
6205202076	0.9436	1.03909232
6205301000	0.4128	0.45457536
6205302010	0.2949	0.32474388
6205302020	0.2949	0.32474388
6205302030	0.2949	0.32474388
6205302040	0.2949	0.32474388
6205302050	0.2949	0.32474388
6205302055	0.2949	0.32474388
6205302060	0.2949	0.32474388
6205302070	0.2949	0.32474388
6205302075	0.2949	0.32474388
6205302080	0.2949	0.32474388
6205900710	0.118	0.1299416
6205900720	0.118	0.1299416
6205901000	0.2359	0.25977308
6205903010	0.5308	0.58451696
6205903030	0.2359	0.25977308
6205903050	0.1769	0.19480228
6205904010	0.5308	0.58451696
6205904030	0.2359	0.25977308
6205904040	0.2359	0.25977308
6206100010	0.5308	0.58451696
6206100030	0.2359	0.25977308
6206100040	0.118	0.1299416
6206100050	0.2359	0.25977308
6206203010	0.059	0.0649708
6206203020	0.059	0.0649708
6206301000	1.1796	1.29897552
6206302000	0.6488	0.71445856
6206303003	0.9436	1.03909232
6206303011	0.9436	1.03909232
6206303021	0.9436	1.03909232
6206303031	0.9436	1.03909232
6206303041	0.9436	1.03909232
6206303051	0.9436	1.03909232
6206303061	0.9436	1.03909232
6206401000	0.4128	0.45457536
6206403010	0.2949	0.32474388
6206403020	0.2949	0.32474388
6206403025	0.2949	0.32474388
6206403030	0.2949	0.32474388
6206403040	0.2949	0.32474388
6206403050	0.2949	0.32474388
6206900010	0.5308	0.58451696
6206900030	0.2359	0.25977308
6206900040	0.1769	0.19480228
6207110000	1.0281	1.13214372
6207199010	0.3427	0.37738124
6207199030	0.4569	0.50313828
6207210010	1.0502	1.15648024
6207210020	1.0502	1.15648024
6207210030	1.0502	1.15648024
6207210040	1.0502	1.15648024
6207220000	0.3501	0.38553012
6207291000	0.1167	0.12851004
6207299030	0.1167	0.12851004
6207911000	1.0852	1.19502224
6207913010	1.0852	1.19502224

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	CONV. factor	Cents/kg.
6207913020	1.0852	1.19502224
6207997520	0.2412	0.26560944
6207998510	0.2412	0.26560944
6207998520	0.2412	0.26560944
6208110000	0.2412	0.26560944
6208192000	1.0852	1.19502224
6208195000	0.1206	0.13280472
6208199000	0.2412	0.26560944
6208210010	1.0026	1.10406312
6208210020	1.0026	1.10406312
6208210030	1.0026	1.10406312
6208220000	0.118	0.1299416
6208299030	0.2359	0.25977308
6208911010	1.0852	1.19502224
6208911020	1.0852	1.19502224
6208913010	1.0852	1.19502224
6208913020	1.0852	1.19502224
6208920010	0.1206	0.13280472
6208920020	0.1206	0.13280472
6208920030	0.1206	0.13280472
6208920040	0.1206	0.13280472
6208992010	0.0603	0.06640236
6208992020	0.0603	0.06640236
6208995010	0.2412	0.26560944
6208995020	0.2412	0.26560944
6208998010	0.2412	0.26560944
6208998020	0.2412	0.26560944
6209201000	1.0967	1.20768604
6209202000	1.039	1.1441468
6209203000	0.9236	1.01706832
6209205030	0.9236	1.01706832
6209205035	0.9236	1.01706832
6209205045	0.9236	1.01706832
6209205050	0.9236	1.01706832
6209301000	0.2917	0.32122004
6209302000	0.2917	0.32122004
6209303010	0.2334	0.25702008
6209303020	0.2334	0.25702008
6209303030	0.2334	0.25702008
6209303040	0.2334	0.25702008
6209900500	0.1154	0.12707848
6209901000	0.2917	0.32122004
6209902000	0.2917	0.32122004
6209903010	0.2917	0.32122004
6209903015	0.2917	0.32122004
6209903020	0.2917	0.32122004
6209903030	0.2917	0.32122004
6209903040	0.2917	0.32122004
6210109010	0.217	0.2389604
6210109040	0.217	0.2389604
6210203000	0.0362	0.03986344
6210205000	0.0844	0.09294128
6210207000	0.1809	0.19920708
6210303000	0.0362	0.03986344
6210305000	0.0844	0.09294128
6210307000	0.0362	0.03986344
6210309020	0.422	0.4647064
6210403000	0.037	0.0407444
6210405020	0.4316	0.47527792
6210405031	0.0863	0.09503356
6210405039	0.0863	0.09503356
6210405040	0.4316	0.47527792
6210405050	0.4316	0.47527792
6210407000	0.111	0.1222332
6210409025	0.111	0.1222332
6210409033	0.111	0.1222332
6210409045	0.111	0.1222332
6210409060	0.111	0.1222332
6210503000	0.037	0.0407444

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	CONV. factor	Cents/kg.
6210505020	0.0863	0.09503356
6210505031	0.0863	0.09503356
6210505039	0.0863	0.09503356
6210505040	0.0863	0.09503356
6210505055	0.0863	0.09503356
6210507000	0.4316	0.47527792
6210509050	0.148	0.1629776
6210509060	0.148	0.1629776
6210509070	0.148	0.1629776
6210509090	0.148	0.1629776
6211111010	0.1206	0.13280472
6211111020	0.1206	0.13280472
6211118010	1.0852	1.19502224
6211118020	1.0852	1.19502224
6211118040	0.2412	0.26560944
6211121010	0.0603	0.06640236
6211121020	0.0603	0.06640236
6211128010	1.0852	1.19502224
6211128020	1.0852	1.19502224
6211128030	0.6029	0.66391348
6211200410	0.7717	0.84979604
6211200420	0.0965	0.1062658
6211200430	0.7717	0.84979604
6211200440	0.0965	0.1062658
6211200810	0.3858	0.42484296
6211200820	0.3858	0.42484296
6211201510	0.7615	0.8385638
6211201515	0.2343	0.25801116
6211201520	0.6443	0.70950316
6211201525	0.2929	0.32254148
6211201530	0.7615	0.8385638
6211201535	0.3515	0.3870718
6211201540	0.7615	0.8385638
6211201545	0.2929	0.32254148
6211201550	0.7615	0.8385638
6211201555	0.41	0.451492
6211201560	0.7615	0.8385638
6211201565	0.2343	0.25801116
6211202400	0.1233	0.13577796
6211202810	0.8016	0.88272192
6211202820	0.2466	0.27155592
6211202830	0.3083	0.33949996
6211203400	0.1233	0.13577796
6211203810	0.8016	0.88272192
6211203820	0.2466	0.27155592
6211203830	0.3083	0.33949996
6211204400	0.1233	0.13577796
6211204815	0.8016	0.88272192
6211204835	0.2466	0.27155592
6211204860	0.3083	0.33949996
6211205400	0.1233	0.13577796
6211205810	0.8016	0.88272192
6211205820	0.2466	0.27155592
6211205830	0.3083	0.33949996
6211206400	0.1233	0.13577796
6211206810	0.8016	0.88272192
6211206820	0.2466	0.27155592
6211206830	0.3083	0.33949996
6211207400	0.1233	0.13577796
6211207810	0.9249	1.01849988
6211207820	0.2466	0.27155592
6211207830	0.3083	0.33949996
6211320003	0.6412	0.70608944
6211320007	0.8016	0.88272192
6211320010	0.9865	1.0863338
6211320015	0.9865	1.0863338
6211320025	0.9865	1.0863338
6211320030	0.9249	1.01849988
6211320040	0.9249	1.01849988

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	CONV. factor	Cents/kg.
6211320050	0.9249	1.01849988
6211320060	0.9249	1.01849988
6211320070	0.9249	1.01849988
6211320075	0.9249	1.01849988
6211320081	0.9249	1.01849988
6211330003	0.0987	0.10868844
6211330007	0.1233	0.13577796
6211330010	0.3083	0.33949996
6211330015	0.3083	0.33949996
6211330017	0.3083	0.33949996
6211330025	0.37	0.407444
6211330030	0.37	0.407444
6211330035	0.37	0.407444
6211330040	0.37	0.407444
6211330054	0.37	0.407444
6211330058	0.37	0.407444
6211330061	0.37	0.407444
6211390510	0.1233	0.13577796
6211390520	0.1233	0.13577796
6211390530	0.1233	0.13577796
6211390540	0.1233	0.13577796
6211390545	0.1233	0.13577796
6211390551	0.1233	0.13577796
6211399010	0.2466	0.27155592
6211399020	0.2466	0.27155592
6211399030	0.2466	0.27155592
6211399040	0.2466	0.27155592
6211399050	0.2466	0.27155592
6211399060	0.2466	0.27155592
6211399070	0.2466	0.27155592
6211399090	0.2466	0.27155592
6211420003	0.6412	0.70608944
6211420007	0.8016	0.88272192
6211420010	0.9865	1.0863338
6211420020	0.9865	1.0863338
6211420025	1.1099	1.22222188
6211420030	0.8632	0.95055584
6211420040	0.9865	1.0863338
6211420054	1.1099	1.22222188
6211420056	1.1099	1.22222188
6211420060	0.9865	1.0863338
6211420070	1.1099	1.22222188
6211420075	1.1099	1.22222188
6211420081	1.1099	1.22222188
6211430003	0.0987	0.10868844
6211430007	0.1233	0.13577796
6211430010	0.2466	0.27155592
6211430020	0.2466	0.27155592
6211430030	0.2466	0.27155592
6211430040	0.2466	0.27155592
6211430050	0.2466	0.27155592
6211430060	0.2466	0.27155592
6211430064	0.3083	0.33949996
6211430066	0.2466	0.27155592
6211430074	0.3083	0.33949996
6211430076	0.37	0.407444
6211430078	0.37	0.407444
6211430091	0.2466	0.27155592
6211499010	0.2466	0.27155592
6211499020	0.2466	0.27155592
6211499030	0.2466	0.27155592
6211499040	0.2466	0.27155592
6211499050	0.2466	0.27155592
6211499060	0.2466	0.27155592
6211499070	0.2466	0.27155592
6211499080	0.2466	0.27155592
6211499090	0.2466	0.27155592
6212105010	0.9138	1.00627656
6212105020	0.2285	0.2516242

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	CONV. factor	Cents/kg.
6212105030	0.2285	0.2516242
6212109010	0.9138	1.00627656
6212109020	0.2285	0.2516242
6212109040	0.2285	0.2516242
6212200010	0.6854	0.75476248
6212200020	0.2856	0.31450272
6212200030	0.1142	0.12575704
6212300010	0.6854	0.75476248
6212300020	0.2856	0.31450272
6212300030	0.1142	0.12575704
6212900010	0.1828	0.20129936
6212900020	0.1828	0.20129936
6212900030	0.1828	0.20129936
6212900050	0.0914	0.10064968
6212900090	0.4112	0.45281344
6213201000	1.1187	1.23191244
6213202000	1.0069	1.10879828
6213900700	0.4475	0.492787
6213901000	0.4475	0.492787
6213902000	0.3356	0.36956272
6214300000	0.1142	0.12575704
6214400000	0.1142	0.12575704
6214900010	0.8567	0.94339804
6214900090	0.2285	0.2516242
6215100025	0.1142	0.12575704
6215200000	0.1142	0.12575704
6215900015	1.0281	1.13214372
6216000800	0.0685	0.0754322
6216001300	0.3427	0.37738124
6216001720	0.6397	0.70443764
6216001730	0.1599	0.17608188
6216001900	0.3427	0.37738124
6216002110	0.578	0.6364936
6216002120	0.2477	0.27276724
6216002410	0.6605	0.7273426
6216002425	0.1651	0.18180812
6216002600	0.1651	0.18180812
6216002910	0.6605	0.7273426
6216002925	0.1651	0.18180812
6216003100	0.1651	0.18180812
6216003300	0.5898	0.64948776
6216003500	0.5898	0.64948776
6216003800	1.1796	1.29897552
6216004100	1.1796	1.29897552
6217109510	0.9646	1.06221752
6217109520	0.1809	0.19920708
6217109530	0.2412	0.26560944
6217909003	0.9646	1.06221752
6217909005	0.1809	0.19920708
6217909010	0.2412	0.26560944
6217909025	0.9646	1.06221752
6217909030	0.1809	0.19920708
6217909035	0.2412	0.26560944
6217909050	0.9646	1.06221752
6217909055	0.1809	0.19920708
6217909060	0.2412	0.26560944
6217909075	0.9646	1.06221752
6217909080	0.1809	0.19920708
6217909085	0.2412	0.26560944
6301300010	0.8305	0.9145466
6301300020	0.8305	0.9145466
6301900030	0.2215	0.2439158
6302100005	1.1073	1.21935876
6302100008	1.1073	1.21935876
6302100015	1.1073	1.21935876
6302213010	1.1073	1.21935876
6302213020	1.1073	1.21935876
6302213030	1.1073	1.21935876
6302213040	1.1073	1.21935876

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	CONV. factor	Cents/kg.
6302213050	1.1073	1.21935876
6302215010	0.7751	0.85354012
6302215020	0.7751	0.85354012
6302215030	0.7751	0.85354012
6302215040	0.7751	0.85354012
6302215050	0.7751	0.85354012
6302217010	1.1073	1.21935876
6302217020	1.1073	1.21935876
6302217030	1.1073	1.21935876
6302217040	1.1073	1.21935876
6302217050	1.1073	1.21935876
6302219010	0.7751	0.85354012
6302219020	0.7751	0.85354012
6302219030	0.7751	0.85354012
6302219040	0.7751	0.85354012
6302219050	0.7751	0.85354012
6302221010	0.5537	0.60973444
6302221020	0.3876	0.42682512
6302221030	0.5537	0.60973444
6302221040	0.3876	0.42682512
6302221050	0.3876	0.42682512
6302221060	0.3876	0.42682512
6302222010	0.3876	0.42682512
6302222020	0.3876	0.42682512
6302222030	0.3876	0.42682512
6302290020	0.2215	0.2439158
6302313010	1.1073	1.21935876
6302313020	1.1073	1.21935876
6302313030	1.1073	1.21935876
6302313040	1.1073	1.21935876
6302313050	1.1073	1.21935876
6302315010	0.7751	0.85354012
6302315020	0.7751	0.85354012
6302315030	0.7751	0.85354012
6302315040	0.7751	0.85354012
6302315050	0.7751	0.85354012
6302317010	1.1073	1.21935876
6302317020	1.1073	1.21935876
6302317030	1.1073	1.21935876
6302317040	1.1073	1.21935876
6302317050	1.1073	1.21935876
6302319010	0.7751	0.85354012
6302319020	0.7751	0.85354012
6302319030	0.7751	0.85354012
6302319040	0.7751	0.85354012
6302319050	0.7751	0.85354012
6302321010	0.5537	0.60973444
6302321020	0.3876	0.42682512
6302321030	0.5537	0.60973444
6302321040	0.3876	0.42682512
6302321050	0.3876	0.42682512
6302321060	0.3876	0.42682512
6302322010	0.5537	0.60973444
6302322020	0.3876	0.42682512
6302322030	0.5537	0.60973444
6302322040	0.3876	0.42682512
6302322050	0.3876	0.42682512
6302322060	0.3876	0.42682512
6302390030	0.2215	0.2439158
6302402010	0.9412	1.03644944
6302511000	0.5537	0.60973444
6302512000	0.8305	0.9145466
6302513000	0.5537	0.60973444
6302514000	0.7751	0.85354012
6302593020	0.5537	0.60973444
6302600010	1.1073	1.21935876
6302600020	0.9966	1.09745592
6302600030	0.9966	1.09745592
6302910005	0.9966	1.09745592

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	CONV. factor	Cents/kg.
6302910015	1.1073	1.21935876
6302910025	0.9966	1.09745592
6302910035	0.9966	1.09745592
6302910045	0.9966	1.09745592
6302910050	0.9966	1.09745592
6302910060	0.9966	1.09745592
6302931000	0.4429	0.48772148
6302932000	0.4429	0.48772148
6302992000	0.2215	0.2439158
6303191100	0.8859	0.97555308
6303910010	0.609	0.6706308
6303910020	0.609	0.6706308
6303921000	0.2768	0.30481216
6303922010	0.2768	0.30481216
6303922030	0.2768	0.30481216
6303922050	0.2768	0.30481216
6303990010	0.2768	0.30481216
6304111000	0.9966	1.09745592
6304113000	0.1107	0.12190284
6304190500	0.9966	1.09745592
6304191000	1.1073	1.21935876
6304191500	0.3876	0.42682512
6304192000	0.3876	0.42682512
6304193060	0.2215	0.2439158
6304910020	0.8859	0.97555308
6304910070	0.2215	0.2439158
6304920000	0.8859	0.97555308
6304996040	0.2215	0.2439158
6505001515	1.1189	1.23213268
6505001525	0.5594	0.61601128
6505001540	1.1189	1.23213268
6505002030	0.9412	1.03644944
6505002060	0.9412	1.03644944
6505002545	0.5537	0.60973444
6507000000	0.3986	0.43893832
9404901000	0.2104	0.23169248
9404908020	0.9966	1.09745592
9404908040	0.9966	1.09745592
9404908505	0.6644	0.73163728
9404908536	0.0997	0.10978964
9404909505	0.6644	0.73163728
9404909570	0.2658	0.29269896
9619002100	0.8681	0.95595172
9619002500	0.1085	0.1194802
9619003100	0.9535	1.0499942
9619003300	1.1545	1.2713354
9619004100	0.2384	0.26252608
9619004300	0.2384	0.26252608
9619006100	0.8528	0.93910336
9619006400	0.2437	0.26836244
9619006800	0.3655	0.4024886
9619007100	1.1099	1.22222188
9619007400	0.2466	0.27155592
9619007800	0.2466	0.27155592
9619007900	0.2466	0.27155592
5007106010	0.2713	0.29875556
5007106020	0.2713	0.29875556
5007906010	0.2713	0.29875556
5007906020	0.2713	0.29875556

* * * * *

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Dated: July 26, 2016.

Elanor Starmer,

Administrator.

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BILLING CODE 3410–02–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[TD 9780]

RIN 1545–BN34

Election Into the Partnership Audit Regime Under the Bipartisan Budget Act of 2015

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Temporary regulations.

SUMMARY: This document contains temporary regulations pursuant to section 1101(g)(4) of the Bipartisan Budget Act of 2015 regarding an election to apply the new partnership audit regime enacted by that act to certain returns of a partnership. The regulations provide the time, form, and manner for making this election. The regulations affect any partnership that wishes to elect to have the new partnership audit regime apply to its returns filed for certain taxable years beginning before January 1, 2018.

DATES:

Effective date: These regulations are effective August 5, 2016.

Applicability Date: For dates of applicability, see § 301.9100–22T(e) and (f).

FOR FURTHER INFORMATION CONTACT: Jenni M. Black at (202) 317–6834 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains amendments to the Procedure and Administration Regulations (26 CFR part 301) to provide rules for the time, form, and manner of making the election under section 1101(g)(4) of the Bipartisan Budget Act of 2015, Public Law 114–74 (BBA) with respect to returns filed for partnership taxable years beginning after November 2, 2015 and before January 1, 2018.

The BBA was enacted on November 2, 2015, and was amended by the Protecting Americans from Tax Hikes Act of 2015, Public Law 114–113, div. Q (PATH Act) on December 18, 2015. Section 1101(a) of the BBA removes subchapter C of chapter 63 of the Internal Revenue Code (Code) effective for partnership taxable years beginning after December 31, 2017. Subchapter C of chapter 63 contains the unified partnership audit and litigation rules that were enacted as part of the Tax Equity and Fiscal Responsibility Act of 1982, Public Law 97–248 (TEFRA). These partnership audit and litigation rules are commonly referred to as the TEFRA partnership procedures.

Section 1101(b) of the BBA also removes subchapter D of chapter 63 of the Code (containing audit rules for electing large partnerships) and part IV of subchapter K of chapter 1 of the Code (prescribing the income tax treatment for electing large partnerships), effective for partnership taxable years beginning after December 31, 2017.

Section 1101(c) of the BBA replaces the rules to be removed by sections 1101(a) and (b) with a new partnership audit regime. Section 1101(c) adds a new subchapter C to chapter 63 of the Code, including amended Code sections 6221–6241. The BBA also makes related and conforming amendments to other provisions of the Code.

On December 18, 2015, President Obama signed into law the PATH Act. Section 411 of the PATH Act corrects and clarifies certain amendments made by the BBA. The amendments under the PATH Act are effective as if included in section 1101 of the BBA, and therefore, subject to the effective dates in section 1101(g) of the BBA.

1. Overview of the New Partnership Audit Regime

Section 6221(a) as added by the BBA provides that, in general, any adjustment to items of income, gain, loss, deduction, or credit of a partnership for a partnership taxable year (and any partner's distributive share thereof) shall be determined, and any tax attributable thereto shall be assessed and collected, at the partnership level. The applicability of any penalty, addition to tax, or additional amount which relates to an adjustment to any such item or share shall also be determined at the partnership level. Section 6221(b) as added by the BBA provides rules for partnerships that are required to furnish 100 or fewer Schedules K–1, *Partner's Share of Income, Deductions, Credits, etc.,* to elect out of this new regime. Generally, a partnership may elect out of the new regime only if each of its partners is an individual, corporation (including certain types of foreign entities), or estate. Special rules apply for purposes of determining the number of partners in the case of a partner that is an S corporation. Section 6221(b)(2)(C) provides that the Secretary by regulation or other guidance may prescribe rules for purposes of the 100-or-fewer-Schedule K–1 requirement similar to the rules for S corporations with respect to any partner that is not an individual, corporation, or estate.

Section 6223 as amended by the BBA provides that the partnership shall designate, in the manner prescribed by the Secretary, a partner or other person with a substantial presence in the United States as the partnership representative who shall have the sole authority to act on behalf of the partnership under subchapter C of chapter 63 of the Code, as amended by the BBA. In any case in which such a designation is not in effect, the Secretary may select any person as the partnership representative. A partnership and all partners of such partnership shall be bound by actions taken under subchapter C by the partnership and by any final decision in a proceeding brought under subchapter C with respect to the partnership.

Section 6225 as amended by the BBA generally addresses partnership adjustments made by the IRS and the calculation of any resulting imputed underpayment. Section 6225(a) generally provides that the amount of any imputed underpayment resulting from an adjustment must be paid by the partnership. Section 6225(b) describes how an imputed underpayment is determined, and section 6225(c) describes modifications that, if approved by the IRS, may reduce the amount of an imputed underpayment. The PATH Act added to section 6225(c) a special rule addressing certain passive losses of publicly traded partnerships.

Section 6226 as amended by the BBA provides an exception to the general rule under section 6225(a)(1) that the partnership must pay the imputed underpayment. Under section 6226, the partnership may elect to have the reviewed year partners take into account the adjustments made by the IRS and pay any tax due as a result of those adjustments. In this case, the partnership is not required to pay the imputed underpayment. Section 6225(d)(1) defines the reviewed year to mean the partnership taxable year to which the item(s) being adjusted relates.

Under section 6227 as amended by the BBA, the partnership may request an administrative adjustment, which is taken into account in the partnership taxable year the administrative adjustment request (AAR) is made. The partnership generally has three years from the date of filing the return to make an AAR for that year, but may not make an AAR for a partnership taxable year after the IRS has mailed the partnership a notice of an administrative proceeding initiated with respect to the taxable year.

Section 6231 as amended by the BBA describes notices of proceedings and adjustments, including certain time

frames for mailing the notices and the authority to rescind any notice of adjustment with the partnership's consent. Section 6232(a) as amended by the BBA provides that any imputed underpayment is assessed and collected in the same manner as if it were a tax imposed for the adjustment year by subtitle A, except that in the case of an AAR that reports an underpayment that the partnership elects to pay, the underpayment shall be paid when the request is filed.

Section 6234 as amended by the BBA generally provides that a partnership may seek judicial review of the adjustments within 90 days of the date the notice of final partnership adjustment is mailed. Section 6235 as amended by the BBA provides the period of limitations on making adjustments.

Section 6241 as amended by the BBA provides definitions and special rules, including rules addressing bankruptcy and treatment when a partnership ceases to exist. In particular, section 6241(4) as amended by the BBA provides that no deduction is allowed under subtitle A for any payment required to be made by a partnership under the new partnership audit regime.

2. Effective Dates

Pursuant to section 1101(g)(1) of the BBA, the amendments made by section 1101, which repeal the TEFRA partnership procedures and the rules applicable to electing large partnerships and which create the new partnership audit regime, generally apply to returns filed for partnership taxable years beginning after December 31, 2017. Section 1101(g)(2) of the BBA provides that, in the case of an AAR under section 6227 as amended by the BBA, the amendments made by section 1101 apply to requests with respect to returns filed for partnership taxable years beginning after December 31, 2017. Similarly, section 1101(g)(3) of the BBA provides that, in the case of an election to use the alternative to payment of the imputed underpayment by the partnership under section 6226 as amended by the BBA, the amendments made by section 1101 apply to elections with respect to returns filed for partnership taxable years beginning after December 31, 2017.

Section 1101(g)(4) of the BBA provides that a partnership may elect (at such time and in such form and manner as the Secretary may prescribe) for the amendments made under section 1101 (other than the election out of the new partnership audit regime under section 6221(b) as added by the BBA) to apply to any of its partnership returns filed for partnership taxable years beginning after November 2, 2015 (the date of the enactment of the BBA) and before January 1, 2018.

Explanation of Provisions

This Treasury decision adopts temporary regulations set forth in § 301.9100–22T to provide the time, form, and manner for a partnership to make an election pursuant to section 1101(g)(4) of the BBA to have the new partnership audit regime apply to any of its partnership returns filed for a partnership taxable year beginning after November 2, 2015 and before January 1, 2018. Section 301.9100–22T(a) provides the general rule that a partnership may elect at the time and in such form and manner as described in § 301.9100–22T for amendments made by section 1101 of the BBA, except section 6221(b) added by the BBA, to apply to any return of the partnership filed for an eligible taxable year (as defined in § 301.9100–22T(d)). Accordingly, a partnership that elects to apply the new partnership audit regime to a partnership return filed for an eligible taxable year may not elect out of the new rules under the small partnership exception under section 6221(b) as added by BBA, with respect to that return.

Section 301.9100–22T(a) further provides that an election made not in accordance with these temporary regulations is not valid, and an election, once made, may only be revoked with consent of the IRS. An election is also not valid if it frustrates the purposes of section 1101 of the BBA, which include the collection of any imputed underpayment that may be due by the partnership under section 6225(a) as amended by the BBA. In addition, partnerships may not request an extension of time for making an election described in § 301.9100–22T under § 301.9100–3.

Section 301.9100–22T(d)(1) generally provides that for purposes of the temporary regulations, an eligible taxable year is any partnership taxable year beginning after November 2, 2015 and before January 1, 2018. Section 301.9100–22T(d)(2) provides exceptions to the definition of an eligible taxable year to avoid proceedings under both the TEFRA partnership procedures and the new partnership audit regime for the same partnership taxable year. To avoid these multiple proceedings, an election under these temporary regulations does not apply if the partnership has taken the affirmative step to apply the TEFRA partnership procedures with respect to the partnership return for that taxable year. This occurs when the tax matters partner has filed a request for an administrative adjustment for the partnership taxable year under section 6227(c) of the TEFRA partnership procedures with respect to a partnership taxable year. Similarly, an election under these temporary regulations also does not apply if a partnership that is not subject to the TEFRA partnership procedures has filed an amended return of partnership income for the partnership taxable year.

Under the general rule in § 301.9100–22T(b), an election to have the new partnership audit regime apply must be made when the IRS first notifies the partnership in writing that a partnership return for an eligible taxable year has been selected for examination (a ''notice of selection for examination''). Section 301.9100–22T(b)(1) provides that a partnership that wishes to make an election must do so within 30 days of the date of the notice of selection for examination. The notice of selection for examination referred to in § 301.9100–22T(b) is a notice that precedes the notice of an administrative proceeding required under section 6231(a) as amended by the BBA. Section 301.9100–22T(b) provides that the IRS will not issue a notice of an administrative proceeding, which cuts off the partnership's time for filing an AAR under section 6227 as amended by the BBA, for at least 30 days after it receives a valid election filed in accordance with § 301.9100–22T(b). During the period of at least 30 days after the IRS receives a valid election and before the IRS mails the notice of an administrative proceeding, the partnership may file an AAR under section 6227 as amended by the BBA.

Section 301.9100–22T(b)(2) provides that an election must be in writing and include a statement that the partnership is electing to have the partnership audit regime enacted by the BBA apply to the partnership return identified in the IRS notification of selection for examination. The partnership must write ''Election under Section 1101(g)(4)'' at the top of the statement. The statement must be provided to the individual identified in the notice of selection for examination as the IRS contact for the examination. In addition, the statement must be dated and signed by the tax matters partner, as defined under section 6231(a)(7) of the TEFRA partnership procedures and the applicable regulations, or an individual who has the authority to sign the partnership return for the taxable year under examination under section 6063 of the Code, the regulations thereunder, and applicable forms and instructions. The statement must include the name,

taxpayer identification number, address, and telephone number of the individual who signs the statement, as well as the partnership's name, taxpayer identification number, and tax year to which the statement applies. The statement must include representations that the partnership is not insolvent and does not reasonably anticipate becoming insolvent, the partnership is not currently and does not reasonably anticipate becoming subject to a bankruptcy petition under title 11 of the United States Code, and the partnership has sufficient assets, and reasonably anticipates having sufficient assets, to pay the potential imputed underpayment that may be determined during the partnership examination. The statement must also include a representation, signed under penalties of perjury, that the individual signing the statement is duly authorized to make the election under § 301.9100–22T(b) and that, to the best of the individual's knowledge and belief, the statement is true, correct, and complete.

A partnership electing into the new partnership audit regime under the BBA will also be required to designate the partnership representative, as defined in section 6223 as amended by the BBA, and provide the partnership representative's name, taxpayer identification number, address and daytime telephone number, and any other information as required in future guidance regarding the partnership representative. The Treasury Department and the IRS expect to issue additional guidance regarding designation of a partnership representative, including who is eligible to be a partnership representative, under section 6223 as amended by the BBA.

Section 301.9100–22T(c) provides an exception to the general rule in § 301.9100–22T(b) that a partnership may only elect into the new partnership audit regime after first receiving a notice of selection for examination. This exception provides that a partnership that has not received a notice of selection for examination described in § 301.9100–22T(b) may make an election to have the new partnership audit regime apply to a partnership return for an eligible taxable year if the partnership wishes to file an AAR under section 6227 as amended by the BBA. Once an election is made under § 301.9100–22T(c), all aspects of the new partnership audit regime, except section 6221(b) as added by the BBA, apply to the return filed for the eligible taxable year subject to the election. As with an election under § 301.9100–22T(b), an election under § 301.9100–22T(c) may not be revoked without consent of the IRS.

An election under § 301.9100–22T(c) must be made only in the manner prescribed by the IRS in accordance with the forms and instructions and other guidance issued by the IRS. In no case may an election under § 301.9100–22T(c) be made earlier than January 1, 2018. Consequently, an AAR under section 6227 as amended by the BBA may not be filed before January 1, 2018 (except by partnerships that have been issued a notice of selection for examination pursuant to the procedures discussed above). An AAR filed before that date (other than an AAR filed by a partnership that made a valid election under § 301.9100–22T(b)) will be treated as an AAR by the partnership under section 6227 of the TEFRA partnership procedures, or as an amended return of partnership income for partnerships not subject to the TEFRA partnership procedures, and will prevent the partnership taxable year for which the request, or return, is filed from being an eligible taxable year. *See* § 301.9100–22T(d)(2). The Treasury Department and the IRS intend to issue guidance regarding AARs under section 6227 as amended by the BBA before January 1, 2018.

Special Analyses

Certain IRS regulations, including this one, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory impact assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to this regulation. These temporary regulations are published pursuant to section 7805(b)(2) of the Code to provide the time, form, and manner for a partnership to make an election pursuant to section 1101(g)(4) of the BBA to have the new partnership audit regime apply to any of its returns filed for a partnership taxable year beginning after November 2, 2015 and before January 1, 2018. Without this necessary guidance, a partnership would not be able to make a valid election pursuant to section 1101(g)(4) of the BBA. For the applicability of the Regulatory Flexibility Act (5 U.S.C. chapter 6), please refer to the Special Analyses section of the cross-reference notice of proposed rulemaking published in the Proposed Rules section of this issue of the **Federal Register**. Pursuant to section 7805(f) of the Code, these regulations were submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Drafting Information

The principal author of these temporary regulations is Jenni M. Black of the Office of the Associate Chief Counsel (Procedure and Administration). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 301

Income taxes, Penalties, Reporting and recordkeeping requirements.

Amendments to the Regulations

Accordingly, 26 CFR part 301 is amended as follows:

PART 301—PROCEDURE AND ADMINISTRATION

■ **Paragraph 1.** The authority citation for part 301 is amended by adding an entry in numerical order to read as follows:

Authority: 26 U.S.C. 7805 * * *

* * * * *

Section 301.9100–22T is also issued under section 1101(g)(4) of Public Law 114–74.

* * * * *

■ **Par. 2.** Section 301.9100–22T is added to read as follows:

§ 301.9100–22T Time, form, and manner of making the election under section 1101(g)(4) of the Bipartisan Budget Act of 2015 for returns filed for partnership taxable years beginning after November 2, 2015 and before January 1, 2018 (temporary).

(a) *Election.* Pursuant to section 1101(g)(4) of the Bipartisan Budget Act of 2015, Public Law 114–74 (BBA), a partnership may elect at the time and in such form and manner as described in this section for amendments made by section 1101 of the BBA, except section 6221(b) as added by the BBA, to apply to any return of the partnership filed for an eligible taxable year as defined in paragraph (d) of this section. An election is valid only if made in accordance with this section. Once made, an election may only be revoked with the consent of the Internal Revenue Service (IRS). An election is not valid if it frustrates the purposes of section 1101 of the BBA. A partnership may not request an extension of time under § 301.9100–3 for an election described in this section.

(b) *Election on notification by the IRS*—(1) *Time for making the election.* Except as described in paragraph (c) of this section, an election under this section must be made within 30 days of the date of notification to a partnership,

in writing, that a return of the partnership for an eligible taxable year has been selected for examination (a notice of selection for examination).

(2) *Form and manner of making the election*—(i) *In general.* The partnership makes an election under this section by providing a written statement with the words ''Election under Section 1101(g)(4)'' written at the top that satisfies the requirements of paragraph (b)(2) of this section to the individual identified in the notice of selection for examination as the IRS contact regarding the examination.

(ii) *Statement requirements.* A statement making an election under this section must be in writing and be dated and signed by the tax matters partner, as defined under section 6231(a)(7) (prior to amendment by the BBA), and the applicable regulations, or an individual who has the authority to sign the partnership return for the taxable year under examination under section 6063, the regulations thereunder, and applicable forms and instructions. The fact that an individual dates and signs the statement making the election described in this paragraph (b) shall be prima facie evidence that the individual is authorized to make the election on behalf of the partnership. A statement making an election must include—

(A) The partnership's name, taxpayer identification number, and the partnership taxable year for which the election described in this paragraph (b) is being made;

(B) The name, taxpayer identification number, address, and daytime telephone number of the individual who signs the statement;

(C) Language indicating that the partnership is electing application of section 1101(c) of the BBA for the partnership return for the eligible taxable year identified in the notice of selection for examination;

(D) The information required to properly designate the partnership representative as defined by section 6223 as amended by the BBA, which must include the name, taxpayer identification number, address, and daytime telephone number of the partnership representative and any additional information required by applicable regulations, forms and instructions, and other guidance issued by the IRS;

(E) The following representations—

(*1*) The partnership is not insolvent and does not reasonably anticipate becoming insolvent before resolution of any adjustment with respect to the partnership taxable year for which the election described in this paragraph (b) is being made;

(*2*) The partnership has not filed, and does not reasonably anticipate filing, voluntarily a petition for relief under title 11 of the United States Code;

(*3*) The partnership is not subject to, and does not reasonably anticipate becoming subject to, an involuntary petition for relief under title 11 of the United States Code; and

(*4*) The partnership has sufficient assets, and reasonably anticipates having sufficient assets, to pay a potential imputed underpayment with respect to the partnership taxable year that may be determined under subchapter C of chapter 63 of the Internal Revenue Code as amended by the BBA; and

(F) A representation, signed under penalties of perjury, that the individual signing the statement is duly authorized to make the election described in this paragraph (b) and that, to the best of the individual's knowledge and belief, all of the information contained in the statement is true, correct, and complete.

(iii) *Notice of Administrative Proceeding.* Upon receipt of the election described in this paragraph (b), the IRS will promptly mail a notice of administrative proceeding to the partnership and the partnership representative, as required under section 6231(a)(1) as amended by the BBA. Notwithstanding the preceding sentence, the IRS will not mail the notice of administrative proceeding before the date that is 30 days after receipt of the election described in paragraph (b) of this section.

(c) *Election for the purpose of filing an administrative adjustment request (AAR) under section 6227 as amended by the BBA*—(1) *In general.* A partnership that has not been issued a notice of selection for examination as described in paragraph (b)(1) of this section may make an election with respect to a partnership return for an eligible taxable year for the purpose of filing an AAR under section 6227 as amended by the BBA. Once an election under this paragraph (c) is made, all of the amendments made by section 1101 of the BBA, except section 6221(b) as added by the BBA, apply with respect to the partnership taxable year for which such election is made.

(2) *Time for making the election.* No election under this paragraph (c) may be made before January 1, 2018.

(3) *Form and manner of making an election.* An election under this paragraph (c) must be made in the manner prescribed by the IRS for that purpose in accordance with applicable regulations, forms and instructions, and other guidance issued by the IRS.

(4) *Effect of filing an AAR before January 1, 2018.* Except in the case of an election made in accordance with paragraph (b) of this section, an AAR filed on behalf of a partnership before January 1, 2018, is deemed for purposes of paragraph (d)(2) of this section, to be an AAR filed under section 6227(c) (prior to amendment by the BBA) or an amended return of partnership income, as applicable.

(d) *Eligible taxable year*—(1) *In general.* For purposes of this section, the term *eligible taxable year* means any partnership taxable year beginning after November 2, 2015 and before January 1, 2018, except as provided in paragraph (d)(2) of this section.

(2) *Exception if AAR or amended return filed or deemed filed.* Notwithstanding paragraph (d)(1) of this section, a partnership taxable year is not an eligible taxable year for purposes of this section if for the partnership taxable year—

(i) The tax matters partner has filed an AAR under section 6227(c) (prior to amendment by the BBA),

(ii) The partnership is deemed to have filed an AAR under section 6227(c) (prior to the amendment by the BBA) in accordance with paragraph (c)(4) of this section, or

(iii) An amended return of partnership income has been filed or has been deemed to be filed under paragraph (c)(4) of this section.

(e) *Applicability date.* These regulations are applicable to returns filed for partnership taxable years beginning after November 2, 2015 and before January 1, 2018.

(f) *Expiration date.* This section will expire on August 5, 2019.

John M. Dalrymple,

Deputy Commissioner for Services and Enforcement.

Approved: July 6, 2016.

Mark J. Mazur,

Assistant Secretary for Tax Policy.

[FR Doc. 2016–18638 Filed 8–4–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2016–0746]

RIN 1625–AA00

Safety Zone; M/V Zhenhuan 14 Wando Terminal Crane Movement; Charleston, SC

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a 100 yard temporary moving safety zone around the M/V Zhenhuan 14 during its inbound and outbound transit as well as all movements in between the Charleston Harbor entrance buoy and the Wando Welch Terminal on the Charleston Harbor, and Wando River, Charleston, SC. The M/V Zhenhuan 14 will be transporting 5 gantry cranes between the dates of August 5, 2016 through August 17, 2016. The safety zone is necessary to protect the public from hazards associated with transporting the large cranes. Persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the safety zone unless authorized by the Captain of the Port Charleston or a designated representative.

DATES: This rule is effective from August 5, 2016 through August 17, 2016.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov* type USCG–2016–0746 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant John Downing, Sector Charleston Office of Waterways Management, Coast Guard; telephone (843) 740–3184, email *John.Z.Downing@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
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 notified of this situation only 10 days prior to the vessel arrival. It is impracticable to publish a NPRM because we must establish this safety zone by August 5, 2016 to protect vessels and people in the vicinity of the M/V Zhenhuan 14's transit.

We are issuing this rule, and under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making it 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 respond to the safety hazards associated with the transit of the M/V Zhenhuan 14.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The Captain of the Port Charleston (COTP) has determined that potential hazards associated with the Transit of the M/V Zhenhuan 14 will be a safety concern for anyone within a 100-yard radius around the outer most points of the vessel. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while the vessel is transiting.

The legal basis for this rule is the Coast Guard's Authority to establish a safety zone: 33 U.S.C. 1231. The purpose of the proposed rule is to ensure safety of life on the navigable water of the United States during the transit of the M/V Zhenhuan 14.

IV. Discussion of the Rule

This rule establishes a safety zone on August 5, 2016 through August 17, 2016 during all movements of the M/V Zhenhuan 14 with its cranes in the downward position. The vessel is 815 ft long with a beam of 450 ft with the cranes in the downward position. The safety zone will cover all navigable waters within a 100-yard radius around the outer most points of the vessel. The duration of the zone is intended to protect personnel, vessels, and the marine environment while the vessel is transiting the Charleston Harbor, and Wando River, Charleston, SC. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget.

The economic impact of this rule is not significant for the following reasons: (1) Although persons and vessels will not be able to enter, transit through, anchor in, or remain within the regulated area without authorization from the Captain of the Port Charleston or a designated representative, they will be able to operate in the surrounding area during the enforcement periods; (2) persons and vessels will still be able to enter, transit through, anchor in, or remain within the regulated area if authorized by the Captain of the Port Charleston or a designated representative; and (3) the Coast Guard will provide advance notification of the regulated area to the local maritime community by Local Notice to Mariners and Broadcast Notice to Mariners.

B. Impact on Small Entities

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

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

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental

jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

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 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 Management Directive 023–01 and Commandant Instruction M16475.lD, 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 rule involves a temporary safety zone, that will prohibit entry within a 100-yard radius around the outer most points of the vessel.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1226, 1231; 50 U.S.C. 191; 33 CFR 1.05–1(g), 6.04–1, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2 . Add a temporary § 165.T07–0746 to read as follows:

§ 100.T07–0746 Safety Zone; M/V Zhenhuan 14 Wando Terminal Crane Movement; Charleston, SC.

(a*) Regulated area.* The following regulated area is a moving safety zone: All waters of the Charleston Harbor and Wando Rivers within a 100 yard radius around the outer most points of the M/V Zhenhuan 14 while the cranes are in the downward position. The safety zone will start in Charleston Harbor, in approximate position 32°46′10″ N., 79°55′15″ W. and transit to the Wando Welch Terminal, in position 32°50′02″ N., 79°53′29″ W. During the outbound transit the M/V Zhenhuan 14 will proceed from the Wando Welch Terminal in approximate position 32°50′02″ N., 79°53′29″ W. to the Charleston Harbor entrance in approximate position 32°46′10″ N., 79°55′15″ W. All coordinates are North American Datum 1983.

(b) *Definition.* As used in this section, ''designated representative'' means Coast Guard Patrol Commanders, including Coast Guard coxswains, petty officers, and other officers operating Coast Guard vessels, and Federal, state, and local officers designated by or assisting the Captain of the Port Charleston in the enforcement of the regulated areas.

(c) *Regulations.* (1) All persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area unless authorized by the Captain of the Port Charleston or a designated representative.

(2) Persons and vessels desiring to enter, transit through, anchor in, or remain within the regulated area may contact the Captain of the Port Charleston by telephone at (843) 740–7050, or a designated representative via VHF radio on channel 16, to request authorization. If authorization to enter, transit through, anchor in, or remain within the regulated area is granted, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Charleston or a designated representative.

(3) The Coast Guard will provide notice of the regulated area by Marine Safety Information Bulletins, Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

(d) *Enforcement period.* This rule will be enforced when the M/V Zhenhuan 14 is transiting Charleston Harbor between August 5, 2016 through 17, 2016.

Dated: August 1, 2016.

G.L. Tomasulo,

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

[FR Doc. 2016–18599 Filed 8–4–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2016–0370]

RIN 1625–AA00

Safety Zone; Annual Roy Webster Cross-Channel Swim, Columbia River, Hood River, OR

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing a safety zone on the Columbia River in Hood River, OR. This safety zone is necessary to help ensure the safety of the maritime public during a cross channel swim and will do so by prohibiting unauthorized persons and vessels from entering the safety zone unless authorized by the Sector Columbia River Captain of the Port or his designated representatives.

DATES: This rule is effective on September 5, 2016.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov*, type USCG–2016–0370 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Ken Lawrenson, Waterways Management Division, Marine Safety Unit Portland, U.S. Coast Guard; telephone 503–240–9319, email *msupdxwwm@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

On April 20, 2016, the Hood River County Chamber of Commerce notified the Coast Guard that it will be conducting a cross-channel swim on the Columbia River in Hood River, OR for the Annual Roy Webster Cross-Channel Swim. In response, on May 16, 2016 the Coast Guard published a notice of proposed rulemaking (NPRM) titled Safety Zone; Annual Roy Webster Cross-Channel Swim, Columbia River, Hood River, OR (81 FR 30503). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to this marine event. During the comment period that ended on June 16, 2016 we received no comments.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The Captain of the Port, Sector Columbia River (COTP) has determined that potential hazards associated with cross-channel swims could be a safety concern for the event participants, any other mariners transiting the area during the event hours, and a potential threat to the marine environment. The purpose of this rule is to ensure the safety of event participants, the marine environment and the protection of the navigable waterway before, during, and after the scheduled event.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments on our NPRM published May 16, 2016. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM.

This rule establishes a safety zone that will be enforced from 6 a.m. to noon on Labor Day each year. The safety zone will encompass all navigable waters of the Columbia River between River Mile 169 and River Mile 170. The duration of the zone is intended to ensure the safety of vessels, participants and these navigable waters before, during, and after the scheduled cross-channel swim. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget.

This regulatory action determination is based on the size, location, short duration, and the event's long history. Commercial vessel traffic will be able to transit the area if they obtain permission from the COTP or a designated representative. Moreover, the Coast Guard will issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule allows vessels to seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

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

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting approximately 6 hours annually that will prohibit entry within a specific section of the Columbia River in the vicinity of Hood River, OR. It is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add, under the undesignated center heading Thirteenth Coast Guard District, § 165.1342 to read as follows:

§ 165.1342 Annual Roy Webster Cross-Channel Swim, Columbia River, Hood River, OR.

(a) *Regulated area.* The following regulated area is a safety zone. The safety zone will encompass all waters of the Columbia River between River Mile 169 and River Mile 170.

(b) *Definitions.* As used in this section—

Designated representative means Coast Guard Patrol Commanders, including Coast Guard coxswains, petty officers, and other officers operating Coast Guard vessels, and Federal, state, and local officers designated by or assisting the Captain of the Port Sector Columbia River in the enforcement of the regulated area.

Non-participant person means a person not registered as a swimmer in the Roy Webster Cross-Channel Swim held on the Columbia River in the vicinity of Hood River, OR, each Labor Day.

(c) *Regulations.* In accordance with the general regulations in 33 CFR part 165, subpart C, non-participant persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area unless authorized by Captain of the Port, Sector Columbia River or a designated representative.

(1) Non-participant persons and vessels may request authorization to enter, transit through, anchor in, or remain within the regulated area by contacting the Captain of the Port Sector, Columbia River or a designated representative via VHF radio on channel 16. If authorization is granted by the Captain of the Port, Sector Columbia River or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Sector, Columbia River or a designated representative.

(2) The Coast Guard will provide notice of the safety zone by Local Notice to Mariners, Broadcast Notice to Mariners and on-scene designated representatives.

(d) *Enforcement period.* This safety zone will be enforced on Labor Day of each year, between the hours of 6 a.m. and Noon.

Dated: July 29, 2016.

W.R. Timmons,

Captain, U.S. Coast Guard, Captain of the Port, Sector Columbia River.

[FR Doc. 2016–18589 Filed 8–4–16; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 257

[EPA–HQ–OLEM–2016–0274; FRL–9949–44–OLEM]

Hazardous and Solid Waste Management System: Disposal of Coal Combustion Residuals From Electric Utilities; Extension of Compliance Deadlines for Certain Inactive Surface Impoundments; Response to Partial Vacatur

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA or the Agency) is taking

direct final action to extend for certain inactive coal combustion residuals (CCR) surface impoundments the compliance deadlines established by the regulations for the disposal of CCR under subtitle D of the Resource Conservation and Recovery Act (RCRA). These revisions are taken in response to a partial vacatur ordered by the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit) on June 14, 2016.

DATES: This rule is effective on October 4, 2016 without further notice, unless EPA receives adverse comment by August 22, 2016. If EPA receives adverse comment, we will publish a timely withdrawal notice in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OLEM–2016–0274, at *http://www.regulations.gov*. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www.epa.gov/dockets/commenting-epa-dockets*.

FOR FURTHER INFORMATION CONTACT: For information concerning this direct final rule, contact Steve Souders, Office of Resource Conservation and Recovery, Environmental Protection Agency, 5304P, Washington, DC 20460; telephone number: (703) 308–8431; email address: *souders.steve@epa.gov*. For more information on this rulemaking please visit *https://www.epa.gov/coalash*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This direct final rule applies only to those owners or operators of inactive CCR surface impoundments that meet all three of the following conditions: (1) Complied with the requirement at 40 CFR 257.105(i)(1) by placing in their facility's written operating record a notification of intent to initiate closure of the CCR unit as required by 40 CFR 257.100(c)(1), no later than December 17, 2015; (2) complied with the requirement at 40 CFR 257.106(i)(1) by providing notification to the relevant State Director and/or appropriate Tribal authority by January 19, 2016, of the intent to initiate closure of the CCR unit; and (3) complied with the requirement at 40 CFR 257.107(i)(1) by placing the notification of intent to initiate closure of the CCR unit on the owner or operator's publicly accessible CCR Web site no later than January 19, 2016.

If you have any questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

B. Why is EPA issuing a direct final rule?

EPA is publishing this rule without a prior proposed rule because we view this as a noncontroversial action and anticipate no adverse comment. This direct final rule merely extends the deadlines for the owners and operators of those inactive CCR surface impoundments that had taken advantage of the ''early closure'' provisions of 40 CFR 257.100, who became newly subject to the rule's requirements for existing CCR surface impoundments on June 14, 2016 when the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit) ordered the vacatur of those provisions. This rule provides time for these owners and operators to bring their units into compliance with the rule's substantive requirements, but does not otherwise amend the rule or otherwise impose new requirements on those units. However, in the ''Proposed Rules'' section of this **Federal Register**, we are publishing a separate document that will serve as the proposed rule to provide new compliance deadlines if adverse comments are received on this direct final rule. We will not institute a second comment period on this action. Any parties interested in commenting must do so at this time.

If EPA receives adverse comment, we will publish a timely withdrawal in the **Federal Register** informing the public that this direct final rule will not take effect. We would address all public comments in any subsequent final rule based on the proposed rule.

II. Statutory Authority

These regulations are established under the authority of sections 1006(b), 1008(a), 2002(a), 4004, and 4005(a) of the Solid Waste Disposal Act of 1970, as amended by the Resource Conservation and Recovery Act of 1976 (RCRA), as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA), 42 U.S.C. 6906(b), 6907(a), 6912(a), 6944, and 6945(a).

III. Background

On April 17, 2015 EPA finalized national regulations to regulate the disposal of coal combustion residuals (CCR) as solid waste under subtitle D of the Resource Conservation and Recovery Act (RCRA) titled, ''Hazardous and Solid Waste Management System; Disposal of Coal Combustion Residuals from Electric Utilities,'' (80 FR 21302) (''CCR rule''). The CCR rule established national minimum criteria for existing and new CCR landfills and existing and new CCR surface impoundments and all lateral expansions consisting of location restrictions, design and operating criteria, groundwater monitoring and corrective action, closure requirements and post-closure care, and recordkeeping, notification and internet posting requirements. The rule also required any existing unlined CCR surface impoundment that is contaminating groundwater above a regulated constituent's groundwater protection standard to stop receiving CCR and either retrofit or close, except in limited circumstances. It also established requirements for inactive CCR surface impoundments, *i.e.,* those units that did not receive CCR after October 15, 2015 but still contain water and CCR. Under the rule as promulgated, inactive CCR surface impoundments must comply with the same requirements as existing CCR surface impoundments, unless the owner or operator of the facility closes the units no later than April 17, 2018. See 80 FR 21408–21409, April 17, 2015; 40 CFR 257.100(b). If an inactive CCR surface impoundment had completely closed by this date, no other requirements applied to that unit (*i.e.,* the ''early closure'' provisions). The effect of these ''early closure'' provisions was that no groundwater monitoring or other post-closure care requirements (such as the requirement to take corrective action for any releases) would apply to these units.

On June 14, 2016 the United States Court of Appeals for the D.C. Circuit ordered the vacatur of these ''early closure'' provisions in 40 CFR 257.100. The effect of the vacatur is that all

inactive CCR surface impoundments must now comply with all of the requirements applicable to existing CCR surface impoundments.

IV. What action is EPA taking in this rule?

As a consequence of the order issued by the United States Court of Appeals for the D.C. Circuit on June 14, 2016, EPA is removing certain provisions of the CCR rule at 40 CFR 257.100(b), (c), and (d) related to the ''early closure'' of inactive CCR surface impoundments by April 17, 2018.

As a result of this order, owners and operators of inactive CCR surface impoundments that had relied on these ''early closure'' provisions must now comply with all of the requirements for existing CCR surface impoundments. These technical requirements are found in the following sections of the CCR rule: Location criteria; design and operating requirements, air criteria, inspection requirements, groundwater monitoring and corrective action; closure and post-closure care; and recordkeeping, notification and publicly accessible internet site requirements. Each of these requirements contained associated compliance deadlines, which must also be met. But the owners and operators of these units would have substantially less time than EPA had originally determined was needed to come into compliance; indeed some of these deadlines have already passed, prior to the issuance of the court's order. In the absence of an extension, these units would, through no fault of their own, become ''open dumps'' under the statute.

Accordingly, EPA is extending the compliance deadlines associated with these newly applicable regulatory requirements to allow the owners or operators of these units adequate time to come into compliance. The Agency is extending each of these compliance deadlines by 547 days, which is the amount of time between the signature date of the final rule and the last business day of the week during which the order from the court granting the motion to vacate 40 CFR 257.100 (b), (c), and (d) was signed. Thus, the 547 days represents the amount of time between December 19, 2014, and June 17, 2016.[1] In essence, this represents the amount of time that would have been available to these facilities had 40 CFR 257.100 not been included in the final rule; *i.e.,* this rule provides the same amount of time EPA granted to existing CCR surface impoundments in the final rule.

EPA defines the units subject to this extension rule as exclusively those units whose owners and operators of inactive CCR surface impoundments have complied with the following three requirements: (1) The requirement at 40 CFR 257.105(i)(1), by placing in their facility's written operating record a notification of intent to initiate closure of the CCR unit as required by 40 CFR 257.100(c)(1), by no later than December 17, 2015; (2) the requirement at 40 CFR 257.106(i)(1), by providing notification to the relevant State Director and/or appropriate Tribal authority no later than January 19, 2016, of the intent to initiate closure of the CCR unit; and (3) the requirement of 40 CFR 257.107(i)(1) by placing the notification of intent to initiate closure of the CCR unit on the owner or operator's publicly accessible CCR Web site, by no later than January 19, 2016.[2] EPA is not revising the regulation to require additional notification or postings from facilities to document that they have a unit(s) subject to the longer compliance deadlines in this extension rule. As noted previously, facilities were required to generate and post documents demonstrating their intent to take advantage of the ''early closure'' provisions by December 2015 and January 2016, pursuant to provisions that were not affected by the court order. Continued maintenance of these documents would be sufficient to establish that a particular unit is eligible for the extended compliance deadlines in this rule.

A brief discussion of the requirements with which these inactive CCR surface impoundments must comply is presented below for the ease of the reader. However, EPA is not soliciting comment on any of these requirements, including the original deadlines associated with these requirements, and is not otherwise reopening any aspect of the final CCR rule. EPA will not consider any comment on any topic other than the extension of the deadlines for the newly subject inactive CCR surface impoundments to be part of the record for this rule, and will not respond to such comments.

A. Location Criteria—Deadline To Complete the Demonstrations for Compliance With the Location Restrictions

To ensure that CCR surface impoundments are appropriately sited, the CCR rule established location restrictions, including restrictions relating to placement of CCR above the uppermost aquifer, in wetlands, within fault areas, in seismic impact zones, and in unstable areas. See 40 CFR 257.60 through 257.64. As discussed in the CCR rule, all of these location restrictions require the owner or operator of a CCR surface impoundment to demonstrate that they meet the specific criteria, as well as providing a deadline by when the demonstrations much be completed. In addition, the CCR rule requires existing CCR surface impoundments that cannot make the required demonstrations to close the unit. However, owners or operators of certain inactive CCR surface impoundments—those owners or operators that elected to comply with the now-vacated ''early closure'' provisions under 40 CFR 257.100(b)—were exempt from the location restrictions finalized in the CCR rule. With the vacatur of the exemption, these inactive CCR surface impoundments become subject to the location restrictions. This direct final rule provides owners or operators of eligible inactive CCR surface impoundments until April 16, 2020 to comply with the requirements for location restrictions; otherwise, the CCR unit must be closed. See also 80 FR 21359 –21368, April 17, 2015.

B. Design Criteria—Deadline To Document Whether the CCR Surface Impoundment Is Lined or Unlined

Owners or operators of inactive CCR surface impoundments subject to the provisions of the new 40 CFR 257.100(e)(3)(i) must by April 17, 2018 comply with the requirements at 40 CFR 257.71(a) and (b) and document, certified by a qualified professional engineer, whether their inactive CCR surface impoundment is constructed with any one of the three liner types: (1) A liner consisting of a minimum of two feet of compacted soil with a hydraulic

[1] The EPA selected June 17, 2016 (the end of the week the vacatur order was signed by the court) instead of June 14, 2016 (the actual date the court signed the order) to limit any potential confusion. Had EPA extended the compliance period based on the June 14 date, any facility that completed closure of their inactive surface impoundment by the original deadline in the vacated provisions would have been subject to certain rule requirements for one day. EPA concluded that no environmental or health protection would be achieved by requiring facilities to comply with requirements that are relevant only to active or inactive impoundments (because they determine whether the unit must close), when the unit would complete closure a single day later.

[2] Inactive CCR surface impoundments that are not affected by this rule: *i.e.,* inactive CCR surface impoundments without a notice of intent to close dated between April 17, 2015 and December 17, 2015, and placed in the facility's operating record and on the facility's publicly accessible internet site by January 19, 2016, remain subject to all of the requirements for existing CCR surface impoundments under 40 CFR part 257, subpart D (see § 257.100(a)), including the original timeframes in 40 CFR 257, subpart C, and are not subject to the new compliance timeframes discussed in this direct final rule.

conductivity of no more than 1 × 10–7 cm/sec; (2) a composite liner that meets the requirements of 40 CFR 257.70(b); or (3) an alternative liner that meets the requirements of 40 CFR 257.70(c). See also 80 FR 21370–21371, April 17, 2015.

C. Design Criteria—Deadline To Install Permanent Markers

Except for incised CCR surface impoundments as defined in 40 CFR 257.53, owners or operators of inactive CCR surface impoundments subject to the provisions of the new 40 CFR 257.100(e)(3)(ii) are subject to 40 CFR 257.73(a)(1) that requires the placement of a permanent identification marker, at least six feet high on or immediately adjacent to the CCR unit with the name associated with the CCR unit and the name of the owner or operator. The placement of the permanent marker must be completed by the owner or operator of the inactive CCR surface impoundment no later than June 16, 2017.

D. Design Criteria—Deadline To Complete the Initial Hazard Potential Classification and Prepare an Emergency Action Plan

Except for incised CCR surface impoundments as defined in 40 CFR 257.53, owners or operators of inactive CCR surface impoundments subject to the provisions of the new 40 CFR 257.100(e)(3)(v) must complete the initial periodic hazard potential classification assessment as required by 40 CFR 257.73 (a)(2) no later than April 17, 2018. Section 257.73(a)(3) requires any CCR surface impoundment that is determined by the owner or operator, through the certification by a qualified professional engineer, to be either a high hazard potential or a significant hazard potential CCR surface impoundment to prepare and maintain a written Emergency Action Plan (EAP). An EAP is a document that identifies potential emergency conditions at a CCR surface impoundment and specifies actions to be followed to minimize loss of life and property damage. In order to prepare an EAP, the owner or operator must accurately and comprehensively identify potential failure modes and at risk developments. Inactive surface impoundments that have been identified as having either a high hazard potential or a significant hazardous potential are subject to the provisions of the new 40 CFR 257.100(e)(3)(iii) and must prepare and maintain an EAP as required by 40 CFR 257.73 no later than October 16, 2018. See also 80 FR 21377–21379, April 17, 2015.

E. Design Criteria—Deadline To Document the CCR Surface Impoundments History of Construction

CCR surface impoundments that either have: (1) A height of five feet or more and a storage volume of 20 acre feet or more; or (2) have a height of 20 feet or more are required to document the design and construction of the CCR surface impoundment as required in 40 CFR 257.73(b) and (c). Owners or operators of inactive CCR surface impoundments that meet this size threshold and are subject to the provisions of the new 40 CFR 257.100(e)(3)(iv) must document the construction history of the CCR unit no later than April 17, 2018. See also 80 FR 21379–21380, April 17, 2015.

F. Design Criteria—Deadline To Complete the Initial Structural Stability Assessment and Initial Safety Factor Assessment

CCR surface impoundments meeting the size threshold discussed in section IV.E of this preamble, are also subject to two different types of technical assessments: (1) A structural stability assessment; and (2) a safety factor assessment. Owners or operators of inactive CCR surface impoundments subject to the provisions of the new 40 CFR 257.100(e)(3)(v) are required to conduct an initial assessment addressing both structural stability and safety factors by April 17, 2018. These requirements can be found at 40 CFR 257.73(b), (d), (e), and (f). See also 80 FR 21380–21386, April 17, 2015.

G. Operating Criteria—Deadline To Prepare a Fugitive Dust Control Plan

The owner or operator of a CCR unit is required under 40 CFR 257.80(b) to adopt measures that will effectively minimize CCR from becoming airborne at the facility, including CCR fugitive dust originating from CCR units, roads, and other CCR management and material handling activities. To meet this requirement, the owner or operator of the CCR unit must prepare and operate in accordance with a fugitive dust control plan. Owners or operators of inactive CCR surface impoundments subject to the provisions of the new 40 CFR 257.100(e)(4)(i) must complete this plan no later than April 18, 2017. See also 80 FR 21386–21388, April 17, 2015.

H. Operating Criteria—Deadline To Prepare an Initial Inflow Design Flood Control System Plan

Owners or operators of all CCR surface impoundments are required to design, construct, operate, and maintain hydraulic and hydrologic capacity to adequately manage flow both into and from a CCR surface impoundment during and after the peak discharge resulting from the inflow design flood, which is based on the Hazard Potential Classification of the CCR surface impoundment (40 CFR 257.82(a)). The rule requires the preparation of an initial inflow design flood control system plan (40 CFR 257.82(c)). Owners and operators of inactive CCR surface impoundments subject to the provisions of the new 40 CFR 257.100(e)(4)(ii) must complete the inflow design flood control system plan by April 17, 2018. See also 80 FR 21390–21392, April 17, 2015.

I. Operating Criteria—Deadline To Initiate Weekly Inspection of the CCR Surface Impoundment and Monthly Monitoring of the CCR Unit's Instrumentation

Under 40 CFR 257.83(a) all CCR surface impoundments must be examined by a qualified person at least once every seven days for any appearance of actual or potential structural weakness or other conditions that are disrupting or that have the potential to disrupt the operation or safety of the CCR unit. The results of the inspection by a qualified person must be recorded in the facility's operating record. Weekly inspections are intended to detect, as early as practicable, signs of distress in a CCR surface impoundment that may result in larger more severe conditions. Inspections are also designed to identify potential issues with hydraulic structures that may affect the structural safety of the unit and impact its hydraulic and hydrologic capacity. 40 CFR 257.83(a) also requires the monitoring of all instrumentation supporting the operation of the CCR unit to be conducted by a qualified person no less than once per month. Owners and operators of inactive CCR surface impoundments subject to the provisions of the new 40 CFR 257.100(e)(4)(iii) must initiate the inspection requirements set forth in 40 CFR 257.83(a) no later than April 18, 2017. See also 80 FR 21394–21395, April 17, 2015.

J. Operating Criteria—Deadline To Complete the Initial Annual Inspection of the CCR Surface Impoundment

Any CCR surface impoundment exceeding the size threshold discussed in section IV.E of this preamble, is required to conduct annual inspections of the CCR unit throughout its operating life (40 CFR 257.83(b)). These inspections are focused primarily on the structural stability of the unit and must ensure that the operation and

maintenance of the unit is in accordance with recognized and generally accepted good engineering standards. Each inspection must be conducted and certified by a qualified professional engineer. Owners and operators of inactive CCR surface impoundments subject to the provisions of the new 40 CFR 257.100(e)(4)(iv) must conduct this initial annual inspection by July 19, 2017. See also 80 FR 21395, April 17, 2015.

K. Groundwater Monitoring and Corrective Action—Deadline To Install the Groundwater Monitoring System and Begin Monitoring

Owners and operators of inactive CCR surface impoundments subject to the provisions of the new 40 CFR 257.100(e)(5)(i) are required to comply with the provisions of 40 CFR 257.90(b) no later than April 17, 2019. These provisions require the installation of a groundwater monitoring system as required by 40 CFR 257.91 and the development of a groundwater sampling and analysis program. This program is to include selection of the statistical procedures to be used for evaluating groundwater monitoring data as required by 40 CFR 257.93. It also includes the initiation of the detection monitoring program and includes obtaining a minimum of eight independent samples for each background and downgradient wells as required by 40 CFR 257.94(b) and to begin evaluating the groundwater monitoring data for a statistically significant increase over background levels for the constituents listed in appendix III as required by 40 CFR 257.94. See also 80 FR at 21396–21407, April 17, 2015.

L. Groundwater Monitoring and Corrective Action—Deadline To Prepare an Initial Groundwater Monitoring and Corrective Action Report

Owners and operators of inactive CCR surface impoundments subject to the provisions of the new 40 CFR 257.100(e)(5)(ii) are required to comply with the provisions of 40 CFR 257.90(e) no later than August 1, 2019 (and annually thereafter) that require the preparation of an annual groundwater monitoring and corrective action report. The report must contain specific information identified in the regulations including but not limited to maps, aerial images or diagrams showing the CCR unit and all upgradient (background) and downgradient wells, identification of any monitoring wells installed or decommissioned in the previous year; monitoring data collected under 40 CFR 257.90–257.98 and a narrative discussion of any transition between monitoring programs (*i.e.,* detection and assessment monitoring).

M. Detection Monitoring Program—Deadline for Collection and Analyses of Eight Independent Samples

Consistent with the groundwater monitoring requirements previously discussed in section IV.K of this preamble, no later than April 17, 2019, owners or operators of inactive CCR surface impoundments subject to the provisions of the new 40 CFR 257.100(e)(5)(i) must collect a minimum of eight independent samples from each background and down gradient well and analyze for constituents listed in appendix III and IV of this part as required under 40 CFR 257.94(b).

N. Closure and Post-Closure Care—Deadline To Prepare a Written Closure Plan

The closure plan describes the steps necessary to close a CCR unit at any point during the active life of the unit based on recognized and generally accepted good engineering practices. Owners and operators of inactive CCR surface impoundments subject to the provisions of the new 40 CFR 257.100(e)(6)(i) are required to comply with the requirements of 40 CFR 257.102, including 40 CFR 257.102(b) requiring the preparation of a written closure plan no later than April 17, 2018. A written closure plan includes information that sets out how the closure of the unit will be conducted. It includes information such as a narrative description of the closure process, whether the closure of the CCR unit will be accomplished by leaving CCR in place or through clean closure. If the CCR is left in place, the closure plan must provide a description of the final cover system and how the final cover system will achieve the regulatory performance standards. The written closure plan must also provide a schedule for completing all activities necessary to satisfy the closure criteria of the rule. See also 80 FR 21410–21425, April 17, 2015.

O. Closure and Post-Closure Care—Deadline To Prepare a Written Post-Closure Care Plan

40 CFR 257.104(d) requires that an owner or operator of a CCR unit prepare a written post-closure plan. The content of the plan includes among other things, a description of the monitoring and maintenance activities required for the unit and the frequency that these activities will be performed. Owners and operators of inactive CCR surface impoundments subject to the provisions of the new 40 CFR 257.100(e)(6)(ii) are required to comply with the requirements of 40 CFR 257.104, including 40 CFR 257.104(d) requiring the preparation of a written post-closure plan no later than April 17, 2018.

P. Recordkeeping, Notification and Publicly Accessible Internet Site Requirements

Inactive CCR surface impoundments subject to the revised compliance deadlines being finalized in this direct final rule are also subject to the recordkeeping, notification and publicly accessible internet reporting requirements. The CCR rule requires the owner or operator of a CCR unit(s) to maintain files of all required information (*e.g.,* demonstrations, plans, notifications, and reports) that supports implementation and compliance with the rule. Each file must be maintained in the operating record for a period of at least 5 years following submittal of the file into the operating record. Submittal into the operating record is required at the time the documentation becomes available or by the specific compliance deadline. Section 257.105 contains a comprehensive listing of each recordkeeping requirement.

Owners or operators are also required to notify State Directors and/or the appropriate Tribal authority when specific documents have been placed in the operating record and on the owner or operators publicly accessible internet site. In most instances, these notifications must be certified by a qualified professional engineer and may, in certain instances, be accompanied with additional information or data supporting the notification. Notification requirements can be found at 40 CFR 257.106, and are required for location criteria, design criteria, operating criteria, groundwater monitoring and corrective action and closure and post-closure care.

Owners and operators of CCR units are also required to establish and maintain a publicly accessible Internet site, titled ''CCR Rule Compliance Data and Information.'' Unless provided otherwise in the rule, information posted to the Internet site must be available for a period no less than 3 years from the initial posting date. Posting of information must be completed no later than 30 days from the submittal of the information to the operating record. Owners and operators of inactive CCR surface impoundments subject to the new provisions of § 257.100(e) have 30 days from the revised compliance deadlines to post applicable information on their publicly accessible internet site.

The preceding discussion provides an abbreviated summary of the compliance deadlines for owners or operators of inactive CCR surface impoundments affected by this direct final rule. These inactive CCR surface impoundments are now also subject to all applicable requirements under 40 CFR part 257, subpart D for existing CCR surface impoundments. The new compliance deadlines for inactive CCR surface impoundments have been collected in a new paragraph (e) under § 257.100.

V. What is the effect of this rule on state programs?

The CCR rule established minimum federal criteria for existing and new CCR surface impoundments and CCR landfills. The regulations promulgated under subtitle D of RCRA require owner or operators of these units to comply with the requirements of the rule without any additional action by a state or federal regulatory agency. As discussed at length in the CCR rule preamble (80 FR 21429–21433, April 17, 2015), under the provisions of subtitle D applicable to solid waste, states are not required to adopt or implement these regulations, to develop a permit program, or submit a program covering these units to EPA for approval and there is no mechanism for EPA to officially approve or authorize a state program to operate ''in lieu of'' the federal regulations. In the CCR rule, however, EPA strongly encouraged states to adopt at least the federal minimum requirements into their regulations. EPA further acknowledged that some states have already adopted requirements that go beyond the minimum federal requirements; for example, some states currently impose financial assurance requirements for CCR units, and require a permit for some or all of these units. The federal criteria promulgated in the CCR rule are minimum requirements and do not preclude states' from adopting more stringent requirements where they deem to be appropriate. EPA also encouraged states to revise their solid waste management plan (SWMP) to address the issuance of the revised federal requirements and to submit the revisions of these plans to EPA for review, using the provision contained in 40 CFR part 256.

This rule amends the final CCR rule to reflect the vacatur of specific provisions of that rule applicable to certain CCR surface impoundments (*i.e.,* 40 CFR 257.100(b), (c), and (d)). This vacatur will likely affect those states that have begun the process of either revising their state programs (and regulations) to be consistent with the federal requirements or those states that have or are in the process of adopting the federal minimum requirements into their state regulations by reference. These states must now ensure that their regulations take into account this vacatur by ensuring that their regulations provide that inactive CCR surface impoundments are subject to all of the requirements in part 257 applicable to existing CCR surface impoundments regardless of their intent to close by a certain date.

VI. Statutory and Executive Order (EO) Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993) and Executive Order 13563 (76 FR 3821, January 21, 2011), this action is not a ''significant regulatory action'' and is therefore not subject to OMB review. Because this action is not subject to notice and comment requirements under the Administrative Procedures Act or any other statute, it is not subject to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) or Sections 202 and 205 of the Unfunded Mandates Reform Act of 1999 (UMRA) (Pub. L. 104–4). In addition, this action does not significantly or uniquely affect small governments. This action does not create new binding legal requirements that substantially and directly affect Tribes under Executive Order 13175 (65 FR 67249, November 9, 2000). This action does not have significant Federalism implications under Executive Order 13132 (64 FR 43255, August 10, 1999). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997). This final rule 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). This action does not involve technical standards; thus, the requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply.

Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before certain actions may take effect, the agency promulgating the action must submit a report, which includes a copy of the action, to each House of the Congress and to the Comptroller General of the United States. This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 257

Environmental protection, Beneficial use, Coal combustion products, Coal combustion residuals, Coal combustion waste, Disposal, Hazardous waste, Landfill, Surface impoundment.

Dated: July 26, 2015.

Gina McCarthy,

Administrator.

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

PART 257—CRITERIA FOR CLASSIFICATION OF SOLID WASTE DISPOSAL FACILITIES AND PRACTICES

■ 1. The authority citation for part 257 continues to read as follows:

Authority: 42 U.S.C. 6907(a)(3), 6912(a)(1), 6944(a), and 6949a(c); 33 U.S.C. 1345(d) and (e).

■ 2. Section 257.90 is amended by revising paragraph (a) to read as follows:

§ 257.90 Applicability.

(a) All CCR landfills, CCR surface impoundments, and lateral expansions of CCR units are subject to the groundwater monitoring and corrective action requirements under §§ 257.90 through 257.98.

* * * * *

■ 3. Section 257.100 is amended by:
■ a. Revising paragraph (a);
■ b. Removing and reserving paragraphs (b) through (d); and
■ c. Adding paragraph (e).

The revisions and additions read as follows:

§ 257.100 Inactive CCR surface impoundments.

(a) Inactive CCR surface impoundments are subject to all of the requirements of this subpart applicable to existing CCR surface impoundments.

* * * * *

(e) *Timeframes for certain inactive CCR surface impoundments.* (1) An

inactive CCR surface impoundment for which the owner or operator has completed the actions by the deadlines specified in paragraphs (e)(1)(i) through (iii) of this section is eligible for the alternative timeframes specified in paragraphs (e)(2) through (6) of this section. The owner or operator of the CCR unit must comply with the applicable recordkeeping, notification, and internet requirements associated with these provisions. For the inactive CCR surface impoundment:

(i) The owner or operator must have prepared and placed in the facility's operating record by December 17, 2015, a notification of intent to initiate closure of the inactive CCR surface impoundment pursuant to § 257.105(i)(1);

(ii) The owner or operator must have provided notification to the State Director and/or appropriate Tribal authority by January 19, 2016, of the intent to initiate closure of the inactive CCR surface impoundment pursuant to § 257.106(i)(1); and

(iii) The owner or operator must have placed on its CCR Web site by January 19, 2016, the notification of intent to initiate closure of the inactive CCR surface impoundment pursuant to § 257.107(i)(1).

(2) *Location restrictions.* (i) No later than April 16, 2020, the owner or operator of the inactive CCR surface impoundment must:

(A) Complete the demonstration for placement above the uppermost aquifer as set forth by § 257.60(a), (b), and (c)(3);

(B) Complete the demonstration for wetlands as set forth by § 257.61(a), (b), and (c)(3);

(C) Complete the demonstration for fault areas as set forth by § 257.62(a), (b), and (c)(3);

(D) Complete the demonstration for seismic impact zones as set forth by § 257.63(a), (b), and (c)(3); and

(E) Complete the demonstration for unstable areas as set forth by § 257.64(a), (b), (c), and (d)(3).

(ii) An owner or operator of an inactive CCR surface impoundment who fails to demonstrate compliance with the requirements of paragraph (e)(2)(i) of this section is subject to the closure requirements of § 257.101(b)(1).

(3) *Design criteria.* The owner or operator of the inactive CCR surface impoundment must:

(i) No later than April 17, 2018, complete the documentation of liner type as set forth by § 257.71(a) and (b).

(ii) No later than June 16, 2017, place on or immediately adjacent to the CCR unit the permanent identification marker as set forth by § 257.73(a)(1).

(iii) No later than October 16, 2018, prepare and maintain an Emergency Action Plan as set forth by § 257.73(a)(3).

(iv) No later than April 17, 2018, compile a history of construction as set forth by § 257.73(b) and (c).

(v) No later than April 17, 2018, complete the initial hazard potential classification, structural stability, and safety factor assessments as set forth by § 257.73(a)(2), (b), (d), (e), and (f).

(4) *Operating criteria.* The owner or operator of the inactive CCR surface impoundment must:

(i) No later than April 18, 2017, prepare the initial CCR fugitive dust control plan as set forth in § 257.80(b).

(ii) No later than April 17, 2018, prepare the initial inflow design flood control system plan as set forth in § 257.82(c).

(iii) No later than April 18, 2017, initiate the inspections by a qualified person as set forth by § 257.83(a).

(iv) No later than July 19, 2017, complete the initial annual inspection by a qualified professional engineer as set forth by § 257.83(b).

(5) *Groundwater monitoring and corrective action.* The owner or operator of the inactive CCR surface impoundment must:

(i) No later than April 17, 2019, comply with groundwater monitoring requirements set forth in §§ 257.90(b) and 257.94(b); and

(ii) No later than August 1, 2019, prepare the initial groundwater monitoring and corrective action report as set forth in § 257.90(e).

(6) *Closure and post-closure care.* The owner or operator of the inactive CCR surface impoundment must:

(i) No later than April 17, 2018, prepare an initial written closure plan as set forth in § 257.102(b); and

(ii) No later than April 17, 2018, prepare an initial written post-closure care plan as set forth in § 257.104(d).

§ 257.102 [Amended]

■ 4. Section 257.102 is amended by removing and reserving paragraph (e)(4)(i).

■ 5. Section 257.104 is amended by revising paragraph (a)(1) and removing paragraph (a)(3) to read as follows:

§ 257.104 Post-closure care requirements.

(a) * * *

(1) Except as provided by paragraph (a)(2) of this section, § 257.104 applies to the owners or operators of CCR landfills, CCR surface impoundments, and all lateral expansions of CCR units that are subject to the closure criteria under § 257.102.

* * * * *

[FR Doc. 2016–18353 Filed 8–4–16; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 64

[Docket ID FEMA–2016–0002; Internal Agency Docket No. FEMA–8443]

Suspension of Community Eligibility

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

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

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

FOR FURTHER INFORMATION CONTACT: If you want to determine whether a particular community was suspended on the suspension date or for further information, contact Patricia Suber, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 400 C Street SW., Washington, DC 20472, (202) 646–4149.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase Federal flood insurance that is not otherwise generally available from private insurers. In return, communities agree to adopt and administer local floodplain management measures aimed

at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits the sale of NFIP flood insurance unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59. Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. We recognize that some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue to be eligible for the sale of NFIP flood insurance. A notice withdrawing the suspension of such communities will be published in the **Federal Register**.

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

Each community receives 6-month, 90-day, and 30-day notification letters addressed to the Chief Executive Officer stating that the community will be suspended unless the required floodplain management measures are met prior to the effective suspension date. Since these notifications were made, this final rule may take effect within less than 30 days.

National Environmental Policy Act. This rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Considerations. No environmental impact assessment has been prepared.

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

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

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

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

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

List of Subjects in 44 CFR Part 64

Flood insurance, Floodplains.

Accordingly, 44 CFR part 64 is amended as follows:

PART 64—[AMENDED]

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

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

§ 64.6 [Amended]

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

State and location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in SFHAs
Region III				
West Virginia:				
Ceredo, Town of, Wayne County	540232	September 25, 1975, Emerg; May 17, 1989, Reg; September 2, 2016, Susp.	September 2, 2016.	September 2, 2016.
Fort Gay, Town of, Wayne County	540202	April 29, 1975, Emerg; January 3, 1979, Reg; September 2, 2016, Susp.	*.....do	Do.
Kenova, City of, Wayne County	540221	April 9, 1975, Emerg; May 17, 1989, Reg; September 2, 2016, Susp.	.....do	Do.
Wayne County, Unincorporated Areas ..	540200	October 31, 1975, Emerg; September 18, 1987, Reg; September 2, 2016, Susp.	.....do	Do.
Region IX				
California:				
Adelanto, City of, San Bernardino County.	060639	September 21, 1979, Emerg; April 15, 1980, Reg; September 2, 2016, Susp.	.....do	Do.
Apple Valley, Town of, San Bernardino County.	060752	N/A, Emerg; June 16, 1995, Reg; September 2, 2016, Susp.	.....do	Do.
Barstow, City of, San Bernardino County.	060271	May 24, 1979, Emerg; February 1, 1980, Reg; September 2, 2016, Susp.	.....do	Do.
Colton, City of, San Bernardino County	060273	January 15, 1974, Emerg; September 17, 1980, Reg; September 2, 2016, Susp.	.....do	Do.

State and location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in SFHAs
Fontana, City of, San Bernardino County.	060274	March 19, 1971, Emerg; June 4, 1987, Reg; September 2, 2016, Susp.	.....do	Do.
Grand Terrace, City of, San Bernardino County.	060737	N/A, Emerg; January 15, 2016, Reg; September 2, 2016, Susp.	.....do	Do.
Hesperia, City of, San Bernardino County.	060733	N/A, Emerg; October 19, 1989, Reg; September 2, 2016, Susp.	.....do	Do.
Highland, City of, San Bernardino County.	060732	N/A, Emerg; October 19, 1989, Reg; September 2, 2016, Susp.	.....do	Do.
Loma Linda, City of, San Bernardino County.	065042	March 19, 1971, Emerg; July 16, 1987, Reg; September 2, 2016, Susp.	.....do	Do.
Needles, City of, San Bernardino County.	060277	March 5, 1975, Emerg; July 16, 1979, Reg; September 2, 2016, Susp.	.....do	Do.
Ontario, City of, San Bernardino County	060278	June 27, 1975, Emerg; December 2, 1980, Reg; September 2, 2016, Susp.	.....do	Do.
Rancho Cucamonga, City of, San Bernardino County.	060671	August 7, 1978, Emerg; September 5, 1984, Reg; September 2, 2016, Susp.	.....do	Do.
Redlands, City of, San Bernardino County.	060279	April 12, 1974, Emerg; January 3, 1979, Reg; September 2, 2016, Susp.	.....do	Do.
Rialto, City of, San Bernardino County	060280	December 17, 1973, Emerg; February 12, 1979, Reg; September 2, 2016, Susp.	.....do	Do.
San Bernardino, City of, San Bernardino County.	060281	December 31, 1970, Emerg; July 16, 1979, Reg; September 2, 2016, Susp.	.....do	Do.
San Bernardino County, Unincorporated Areas.	060270	January 29, 1971, Emerg; September 29, 1978, Reg; September 2, 2016, Susp.	.....do	Do.
Upland, City of, San Bernardino County	065067	December 31, 1970, Emerg; December 23, 1981, Reg; September 2, 2016, Susp.	.....do	Do.
Victorville, City of, San Bernardino County.	065068	June 11, 1971, Emerg; September 21, 1973, Reg; September 2, 2016, Susp.	.....do	Do.
Yucca Valley, Town of, San Bernardino County.	060750	N/A, Emerg; March 31, 1993, Reg; September 2, 2016, Susp.	.....do	Do.
Region X				
Washington:				
Lacey, City of, Thurston County	530190	May 7, 1975, Emerg; July 16, 1980, Reg; September 2, 2016, Susp.	.....do	Do.
Olympia, City of, Thurston County	530191	October 3, 1974, Emerg; February 17, 1982, Reg; September 2, 2016, Susp.	.....do	Do.
Rainier, City of, Thurston County	530260	N/A, Emerg; March 29, 1999, Reg; September 2, 2016, Susp.	.....do	Do.
Thurston County, Unincorporated Areas	530188	September 13, 1974, Emerg; December 1, 1982, Reg; September 2, 2016, Susp.	.....do	Do.
Tumwater, City of, Thurston County	530192	December 18, 1974, Emerg; August 1, 1980, Reg; September 2, 2016, Susp.	.....do	Do.

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

Dated: July 25, 2016.

Michael M. Grimm,

Assistant Administrator for Mitigation, Federal Insurance and Mitigation Administration, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2016–18431 Filed 8–4–16; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 150121066–5717–02]

RIN 0648–XE725

Atlantic Highly Migratory Species; Atlantic Bluefin Tuna Fisheries

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

ACTION: Temporary rule; closure of Angling category northern area trophy fishery.

SUMMARY: NMFS closes the northern area Angling category fishery for large medium and giant (''trophy'' (*i.e.,* measuring 73 inches curved fork length or greater)) Atlantic bluefin tuna (BFT). This action is being taken to prevent any further overharvest of the Angling category northern area trophy BFT subquota.

DATES: Effective 11:30 p.m., local time, August 6, 2016 through December 31, 2016.

FOR FURTHER INFORMATION CONTACT: Sarah McLaughlin or Brad McHale, 978–281–9260.

SUPPLEMENTARY INFORMATION: Regulations implemented under the authority of the Atlantic Tunas Convention Act (ATCA; 16 U.S.C. 971 *et*

seq.) and the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*) governing the harvest of BFT by persons and vessels subject to U.S. jurisdiction are found at 50 CFR part 635. Section 635.27 subdivides the U.S. BFT quota recommended by the International Commission for the Conservation of Atlantic Tunas (ICCAT) among the various domestic fishing categories, per the allocations established in the 2006 Consolidated Atlantic Highly Migratory Species Fishery Management Plan (2006 Consolidated HMS FMP) (71 FR 58058, October 2, 2006), as amended by Amendment 7 to the 2006 Consolidated HMS FMP (Amendment 7) (79 FR 71510, December 2, 2014), and in accordance with implementing regulations.

NMFS is required, under § 635.28(a)(1), to file a closure notice with the Office of the Federal Register for publication when a BFT quota is reached or is projected to be reached. On and after the effective date and time of such notification, for the remainder of the fishing year or for a specified period as indicated in the notification, retaining, possessing, or landing BFT under that quota category is prohibited until the opening of the subsequent quota period or until such date as specified in the notice.

Angling Category Large Medium and Giant Northern ''Trophy'' Fishery Closure

The 2016 BFT fishing year, which is managed on a calendar-year basis and subject to an annual calendar-year quota, began January 1, 2016. The Angling category season opened January 1, 2016, and continues through December 31, 2016. The currently codified Angling category quota is 195.2 mt, of which 4.5 mt is allocated for the harvest of large medium and giant (trophy) BFT from the regulatory area by vessels fishing under the Angling category quota, with 1.5 mt allocated for each of the following areas: North of 39°18′ N. lat. (off Great Egg Inlet, NJ); south of 39°18′ N. lat. and outside the Gulf of Mexico; and in the Gulf of Mexico. Trophy BFT measure 73 inches (185 cm) curved fork length or greater.

As of July 26, 2016, reported landings from the NMFS Automated Catch Reporting System total approximately 1.7 mt. NMFS has determined that the codified Angling category northern area trophy BFT subquota has been reached and that a closure of the northern area trophy BFT fishery is warranted at this time. Therefore, retaining, possessing, or landing large medium or giant BFT north of 39°18′ N. lat. by persons aboard vessels permitted in the HMS Angling category and the HMS Charter/Headboat category (when fishing recreationally) must cease at 11:30 p.m. local time on August 6, 2016. This closure will remain effective through December 31, 2016. This action is intended to prevent any further overharvest of the Angling category northern area trophy BFT subquota, and is taken consistent with the regulations at § 635.28(a)(1).

If needed, subsequent Angling category adjustments will be published in the **Federal Register**. Information regarding the Angling category fishery for Atlantic tunas, including daily retention limits for BFT measuring 27 inches (68.5 cm) to less than 73 inches and any further Angling category adjustments, is available at *hmspermits.noaa.gov* or by calling (978) 281–9260.

HMS Angling and HMS Charter/Headboat category permit holders may catch and release (or tag and release) BFT of all sizes, subject to the requirements of the catch-and-release and tag-and-release programs at § 635.26. Anglers are also reminded that all BFT that are released must be handled in a manner that will maximize survival, and without removing the fish from the water, consistent with requirements at § 635.21(a)(1). For additional information on safe handling, see the ''Careful Catch and Release'' brochure available at *www.nmfs.noaa.gov/sfa/hms/.*

Classification

The Assistant Administrator for NMFS (AA) finds that it is impracticable and contrary to the public interest to provide prior notice of, and an opportunity for public comment on, this action for the following reasons:

The regulations implementing the 2006 Consolidated HMS FMP, as amended, provide for inseason retention limit adjustments and fishery closures to respond to the unpredictable nature of BFT availability on the fishing grounds, the migratory nature of this species, and the regional variations in the BFT fishery. The closure of the northern area Angling category trophy fishery is necessary to prevent any further overharvest of the northern area trophy fishery subquota. NMFS provides notification of closures by publishing the notice in the **Federal Register**, emailing individuals who have subscribed to the Atlantic HMS News electronic newsletter, and updating the information posted on the Atlantic Tunas Information Line and on *hmspermits.noaa.gov.*

These fisheries are currently underway and delaying this action would be contrary to the public interest as it could result in excessive trophy BFT landings that may result in future potential quota reductions for the Angling category, depending on the magnitude of a potential Angling category overharvest. NMFS must close the northern area trophy BFT fishery before additional landings of these sizes of BFT accumulate. Therefore, the AA finds good cause under 5 U.S.C. 553(b)(B) to waive prior notice and the opportunity for public comment. For all of the above reasons, there is good cause under 5 U.S.C. 553(d) to waive the 30-day delay in effectiveness.

This action is being taken under 50 CFR 635.28(a)(1), and is exempt from review under Executive Order 12866.

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

Dated: August 1, 2016.

Emily H. Menashes,

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

[FR Doc. 2016–18593 Filed 8–3–16; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 81, No. 151
Friday, August 5, 2016

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 ENERGY

10 CFR Parts 429 and 431

[Docket Number EERE–2014–BT–STD–0042]

RIN 1904–AD34

Energy Conservation Program: Energy Conservation Standards for Commercial Water Heating Equipment; Reopening of Comment Period

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Reopening of public comment period.

SUMMARY: On May 31, 2016, the U.S. Department of Energy (DOE) published in the **Federal Register** a notice of proposed rulemaking (NOPR) that proposed amended energy conservation standards for commercial water heaters. DOE published this NOPR so stakeholders can review and provide input on these proposed revisions. The comment period for the NOPR pertaining to the subject commercial water heating equipment was scheduled to end August 1, 2016. After receiving a number of requests for additional time to comment, DOE has decided to reopen the public comment period until August 30, 2016 for the purposes of submitting comments on the NOPR or any other aspect of the energy conservation standards rulemaking for commercial water heating equipment.

DATES: The comment period for the proposed rule published on May 31, 2016 (81 FR 34440) is reopened. DOE will accept comments, data, and information regarding the notice of proposed rulemaking received no later than August 30, 2016.

ADDRESSES: *Instructions:* Any comments submitted must identify the NOPR on Energy Conservation Standards for Commercial Water Heating Equipment, and provide docket number EERE–2014–BT–STD–0042 and/or regulatory information number (RIN) 1904–AD34. Comments may be submitted using any of the following methods:

1. Federal eRulemaking Portal: www.regulations.gov. Follow the instructions for submitting comments.

2. Email: ComWaterHeating2014STD0042@ee.doe.gov. Include the docket number and/or RIN in the subject line of the message. Submit electronic comments in WordPerfect, Microsoft Word, PDF, or ASCII file format, and avoid the use of special characters or any form of encryption.

3. Postal Mail: Ms. Ashley Armstrong, U.S. Department of Energy, Building Technologies Office, Mailstop EE–5B, 1000 Independence Avenue SW., Washington, DC 20585–0121. If possible, please submit all items on a compact disc (CD), in which case it is not necessary to include printed copies.

4. Hand Delivery/Courier: Appliance and Equipment Standards Staff, U.S. Department of Energy, Building Technologies Office, 950 L'Enfant Plaza SW., Suite 600, Washington, DC 20024. Telephone: (202) 586–6656. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

No telefacsimilies (faxes) will be accepted. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Public Participation'' section of the May 31, 2016 NOPR. 81 FR 34440, 34532–33.

Docket: The docket is available for review at *www.regulations.gov,* including **Federal Register** notices, public meeting attendee lists and transcripts, comments, and other supporting documents/materials. All documents in the docket are listed in the *www.regulations.gov* index. However, not all documents listed in the index may be publicly available, such as information that is exempt from public disclosure.

A link to the docket Web page can be found at: *https://www.regulations.gov/docket?D=EERE-2014-BT-STD-0042.* This Web page contains a link to the docket for this document on the *www.regulations.gov* site. The *www.regulations.gov* Web page contains simple instructions on how to access all documents, including public comments, in the docket. See section VII, ''Public Participation,'' of the May 31, 2016 NOPR for further information on how to submit comments through *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT:
Ms. Ashley Armstrong, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–5B, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 586–6590. Email: *Ashley.Armstrong@ee.doe.gov.*
Mr. Eric Stas, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 586–9507. Email: *Eric.Stas@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: On May 31, 2016, DOE published in the **Federal Register** a notice of proposed rulemaking (NOPR) that proposed amended energy conservation standards for commercial water heaters. 81 FR 34440. The NOPR provided opportunity for submitting written comments, data, and information regarding the proposed amendments for the subject equipment by August 1, 2016. However, DOE received a request from the Air-Conditioning, Heating, and Refrigeration Institute (AHRI), dated July 22, 2016, to provide an additional 90 days in which to submit comments pertaining to the rulemaking for commercial water heaters. AHRI's request can be found at: *http://www.regulations.gov/document?D=EERE-2014-BT-STD-0042-0023.* AHRI and its members stated that they need more time to sufficiently review and digest the information in order to provide substantive comments. A reopening of the comment period would allow additional time for AHRI and its members and other interested parties to examine the data, information, and analysis presented in the Commercial Water Heaters Technical Support Document, to gather any additional data and information to address the proposed standards, and to submit comments to DOE. DOE also received requests from Raypak on July 25, 2016 and Spire on July 28, 2016 asking for additional time to carefully review the information provided by DOE and to provide substantive comments. Raypak's request can be found at: *http://www.regulations.gov/document?D=EERE-2014-BT-STD-0042-0025.* Spire's request can be found at: *http://www.regulations.gov/document?D=EERE-2014-BT-STD-0042-*

0026. After carefully considering the requests for additional time, DOE has determined that a reopening of the public comment period is appropriate, based upon the foregoing reasons. DOE believes that reopening the comment period until August 30, 2016 will provide the public with sufficient time to submit comments responding to DOE's proposed energy conservation standards. Accordingly, DOE is reopening the comment period to midnight of August 30, 2016 and will deem any comments received by that date to be timely submitted. DOE further notes that any submissions of comments or other information submitted between the original comment end date and the reopening of the comment period will be deemed timely filed.

Issued in Washington, DC, on July 28, 2016.

Kathleen B. Hogan,

Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

[FR Doc. 2016–18674 Filed 8–4–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–8185; Directorate Identifier 2016–NM–050–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to supersede Airworthiness Directive (AD) 2003–18–06, for certain Airbus Model A319–131 and –132 airplanes; Model A320–231, –232, and –233 airplanes; and Model A321–131 and –231 airplanes. AD 2003–18–06 currently requires installing new anti-swivel plates and weights on the engine fan cowl door (FCD) latches and a new cowl door hold-open device. Since we issued AD 2003–18–06, we have received reports of additional engine FCD in-flight losses, and a new FCD front latch and keeper assembly has been developed to address this unsafe condition. This proposed AD would retain the current actions and require modifying the engine FCDs, installing placards, and re-identifying the FCDs with the new part numbers. This proposed AD would also revise the applicability to include all Model A319–131 and –132 airplanes; Model A320–231, –232, and –233 airplanes; and Model A321–131 and –231 airplanes. We are proposing this AD to prevent in-flight loss of an engine FCD and possible consequent damage to the airplane and hazards to persons or property on the ground.

DATES: We must receive comments on this proposed AD by September 19, 2016.

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

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

For service information identified in this NPRM, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–8185; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Sanjay Ralhan, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone: 425–227–1405; fax: 425–227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2016–8185; Directorate Identifier 2016–NM–050–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

On August 29, 2003, we issued AD 2003–18–06, Amendment 39–13297 (68 FR 53501, September 11, 2003) (''AD 2003–18–06''). AD 2003–18–06 requires actions intended to address an unsafe condition on certain Airbus Model A319–131 and –132 airplanes; Model A320–231, –232, and –233 airplanes; and Model A321–131 and –231 airplanes.

Since we issued AD 2003–18–06, we have received reports of additional engine FCD in-flight losses, and a new FCD front latch and keeper assembly has been developed to address this unsafe condition.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2016–0053, dated March 14, 2016 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for all Airbus Model A319–131 and –132; A320–231, –232, and –233; and A321–131 and –231 airplanes. The MCAI states:

> Fan Cowl Door (FCD) losses during take-off were reported on aeroplanes equipped with IAE V2500 engines. Prompted by these occurences, [Direction Générale de l'Aviation Civile] DGAC France issued AD 2000–444–156(B), mandating FCD latch improvements. This [DGAC] AD was later superseded by AD 2001–381(B) [which corresponds to FAA AD 2003–18–06], requiring installation of additional fan cowl latch improvement by installing a hold open device.
>
> Since that [DGAC] AD was issued, further FCD in flight losses were experienced in service. Investigations confirmed that in all

cases, the fan cowls were opened prior to the flight and were not correctly re-secured. During the pre-flight inspection, it was then not detected that the FCD were not properly latched.

This condition, if not corrected, could lead to in-flight loss of a FCD, possibly resulting in damage to the aeroplane and/or injury to persons on the ground.

Prompted by these recent events, new FCD front latch and keeper assembly were developed, having a specific key necessary to un-latch the FCD. This key cannot be removed unless the FCD front latch is safely closed. The key, after removal, must be stowed in the flight deck at a specific location, as instructed in the applicable Aircraft Maintenance Manual. Applicable Flight Crew Operating Manual has been amended accordingly. After modification, the FCD is identified with a different Part Number (P/N).

For the reasons described above, this [EASA] AD retains the requirements of DGAC AD 2001–381(B), which is superseded, and requires modification and re-identification of FCD.

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–8185.

Related Service Information Under 1 CFR Part 51

Airbus has issued Service Bulletin A320–71–1069, dated December 18, 2015. The service information describes procedures for modifying the engine FCDs, installing placards, and re-identifying the FCDs with the new part numbers. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of these same type designs.

Costs of Compliance

We estimate that this proposed AD affects 558 airplanes of U.S. registry.

The actions required by AD 2003–18–06, and retained in this proposed AD, take about 8 work-hours per product, at an average labor rate of $85 per work-hour. Required parts cost about $1,500 per product. Based on these figures, the estimated cost of the actions that are required by AD 2003–18–06 is $2,180 per product.

We also estimate that it would take about 6 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is $85 per work-hour. Required parts would cost about $4,813 per product. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be $2,970,234, or $5,323 per product.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

3. Will not affect intrastate aviation in Alaska; and

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2003–18–06, Amendment 39–13297 (68 FR 53501, September 11, 2003), and adding the following new AD:

Airbus: Docket No. FAA–2016–8185; Directorate Identifier 2016–NM–050–AD.

(a) Comments Due Date

We must receive comments by September 19, 2016.

(b) Affected ADs

This AD replaces AD 2003–18–06, Amendment 39–13297 (68 FR 53501, September 11, 2003) (''AD 2003–18–06'').

(c) Applicability

This AD applies to Airbus Model A319–131 and –132 airplanes; Model A320–231, –232, and –233 airplanes; and Model A321–131 and –231 airplanes; certificated in any category; all manufacturer serial numbers.

(d) Subject

Air Transport Association (ATA) of America Code 71, Powerplant.

(e) Reason

This AD was prompted by reports of engine fan cowl door (FCD) in-flight losses. We are issuing this AD to prevent in-flight loss of an engine FCD and possible consequent damage to the airplane and hazards to persons or property on the ground.

(f) Compliance

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

(g) Retained Modification and/or Installation, With No Changes

This paragraph restates the requirements of paragraph (a) of AD 2003–18–06, with no changes. Within 18 months after October 16, 2003 (the effective date of AD 2003–18–06), do the action(s) specified in paragraph (g)(1) or (g)(2) of this AD, as applicable.

(1) For Configuration 01 airplanes identified in Airbus Service Bulletin A320–71–1028, dated March 23, 2001: Modify the door latches of the fan cowl of both engines (*i.e.,* installation of new anti-swivel plates and weights), and install a new hold-open

device, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–71–1028, dated March 23, 2001.

(2) For Configuration 02 airplanes identified in Airbus Service Bulletin A320–71–1028, dated March 23, 2001: Install a new hold-open device, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–71–1028, dated March 23, 2001.

(h) New Modifications

Within 36 months after the effective date of this AD, do the actions required by paragraphs (h)(1), (h)(2), and (h)(3) of this AD, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–71–1069, dated December 18, 2015.

(1) Modify the left-hand and right-hand FCDs on engines 1 and 2.

(2) Install a placard on the box located at the bottom of the 120 VU panel or at the bottom of the coat stowage, as applicable.

(3) Re-identify both engine FCDs with the new part numbers (P/Ns), as specified in table 1 to paragraph (h) of this AD and table 2 to paragraph (h) of this AD, as applicable.

TABLE 1 TO PARAGRAPH (h) OF THIS AD—LEFT-SIDE DOOR

Old part No.	New part No.
740–4000–501	740–4000–9501
740–4000–503	740–4000–9503
745–4000–501	745–4000–513
745–4000–503	745–4000–515
745–4000–505	745–4000–517

TABLE 2 TO PARAGRAPH (h) OF THIS AD—RIGHT-SIDE DOOR

Old part No.	New part No.
740–4000–502	740–4000–9502
740–4000–504	740–4000–9504
740–4000–506	740–4000–9506
740–4000–508	740–4000–9508
745–4000–502	745–4000–9502
745–4000–504	745–4000–9504
745–4000–506	745–4000–9506
745–4000–508	745–4000–514
745–4000–510	745–4000–516
745–4000–512	745–4000–518

(i) New Alternative Compliance

(1) Replacing an engine FCD having a part number listed as ''Old Part Number'' in table 1 to paragraph (h) of this AD or table 2 to paragraph (h) of this AD, as applicable, with a FCD having the corresponding part number listed as ''New Part Number'' in table 1 to paragraph (h) of this AD or table 2 to paragraph (h) of this AD, as applicable, is an acceptable method of compliance with the requirements of paragraphs (h)(1) and (h)(3) of this AD for that engine FCD only.

(2) An airplane on which Airbus Modification 157516 has been embodied in production is compliant with the requirements of paragraph (h)(1) and (h)(3) of this AD, provided no engine FCD, having a part number identified as ''Old Part Number'' in table 1 to paragraph (h) of this AD or table 2 to paragraph (h) of this AD, as applicable, is installed on that airplane.

(3) An airplane on which Airbus Modification 157718 has been embodied in production is compliant with the requirements of paragraph (h)(2) of this AD.

(j) New Parts Installation Limitations

(1) For an airplane with an engine FCD installed having a part number identified as ''Old Part Number'' in table 1 to paragraph (h) of this AD or table 2 to paragraph (h) of this AD, as applicable: After modification of that airplane as required by paragraph (h) of this AD, do not install an engine FCD, having a part number identified as ''Old Part Number'' in table 1 to paragraph (h) of this AD or table 2 to paragraph (h) of this AD, as applicable.

(2) For an airplane that does not have an engine FCD installed having a part number identified as ''Old Part Number'' in table 1 to paragraph (h) of this AD or table 2 to paragraph (h) of this AD, as applicable: On or after the effective date of this AD, do not install an engine FCD, having a part number identified as ''Old Part Number'' in table 1 to paragraph (h) of this AD or table 2 to paragraph (h) of this AD, as applicable.

(k) New Method of Compliance

Installation on an engine of a right-hand and left-hand engine FCD having a part number approved after the effective date of this AD is a method of compliance with the requirements of paragraphs (g), (h)(1), and (h)(3) of this AD for that engine only, provided the part number is approved, and the installation is accomplished, in accordance with a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA).

(l) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Sanjay Ralhan, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone: 425–227–1405; fax: 425–227–1149. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov*. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Contacting the Manufacturer:* As of the effective date of this AD, for any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or EASA; or Airbus's EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* Except as required by paragraph (k) of this AD, if any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(m) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2016–0053, dated March 14, 2016, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–8185.

(2) For service information identified in this AD, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com*. You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on July 26, 2016.

Victor Wicklund,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–18492 Filed 8–4–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–3143; Directorate Identifier 2015–NM–047–AD]

RIN 2120–AA64

Airworthiness Directives; Empresa Brasileira de Aeronautica S.A. (Embraer) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Supplemental notice of proposed rulemaking (NPRM); reopening of comment period.

SUMMARY: We are revising an earlier proposed airworthiness directive (AD) for certain Empresa Brasileira de Aeronautica S.A. (Embraer) Model EMB–135 airplanes and Model EMB–145, –145ER, –145MR, –145LR, –145MP, and –145EP airplanes. The NPRM proposed to require a detailed inspection for chafing on the electrical harness of each electrical fuel pump in the fuel tanks, replacement of the affected electrical fuel pump with a new or serviceable pump if necessary, and installation of clamps on the fuel pump electrical harnesses. The NPRM was prompted by a report of chafing found between the fuel pump electrical harness and the fuel pump tubing during scheduled maintenance. This action revises the NPRM by expanding the proposed applicability and revising the compliance time for the detailed inspection. We are proposing this supplemental NPRM (SNPRM) to detect and correct chafing of the fuel pump harnesses with other parts inside the fuel tank, which could present a potential ignition source that could result in a fire or fuel tank explosion. Since certain actions impose an additional burden over those proposed in the NPRM, we are reopening the comment period to allow the public the chance to comment on these proposed changes.

DATES: We must receive comments on this SNPRM by September 19, 2016.

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

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

For service information identified in this SNPRM, contact Empresa Brasileira de Aeronautica S.A. (Embraer), Technical Publications Section (PC 060), Av. Brigadeiro Faria Lima, 2170—Putim—12227–901 São Jose dos Campos—SP—Brasil; telephone +55 12 3927–5852 or +55 12 3309–0732; fax +55 12 3927–7546; email *distrib@embraer.com.br;* Internet *http://www.flyembraer.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–3143; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Todd Thompson, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1175; fax 425–227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2015–3143; Directorate Identifier 2015–NM–047–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Empresa Brasileira de Aeronautica S.A. (Embraer) Model EMB–135 airplanes and Model EMB–145, –145ER, –145MR, –145LR, –145MP, and –145EP airplanes. The NPRM published in the **Federal Register** on August 21, 2015 (80 FR 50812) (''the NPRM'').

Actions Since Previous NPRM was Issued

Since we issued the NPRM, we have determined that certain airplanes were inadvertently omitted from the applicability, and the compliance time for the detailed inspection required by paragraph (h)(1) of this AD must be revised to ''within 5,000 flight hours or 24 months after the effective date of this AD, whichever occurs first.''

The Agência Nacional de Aviação Civil (ANAC), which is the aviation authority for Brazil, has issued Brazilian Airworthiness Directive 2015–03–01, effective March 23, 2015 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition on certain Empresa Brasileira de Aeronautica S.A. (Embraer) Model EMB–135 airplanes and Model EMB–145, –145ER, –145MR, –145LR, –145MP, and –145EP airplanes. The MCAI states:

> Chafing between the fuel pump electrical harness and fuel pump tubing was detected during scheduled maintenance. We are issuing this [Brazilian] AD to protect the fuel pump harnesses against chafing with other parts inside the fuel tank, which could present a potential ignition source that could result in a fire or fuel tank explosion.

The required actions include a detailed inspection for chafing on the electrical harness of each electrical fuel pump in the fuel tanks, replacement of the affected electrical fuel pump with a new or serviceable pump if necessary, and installation of clamps on the fuel pump electrical harnesses. You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–3143.

Related Service Information Under 1 CFR Part 51

Embraer has issued Service Bulletin 145–28–0030, Revision 01, dated October 22, 2010; and Service Bulletin 145LEG–28–0032, Revision 01, dated November 20, 2012. The service information describes procedures for a detailed inspection for chafing on the electrical harness of each electrical fuel pump in the fuel tanks, replacement of the affected electrical fuel pump with a new or serviceable pump if necessary, and installation of clamps on the fuel pump electrical harnesses. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Comments

We gave the public the opportunity to participate in developing this proposed AD. We considered the comments received.

Request To Clarify Airplane Applicability

ExpressJet Airlines stated that the airplane effectivity in Embraer Service Bulletin 145–28–0030, Revision 01, dated October 22, 2010, included Model EMB–145XR airplanes. ExpressJet Airlines stated that Model EMB–145XR airplanes are not included in paragraph (c), ''Applicability,'' of the proposed AD (in the NPRM) and asked if this is the intent of the NPRM or if the Model EMB–145XR airplanes should be included.

We agree with the commenter to clarify the applicability of this SNPRM. Although ANAC unintentionally omitted Model EMB–145XR airplanes from the applicability of its AD, the serial numbers corresponding to Model EMB–145XR airplanes are identified in the Embraer Service Bulletin 145–28–0030, Revision 01, dated October 22, 2010. We have added Model EMB–145XR airplanes to the applicability of this SNPRM. We have coordinated this issue with ANAC.

Request To Extend the Compliance Time

ExpressJet requested that we revise the compliance time for the detailed inspection in the proposed AD (in the NPRM) to ''within 5,000 flight hours or 24 months after the effective date of this AD, whichever occurs first,'' instead of ''within 2,500 flight hours or 24 months after the effective date of this AD, whichever occurs first.'' ExpressJet stated that this would allow the majority of the airplanes to be inspected during a C-check interval, which would be the most effective time to accomplish the task as the fuel tanks have to be drained and vented for the inspection to be performed. ExpressJet commented that these limits also line up with the current recommendations in the service information.

We agree with the commenter for the reasons stated previously. Data from Embraer confirms that increasing the flight hours another 2,500 flight hours is acceptable. We have changed this SNPRM accordingly.

FAA's Determination and Requirements of This SNPRM

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of these same type designs.

Certain changes described above expand the scope of the NPRM. As a result, we have determined that it is necessary to reopen the comment period to provide additional opportunity for the public to comment on this SNPRM.

Costs of Compliance

We estimate that this SNPRM affects 731 airplanes of U.S. registry.

We estimate that it would take about 11 work-hours per product to comply with the new basic requirements of this SNPRM. The average labor rate is $85 per work-hour. Required parts would cost about $0 per product. Based on these figures, we estimate the cost of this SNPRM on U.S. operators to be $683,485, or $935 per product.

In addition, we estimate that any necessary follow-on actions would take about 6 work-hours and would require parts costing $11,242, for a cost of $11,752 per product. We have no way of determining the number of aircraft that might need this action.

According to the manufacturer, some of the costs of this SNPRM may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all costs in our cost estimate.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

3. Will not affect intrastate aviation in Alaska; and

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Empresa Brasileira de Aeronautica S.A. (Embraer): Docket No. FAA–2015–3143; Directorate Identifier 2015–NM–047–AD.

(a) Comments Due Date

We must receive comments by September 19, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the airplanes specified in paragraphs (c)(1) and (c)(2) of this AD.

(1) Empresa Brasileira de Aeronautica S.A. (Embraer) Model EMB–135ER, –135KE, –135KL, and –135LR airplanes; and Model EMB–145, –145ER, –145MR, –145LR, –145MP, –145EP, and –145XR airplanes, certificated in any category, as identified in Embraer Service Bulletin 145–28–0030, Revision 01, dated October 22, 2010.

(2) Empresa Brasileira de Aeronautica S.A. (Embraer) Model EMB–135BJ airplanes,

certificated in any category, as identified in Embraer Service Bulletin 145LEG–28–0032, Revision 01, dated November 20, 2012.

(d) Subject

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

(e) Reason

This AD was prompted by a report of chafing found between the fuel pump electrical harness and the fuel pump tubing during scheduled maintenance. We are issuing this AD to detect and correct chafing of the fuel pump harnesses with other parts inside the fuel tank, which could present a potential ignition source that could result in a fire or fuel tank explosion.

(f) Compliance

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

(g) Detailed Inspection and Corrective Action

Do the actions specified in paragraphs (g)(1) and (g)(2) of this AD at the applicable times specified in paragraph (h)(1) or (h)(2) of this AD.

(1) Do a detailed inspection for chafing on the electrical harness of each electrical fuel pump in the fuel tanks, in accordance with the Accomplishment Instructions of Embraer Service Bulletin 145–28–0030, Revision 01, dated October 22, 2010 (for Model EMB–135ER, –135KE, –135KL, and –135LR airplanes; and Model EMB–145, –145ER, –145MR, –145LR, –145MP, –145EP, and –145XR airplanes); or Embraer Service Bulletin 145LEG–28–0032, Revision 01, dated November 20, 2012 (for Model EMB–135BJ airplanes). If any chafing is found, before further flight, replace the affected electrical fuel pump with a new or serviceable pump having the same part number, in accordance with the Accomplishment Instructions of Embraer Service Bulletin 145–28–0030, Revision 01, dated October 22, 2010; or Embraer Service Bulletin 145LEG–28–0032, Revision 01, dated November 20, 2012; as applicable.

(2) Install clamps on the fuel pump electrical harnesses, in accordance with the Accomplishment Instructions of Embraer Service Bulletin 145–28–0030, Revision 01, dated October 22, 2010 (for Model EMB–135ER, –135KE, –135KL, and –135LR airplanes; and Model EMB–145, –145ER, –145MR, –145LR, –145MP, –145EP, and –145XR airplanes); or Embraer Service Bulletin 145LEG–28–0032, Revision 01, dated November 20, 2012 (for Model EMB–135BJ airplanes).

(h) Compliance Times

(1) For Model EMB–135ER, –135KE, –135KL, and –135LR airplanes; and Model EMB–145, –145ER, –145MR, –145LR, –145MP, –145EP, and –145XR airplanes: Do the actions specified in paragraph (g) of this AD within 5,000 flight hours or 24 months after the effective date of this AD, whichever occurs first.

(2) For Model EMB–135BJ airplanes: Do the actions specified in paragraph (g) of this AD within 4,800 flight hours or 48 months after the effective date of this AD, whichever occurs first.

(i) Credit for Previous Actions

This paragraph provides credit for actions required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Embraer Service Bulletin 145–28–0030, dated September 1, 2010 (for Model EMB–135ER, –135KE, –135KL, and –135LR airplanes; and Model EMB–145, –145ER, –145MR, –145LR, –145MP, –145EP, and –145XR airplanes); or Embraer Service Bulletin 145LEG–28–0032, dated September 15, 2011 (for Model EMB–135BJ airplanes), as applicable. This service information is not incorporated by reference in this AD.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) Alternative Methods of Compliance (AMOCs): The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Todd Thompson, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1175; fax 425–227–1149. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the Agência Nacional de Aviação Civil (ANAC); or ANAC's authorized Designee. If approved by the ANAC Designee, the approval must include the Designee's authorized signature.

(k) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) Brazilian Airworthiness Directive 2015–03–01, effective March 23, 2015, for related information. This MCAI may be found in the AD docket on the Internet by searching for and locating Docket No. FAA–2015–3143.

(2) For service information identified in this AD, contact Empresa Brasileira de Aeronautica S.A. (Embraer), Technical Publications Section (PC 060), Av. Brigadeiro Faria Lima, 2170—Putim—12227–901 São Jose dos Campos—SP—Brasil; telephone +55 12 3927–5852 or +55 12 3309–0732; fax +55 12 3927–7546; email *distrib@embraer.com.br;* Internet *http://www.flyembraer.com.* You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on July 25, 2016.

Victor Wicklund,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–18500 Filed 8–4–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–8184; Directorate Identifier 2016–NM–036–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all Airbus Model A300 series airplanes; and Airbus Model A300 B4–600, B4–600R, and F4–600R series airplanes, and Model A300 C4–605R Variant F airplanes (collectively called Model A300–600 series airplanes). This proposed AD was prompted by reports of cracks in certain pins in the main landing gear (MLG). This proposed AD would require repetitive detailed visual inspections of the pins for cracks, and replacing the MLG leg if necessary. We are proposing this AD to detect and correct cracking of certain pins in the MLG, which could result in a MLG collapse, and consequent damage to the airplane and injury to the airplane occupants.

DATES: We must receive comments on this proposed AD by September 19, 2016.

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

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

p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Airbus SAS, Airworthiness Office—EAW, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.* You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–8184; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone: 425–227–2125; fax: 425–227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2016–8184; Directorate Identifier 2016–NM–036–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2016–0058, dated March 21, 2016, (referred to after this as ''the MCAI''), to correct an unsafe condition for all Airbus Model A300 series airplanes; and Airbus Model A300 B4–600, B4–600R, and F4–600R series airplanes, and Model A300 C4–605R Variant F airplanes (collectively called Model A300–600 series airplanes). The MCAI states:

> Two cases were reported of finding a cracked main landing gear (MLG) hinge arm/barrel pin, one was discovered in service during a maintenance task and the other one was identified during MLG overhaul.
>
> This condition, if not detected and corrected, could lead to MLG collapse, resulting in damage to the aeroplane and potential injury to occupants.
>
> To address this potential unsafe condition, and awaiting a final fix establishment, Airbus issued Alert Operators Transmission (AOT) 32W008–16 to provide instructions for detailed visual inspections (DET) to detect through cracks.
>
> For the reasons described above, this [EASA] AD requires repetitive DET of the MLG hinge arm/barrel pin and, depending on findings, replacement of the affected MLG leg.

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–8184.

Related Service Information Under 1 CFR Part 51

We reviewed Airbus Alert Operators Transmission (AOT) 32W008–16, dated February 25, 2016. This service information describes detailed visual inspection and replacement procedures for the MLG hinge arm and barrel pin. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of these same type designs.

Costs of Compliance

We estimate that this proposed AD affects 128 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Detailed Visual Inspection	1 work-hour × $85 per hour = $85 per inspection cycle	0	$85	$10,880 per inspection cycle.
Reporting	1 work-hour × $85 per hour	0	85	$10,880.

We estimate the following costs to do any necessary replacement that would be required based on the results of the proposed inspection. We have no way of determining the number of airplanes that might need this replacement.

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Remove and Replace MLG Leg	20 work-hours × $85 per hour = $1,700	$3,400,000	$3,401,700

Paperwork Reduction Act

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB control number. The control number for the collection of information required by this proposed AD is 2120–0056. The paperwork cost associated with this proposed AD has been detailed in the Costs of Compliance section of this document and includes time for reviewing instructions, as well as completing and reviewing the collection of information. Therefore, all reporting associated with this proposed AD is mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at 800 Independence Ave. SW., Washington, DC 20591, ATTN: Information Collection Clearance Officer, AES–200.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

3. Will not affect intrastate aviation in Alaska; and

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Airbus: Docket No. FAA–2016–8184; Directorate Identifier 2016–NM–036–AD.

(a) Comments Due Date

We must receive comments by September 9, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus airplanes identified in paragraphs (c)(1) through (c)(5) of this AD, certificated in any category, all manufacturer serial numbers.

(1) Model A300 B2–1A, B2–1C, B2K–3C, B2–203, B4–2C, B4–103, and B4–203 airplanes.

(2) Model A300 B4–601, B4–603, B4–620, and B4–622 airplanes.

(3) Model A300 B4–605R and B4–622R airplanes.

(4) Model A300 F4–605R and F4–622R airplanes.

(5) Model A300 C4–605R Variant F airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 32, Landing Gear.

(e) Reason

This AD was prompted by reports of cracks in certain pins in the main landing gear (MLG). We are issuing this AD to detect and correct cracking of certain pins in the MLG, which could result in a MLG collapse, and consequent damage to the airplane and injury to the airplane occupants.

(f) Compliance

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

(g) Repetitive Detailed Visual Inspections

Within the compliance time specified in paragraphs (g)(1) and (g)(2) of this AD, whichever occurs later, and thereafter at intervals not to exceed 100 flight cycles, accomplish a detailed visual inspection of the internal diameter of each affected MLG hinge arm/barrel pin, in accordance with the instructions of Airbus Alert Operators Transmission (AOT) A32W008–16, dated February 25, 2016. The affected MLG hinge arm/barrel pins are those with part number C66441–(x) and part number C65543–(x), where the x represents a variable number.

(1) Within 30 months since the pin's first flight on an airplane, or since the pin's first flight on an airplane after overhaul, as applicable.

(2) Within 30 days after the effective date of this AD.

(h) Corrective Action for Detailed Visual Inspection

If any crack is found during any inspection required by paragraph (g) of this AD, before further flight, replace the MLG leg with a serviceable unit, in accordance with the instructions of Airbus AOT A32W008–16, dated February 25, 2016. Replacement of a MLG leg does not constitute terminating action for the repetitive inspections required by paragraph (g) of this AD.

(i) Reporting Requirement

At the applicable time specified in paragraph (i)(1) or (i)(2) of this AD, report the results of the inspections required by paragraph (g) of this AD to Airbus in accordance with the instructions of Airbus AOT A32W008–16, dated February 25, 2016.

(1) If the inspection was done on or after the effective date of this AD: Submit the report within 30 days after the inspection.

(2) If the inspection was done before the effective date of this AD: Submit the report within 30 days after the effective date of this AD.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) Alternative Methods of Compliance (AMOCs): The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone: 425–227–2125; fax: 425–227–1149. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or

lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) Contacting the Manufacturer: For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Reporting Requirements:* A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES–200.

(k) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2016–0058, dated March 21, 2016, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–8184.

(2) For service information identified in this AD, contact Airbus SAS, Airworthiness Office—EAW, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.* You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on July 26, 2016.

Victor Wicklund,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–18486 Filed 8–4–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–8183; Directorate Identifier 2015–NM–083–AD]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to supersede Airworthiness Directive (AD) 2012–08–11 for certain Bombardier, Inc. Model DHC–8–400 series airplanes. AD 2012–08–11 currently requires repetitive detailed inspections for defects and damage of the retract port flexible hoses on the left and right Main Landing Gear (MLG) retraction actuator, and replacement of the flexible hoses if necessary. Since we issued AD 2012–08–11, we determined that the orientation of the retraction actuator ports must be revised to address the identified unsafe condition. This proposed AD would continue to require the actions required by AD 2012–08–11, and would require reorientation of the retraction actuator of the MLG, which would terminate the repetitive inspections. This proposed AD would also remove airplanes from the applicability. We are proposing this AD to prevent hydraulic fluid leakage in the event of a damaged retract port flexible hose failure; this condition could lead to an undamped extension of the MLG and could result in MLG structural failure, leading to an unsafe, asymmetric landing configuration.

DATES: We must receive comments on this proposed AD by September 19, 2016.

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

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

- For Bombardier service information identified in this NPRM, contact Bombardier, Inc., Q-Series Technical Help Desk, 123 Garratt Boulevard, Toronto, Ontario M3K 1Y5, Canada; telephone 416–375–4000; fax 416–375–4539; email *thd.qseries@aero.bombardier.com;* Internet *http://www.bombardier.com.* For Goodrich service information identified in this NPRM, contact Goodrich Corporation, Landing Gear, 1400 South Service Road, West Oakville, ON, Canada L6L 5Y7; telephone +1–877–808–7575; fax: +1–860–660–0372; Internet: *https://techpubs.goodrich.com/ContactUs.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–8183; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Cesar Gomez, Mechanical Systems Engineer, Airframe and Mechanical Systems Branch, ANE–171, FAA, New York Aircraft Certification Office (ACO), 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7318; fax 516–794–5531.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2016–8183; Directorate Identifier 2015–NM–083–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any

personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

On April 11, 2012, we issued AD 2012–08–11, Amendment 39–17028 (77 FR 24351, April 24, 2012) (''AD 2012–08–11''). AD 2012–08–11 requires actions intended to address an unsafe condition on certain Bombardier, Inc. Model DHC–8–400 series airplanes.

Since we issued AD 2012–08–11, we determined that the left and right MLG retraction actuator ports must be reoriented and the retract port flexible hoses replaced with hydraulic tube assemblies to address the identified unsafe condition. Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian Airworthiness Directive CF–2011–14R1, dated May 21, 2015 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Bombardier, Inc. Model DHC–8–400, –401, and –402 airplanes. The MCAI states:

> Testing has shown that in the event of a main landing gear (MLG) retraction actuator retract port flexible hose failure, in-flight vibrations may cause excessive hydraulic fluid leakage. This could potentially lead to an undamped extension of the MLG, which may result in MLG structural failure, leading to an unsafe asymmetric landing configuration.
>
> The original issue of this [Canadian] AD mandated the [detailed] inspection [for defects and damage] of the retract port flexible hose and its replacement [installing a new retract port flexible hose], when required, to prevent damage to the MLG caused by undamped gear extensions.
>
> Revision 1 of this [Canadian] AD mandates the reorientation of the MLG Retraction Actuator to prevent hydraulic fluid leakage in the event of a damaged retract port flexible hose.

This proposed AD also would remove certain airplanes from the applicability of AD 2012–08–11. Airplanes having serial number 4425 and on were modified in production and therefore the identified unsafe condition does not apply to these airplanes. You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–8183.

Related Service Information Under 1 CFR Part 51

Bombardier, Inc. has issued Bombardier Service Bulletin 84–32–105, Revision A, dated April 24, 2015; and Service Bulletin 84–32–106, Revision A, dated April 24, 2015. The service information describes procedures to reorient the retraction actuator, which includes modifying and reorienting the retraction actuator assembly, and installing reconfigured hydraulic tube assemblies.

Goodrich Aerospace Canada Ltd. has issued Service Bulletin 46550–32–99 R2, dated February 19, 2015; and Service Bulletin 46455–32–100 R1, dated March 20, 2013. This service information describes procedures for reworking and re-identifying the retraction actuator hydraulic tube assembly and dressed yoke assembly, and reworking the retraction actuators.

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

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

Costs of Compliance

We estimate that this proposed AD affects 82 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection [retained action from AD 2012–08–11].	1 work-hour × $85 per hour = $85 per inspection cycle.	$0	$85 per inspection cycle	$6,970 per inspection cycle.
Reorient MLG retraction actuators (new proposed action).	4 work-hours × $85 per hour = $340.	0	340	$27,880.

We estimate the following costs to do any necessary replacements that would be required based on the results of the proposed inspection. We have no way of determining the number of aircraft that might need this replacement:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replace the retract port flexible hose (retained action from AD 2012–08–11).	4 work-hours × $85 per hour = $340	$713	$1,053

According to the manufacturer, some of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all costs in our cost estimate.

Authority for This Rulemaking

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

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in

air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

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

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

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

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

3. Will not affect intrastate aviation in Alaska; and

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2012–08–11, Amendment 39–17028 (77 FR 24351, April 24, 2012), and adding the following new AD:

Bombardier, Inc.: Docket No. FAA–2016–8183; Directorate Identifier 2015–NM–083–AD.

(a) Comments Due Date

We must receive comments by September 19, 2016.

(b) Affected ADs

This AD replaces AD 2012–08–11, Amendment 39–17028 (77 FR 24351, April 24, 2012) (''AD 2012–08–11'').

(c) Applicability

This AD applies to Bombardier, Inc. Model DHC–400, –401, and –402 airplanes, certificated in any category, serial numbers 4001 through 4424 inclusive.

(d) Subject

Air Transport Association (ATA) of America Code 32, Landing gear.

(e) Reason

This AD was prompted by test reports that showed that failure of a retract port flexible hose of a main landing gear (MLG) retraction actuator could cause excessive hydraulic fluid leakage. We are issuing this AD to prevent hydraulic fluid leakage in the event of a damaged retract port flexible hose failure; this condition could lead to an undamped extension of the MLG and could result in MLG structural failure, leading to an unsafe asymmetric landing configuration.

(f) Compliance

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

(g) Retained Repetitive Inspections and Follow-On Action, With New Reference

This paragraph restates the requirements of paragraph (g) of AD 2012–08–11, with new reference to terminating action. Within 600 flight hours after May 29, 2012 (the effective date of AD 2012–08–11), do a detailed inspection for defects and damage of the retract port flexible hose of the left and right MLG retraction actuators, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 84–32–89, dated March 22, 2011. Repeat the inspection thereafter at intervals not to exceed 600 flight hours. If any defect or damage is found, before further flight, replace the retract port flexible hose with a new or serviceable retract port flexible hose, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 84–32–89, dated March 22, 2011. Doing the actions required by paragraph (h) of this AD terminates the inspections required by this paragraph.

(h) New Requirement of This AD: Reorient MLG Retraction Actuators

Within 6,000 flight hours or 36 months, whichever occurs first after the effective date of this AD: Reorient the MLG retraction actuator by incorporating Bombardier ModSums 4–902418 and 4–902327, in accordance with the Accomplishment Instructions of the applicable service information specified in paragraphs (h)(1) and (h)(2) of this AD. Accomplishment of the actions required by this paragraph terminates the actions required by paragraph (g) of this AD.

(1) Bombardier Service Bulletin 84–32–105, Revision A, dated April 24, 2015, including Goodrich Service Bulletin 46550–32–99 R2, dated February 19, 2015.

(2) Bombardier Service Bulletin 84–32–106, Revision A, dated April 24, 2015, including Goodrich Service Bulletin 46455–32–100 R1, dated March 20, 2013.

(i) Credit for Previous Actions

This paragraph provides credit for actions required by paragraph (h) of this AD, if those actions were performed before the effective date of this AD using the service information identified in paragraphs (i)(1)and (i)(2) of this AD.

(1) Bombardier Service Bulletin 84–32–105, dated September 28, 2012.

(2) Bombardier Service Bulletin 84–32–106, dated September 10, 2012.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York Aircraft Certification Office (ACO), ANE–170, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the New York ACO, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

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

(ii) AMOCs approved previously for AD 2012–08–11 are approved as AMOCs for the corresponding provisions of this AD.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, New York ACO, ANE–170, FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier, Inc.'s TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(k) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) Canadian Airworthiness Directive CF–2011–24R1, dated May 21, 2015, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–8183.

(2) For Bombardier service information identified in this AD, contact Bombardier, Inc., Q-Series Technical Help Desk, 123 Garratt Boulevard, Toronto, Ontario M3K 1Y5, Canada; telephone 416–375–4000; fax 416–375–4539; email *thd.qseries@aero.bombardier.com;* Internet *http://www.bombardier.com.* For Goodrich service information identified in this AD, contact Goodrich Corporation, Landing Gear, 1400

South Service Road, West Oakville, ON, Canada L6L 5Y7; telephone +1–877–808–7575; fax: +1–860–660–0372; Internet: *https://techpubs.goodrich.com/ContactUs.* You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on July 25, 2016.

Victor Wicklund,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–18482 Filed 8–4–16; 8:45 am]

BILLING CODE 4910–13–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Chapter II

Children's Sleepwear Seminar

AGENCY: Consumer Product Safety Commission.

ACTION: Announcement of meeting.

SUMMARY: The Consumer Product Safety Commission (CPSC, Commission, or we) staff is holding a 1-day Flammable Fabrics Act (FFA) Children's Sleepwear Seminar (the Seminar). The Seminar will focus on testing, certification, and other compliance guidance relating to mandatory FFA standards and requirements for children's sleepwear. The Seminar will be held on October 20, 2016, at the CPSC offices in Bethesda Towers, Bethesda, MD. We invite interested parties to participate in or attend the Seminar.

DATES: The Seminar will be held on October 20, 2016 at 8:30 a.m. Individuals interested in serving on panels or presenting information at the Seminar should register by August 26, 2016; all other individuals who wish to attend in person should register as soon as possible because available spots may fill up.

ADDRESSES: The Seminar will be held in the 4th floor Hearing Room at the CPSC offices in Bethesda Towers, 4330 East West Highway, Bethesda, MD 20814. Persons interested in serving on a panel, presenting information, or attending the Seminar should register online at: *http://www.cpsc.gov/meetingsignup.html* (click on the link titled, ''Children's Sleepwear Seminar''). Some sessions of the Seminar may be available through a webcast, but viewers will not be able to interact with the panels and presenters.

FOR FURTHER INFORMATION CONTACT: Carolyn Carlin, Textile Flammability Compliance Officer, Office of Compliance, 4330 East West Highway, Room 610–33, Bethesda, MD 20814. Telephone: 301–504–7889, Email: *ccarlin@cpsc.gov;* or, Paige Witzen, Textile Technologist, Division of Engineering; Directorate for Laboratory Sciences, 5 Research Place, Rockville, MD 20850, Room 117–03. Telephone: 301–987–2029, Email: *pwitzen@cpsc.gov.*

SUPPLEMENTARY INFORMATION: The FFA, 15 U.S.C. 1191–1204, regulates the manufacture of highly flammable clothing, including children's sleepwear. The FFA standards governing the flammability of children's sleepwear are found at 16 CFR parts 1615 and 1616. These regulations protect children from burns by requiring that children's sleepwear must be flame resistant, as demonstrated through prescribed flammability tests, and self-extinguish if the item catches fire.

The goal of the Seminar is to bring together CPSC staff and stakeholders (manufacturers, importers, retailers, suppliers, legal counsel, testing laboratories and other interested parties) to discuss testing, certification, and other compliance guidance relating to mandatory FFA standards and requirements for children's sleepwear products. The Seminar will include presentations by CPSC staff and industry representatives, as well as a panel discussion among manufacturers, importers, retailers, suppliers, legal counsel, testing laboratories, and other parties involved in the children's sleepwear industry. Topics covered during the Seminar may include:

- Issues and questions about testing and compliance for children's sleepwear products regulated under the FFA.
- challenges faced in implementing testing, certification, and quality control programs to ensure that regulated products are accurately identified, tested according to applicable children's sleepwear testing methods, and certified as conforming to the applicable children's sleepwear standard.

This Seminar will focus exclusively on issues related to current CPSC requirements for children's sleepwear.

Staff intends to organize and develop panels to address these topics, informed by responses to this announcement. In addition, participants may present individually. If you would like to be a presenter or panel member, you should register by August 26, 2016 (see the **ADDRESSES** portion of this document for the Web site link and instruction on how to register). Please submit a brief summary of the topic on which you would like to make a presentation or speak as a panel participant, and your area of expertise. Although every effort will be made to accommodate all persons who wish to be a presenter or panelist, CPSC staff will determine the final agenda. To assist in making the final panelist selections, CPSC staff may request that potential panelists submit presentations in addition to the initial summary. We will notify those who are selected as presenters and panelists by September 2, 2016. If you wish to attend and participate in the Seminar, but do not wish to be a presenter or panelist, you should also register as soon as possible because the CPSC Hearing Room has a limited occupancy. Please identify your affiliation with your registration.

Dated: August 2, 2016.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2016–18597 Filed 8–4–16; 8:45 am]

BILLING CODE 6355–01–P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 3

RIN 3038–AE46

Exemption From Registration for Certain Foreign Persons

AGENCY: Commodity Futures Trading Commission.

ACTION: Proposed rule.

SUMMARY: The Commodity Futures Trading Commission (''Commission'') is proposing to amend one of its regulations. The proposed amendment would amend the conditions under which persons located outside the United States (''U.S.'') acting in the capacity of a futures commission merchant (''FCM''), an introducing broker (''IB''), commodity trading advisor (''CTA''), or commodity pool operator (''CPO'') in connection with commodity interest transactions solely on behalf of persons located outside the U.S., or on behalf of certain international financial institutions, would qualify for an exemption from registration with the Commission.

DATES: Comments must be received on or before September 6, 2016.

ADDRESSES: You may submit comments, identified by RIN number 3038–AE46, by any of the following methods:

- *CFTC Web site: http://comments.cftc.gov.* Follow the instructions for submitting comments through the Comments Online process on the Web site.

• *Mail:* Send to Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581.

• *Hand Delivery/Courier:* Same as Mail, above.

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Please submit your comments using only one of these methods.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *http://www.cftc.gov.* You should submit only information that you wish to make publicly available. If you wish the Commission to consider information that may be exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted according to the procedures established in § 145.9 of the Commission's regulations.[1]

The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from *www.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the rulemaking will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the Freedom of Information Act.

FOR FURTHER INFORMATION CONTACT: Frank Fisanich, Chief Counsel, or Andrew Chapin, Associate Chief Counsel, at (202) 418–5430, Division of Swap Dealer and Intermediary Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581. Electronic mail: *ffisanich@cftc.gov* or *achapin@cftc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Registration and Exemption From Registration of Intermediaries

Part 3 of the Commission's regulations governs the registration of intermediaries engaged in the offer and sale of, and providing advice concerning, all commodity interest transactions, including those futures, options on futures, and swaps traded on U.S. trading facilities, including both designated contract markets (''DCMs'') and swap execution facilities (''SEFs''). Commission Regulation 3.10 sets forth the manner in which intermediaries, including FCMs, IBs, CPOs, and CTAs, must apply for registration with the Commission. Currently, § 3.10(c) provides an exemption from registration, subject to certain conditions, for certain persons located outside the U.S. (such intermediaries are referred to herein as ''Foreign Intermediaries'') acting as intermediaries with respect to persons also located outside the U.S., even though such transactions may be executed bilaterally, or on or subject to the rules of a DCM or SEF.

As a result of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010,[2] swaps [3] became subject to regulation under the Commodity Exchange Act (''CEA''). Accordingly, the Commission promulgated conforming amendments to its regulations to include swaps in the definition of ''commodity interest'' in Regulation 1.3(yy). Thus, acting as an intermediary for persons located within the U.S. in connection with swaps, whether executed bilaterally, or on or subject to the rules of a DCM or SEF, may require Foreign Intermediaries to register with the Commission. On the other hand, certain Foreign Intermediaries acting only for persons located outside the U.S. in connection with swaps may be exempt from registration with the Commission under § 3.10(c).[4]

With respect to activities involving commodity interest transactions (which, as explained above, includes swaps) executed bilaterally, or made on or subject to the rules of any DCM or SEF, existing Regulation 3.10(c)(3)(i) provides an exemption from registration as a CPO, CTA, or IB if a person [5] and the transaction meet the following conditions:

1. The person is located outside the U.S.;

2. The person acts only on behalf of persons located outside the U.S.; and

3. The commodity interest transaction is submitted for clearing through a registered FCM.

Regulation 3.10(c)(2)(i) provides a similar exemption from registration for any Foreign Intermediary acting as an FCM.

In 2015 and 2016, the Commission's Division of Swap Dealer and Intermediary Oversight (''Division'') issued staff no-action relief that permitted Foreign Intermediaries to rely on the exemption from registration in § 3.10(c)(3)(i) if their activities involve swaps that are not subject to a Commission clearing requirement.[6] The Division noted that the CEA and Commission regulations do not require that all swaps be cleared and some swaps are not yet accepted for clearing by any Commission-registered derivatives clearing organization (''DCO''). Thus, the Division stated that it did not believe the Commission intended that Foreign Intermediaries acting only for persons located outside the U.S. be required to register if the intermediaries merely acted for such persons in connection with transactions not required to be cleared by the CEA or Commission regulations.

Similarly, pursuant to additional no-action relief provided in 2015, the Division also provided relief from registration as an IB or CTA for intermediaries acting for International Financial Institutions (''IFIs'').[7] While such institutions may have headquarters or another significant presence in the U.S.,[8] the Division recognized that the unique attributes and multinational status of these institutions did not warrant treating them as domestic persons.

[1] 17 CFR 145.9. Commission regulations referred to herein are found at 17 CFR Chapter I.

[2] Pub. L. 111–203, 124 Stat. 137 (2010).

[3] Swaps are defined in Section 1a(47) of the CEA and Commission Regulation § 1.3(xxx).

[4] *See* Adaptation of Regulations To Incorporate Swaps, 77 FR 66288, 66295 (Nov. 2, 2012) (discussing the modification of the term, ''commodity interest,'' to include swaps); Registration of Intermediaries, 77 FR 51898, 51899 (Aug. 28, 2012) (discussing the conforming amendments to Regulation 3.10(c)).

[5] Under Section 1a(38) of the CEA and Regulation 1.3(u), the term ''person'' imports the plural and singular, and includes individuals, associations, partnerships, corporations and trusts. 7 U.S.C. 1a(38); 17 CFR 1.3(u).

[6] *See* CFTC Letters 15–37 (June 4, 2015) and 16–08 (Feb. 12, 2016).

[7] IFIs are those institutions defined in the Commission's previous rulemakings and staff no-action letters, *i.e.,* Int'l Monetary Fund, Int'l Bank for Reconstruction and Development, European Bank for Reconstruction and Development, Int'l Development Association, Int'l Finance Corp., Multilateral Investment Guarantee Agency, African Development Bank, African Development Fund, Asian Development Bank, Inter-American Development Bank, Bank for Economic Cooperation and Development in the Middle East and North Africa, Inter-American Investment Corp., Council of Europe Development Bank, Nordic Investment Bank, Caribbean Development Bank, European Investment Bank and European Investment Fund (Int'l Bank for Reconstruction and Development, Int'l Finance Corp. and Multilateral Investment Guarantee Agency are parts of the World Bank Group). *See, e.g.,* Further Definition of ''Swap Dealer,'' ''Security-Based Swap Dealer,'' ''Major Swap Participant,'' ''Major Security-Based Swap Participant,'' and ''Eligible Contract Participant,'' 77 FR 30596, 30692 n.1180 (May 23, 2012).

[8] *See* CFTC No-Action Letter 15–37 (June 4, 2015).

II. The Proposal

A. Proposal Rationale

Given the various execution venues and clearing requirements applicable to swaps,[9] the Commission now proposes to amend § 3.10(c)(2)(i) and (3)(i) in tandem to simplify the registration exemption that is available to Foreign Intermediaries. Specifically, the proposed amendments would permit a Foreign Intermediary to be eligible for an exemption from registration with the Commission if the Foreign Intermediary, in connection with a commodity interest transaction, only acts on behalf of (1) persons located outside the U.S., or (2) IFIs (as defined in the proposed rule amendments), without regard to whether such persons or institutions clear such commodity interest transaction.

The Commission notes at the outset that the exemptions from registration in § 3.10(c)(2) and (3) do not in themselves excuse any person (including any IFI) from compliance with any provision of the CEA or Commission regulations otherwise applicable to such persons, including, without limitation, any requirement that a resulting commodity interest transaction be cleared by a DCO registered or exempt from registration with the Commission. Commission Regulation 3.10 in its current form makes it a condition of the Foreign Intermediary's exemption that its foreign located customer's commodity interest transactions be cleared through a registered FCM. However, as explained above, not all commodity interest transactions are subject to a clearing requirement under the CEA or Commission regulations, and some are not available for clearing by any DCO registered with the Commission.

Thus, the Commission is proposing to amend the language of the exemptions by removing the clearing requirement because persons located outside the U.S. that are subject to any applicable clearing requirement for futures or swaps, or any other applicable provision of the CEA or Commission regulations, must comply with those requirements regardless of any registration exemption for a Foreign Intermediary.

The Commission has come to the view that the focus of the exemption should be the activity of the Foreign Intermediary, not its customer. Accordingly, the Commission believes that the proposed amendments are consistent with its longstanding policy to focus its customer protection activities upon domestic firms and upon firms soliciting or accepting orders from domestic participants. Where a Foreign Intermediary's customers are located outside the U.S., the Commission believes the jurisdiction where the customer is located has the preeminent interest in protecting such customers.

B. Proposed Amended Rule Text

Further to the foregoing, with respect to the amended rule text, the Commission is proposing to eliminate from § 3.10(c)(2)(i) and (3)(i) both the clearing requirement and references to DCMs and SEFs. The Commission is retaining the reference to the definition of ''foreign broker'' in paragraph (c)(2)(i) because ''foreign broker'' is not a Commission intermediary registration category (as are IB, CTA, and CPO) and the definition is necessary to make clear that a foreign broker is one who is ''engaged in soliciting or in accepting orders *only* from persons located outside the United States, its territories or possessions.'' This definitional reference also maintains symmetry with paragraph (c)(3)(i), which specifies that the exemption from registration applies to intermediary activity, as described in the IB, CTA, and CPO definitions, on behalf of IFIs or persons located outside the U.S., its territories, or possessions.

Finally, because the Commission is proposing to codify the registration relief in No-Action Letter 15–37 with respect to intermediary activities on behalf of IFIs, the Commission proposes to add a new § 3.10(c)(6) to define IFIs for the purposes of § 3.10 in order to provide legal clarity on the scope of the registration exemption.

The Commission requests comment on all aspects of this proposed rulemaking.

III. Related Matters

A. Regulatory Flexibility Act

The Regulatory Flexibility Act (''RFA'') requires Federal agencies, in promulgating regulations, to consider whether the rules they propose will have a significant economic impact on a substantial number of small entities and, if so, to provide a regulatory flexibility analysis regarding the economic impact on those entities. Each Federal agency is required to conduct an initial and final regulatory flexibility analysis for each rule of general applicability for which the agency issues a general notice of proposed rulemaking.[10]

The rule proposed by the Commission would affect only FCMs, IBs, CTAs, and CPOs. The Commission has previously determined that FCMs and CPOs are not small entities for purposes of the RFA. Therefore, the requirements of the RFA do not apply to those entities.[11] The Commission notes that the foreign persons affected by the proposed changes would be registered FCMs and CPOs if not for the exemption provided therein. Further, the Commission notes that the proposed rule would impose no new obligation, significant or otherwise, on any of the entities remaining entities.

With respect to CTAs and IBs, the Commission has found it appropriate to consider whether such registrants should be deemed small entities for purposes of the RFA on a case-by-case basis, in the context of the particular Commission regulation at issue.[12] As certain of these registrants may be small entities for purposes of the RFA, the Commission considered whether this rulemaking would have a significant economic impact on such registrants. This proposal would clarify in what circumstances certain foreign persons acting in the capacity of a FCM or an IB, CTA, or CPO would be exempt from registration, in connection with commodity interest transactions solely on behalf of persons located outside the U.S. This proposal is not expected to impose any new burdens on market participants. Rather, to the extent that this proposal provides an exemption to the intermediary registration requirement, the Commission believes it is reasonable to infer that the exemption would be less burdensome to such participant. The Commission does not, therefore, expect small entities to incur any additional costs as a result of this proposal. Therefore, the Commission has determined that the proposed rule will not create a significant economic impact on a substantial number of small entities. Accordingly, the Chairman, on behalf of the Commission, hereby certifies pursuant to 5 U.S.C. 605(b) that the proposed rule will not have a

[9] *E.g.,* A swap may be executed bilaterally and then performed bilaterally between those counterparties or could be submitted for clearing where each counterparty would then face the clearing house for performance; a swap could be executed on a SEF and then performed bilaterally between the counterparties or could be cleared; a swap could be executed on a DCM and cleared. Under Part 50 of the Commission's regulations, some swaps are required to cleared, but some swaps can be either performed bilaterally or voluntarily cleared if a clearing house accepts such swaps for clearing.

[10] 5 U.S.C. 601 *et seq.*

[11] *See* Policy Statement and Establishment of Definitions of ''Small Entities'' for Purposes of the Regulatory Flexibility Act, 47 FR 18618, 18620 (Apr. 30, 1982) (FCMs and CPOs).

[12] *See* 47 FR at 18620 (CTAs); and Introducing Brokers and Associated Persons of Introducing Brokers, Commodity Trading Advisors and Commodity Pool Operators; Registration and Other Regulatory Requirements, 48 FR 35248, 35276 (Aug. 3, 1983) (IBs).

significant impact on a substantial number of small entities.

B. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (''PRA'') imposes certain requirements on Federal agencies, including the Commission, in connection with their conducting or sponsoring any collection of information, as defined the PRA.[13] 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 control number. The proposed rules will not impose any new recordkeeping or information collection requirements, or other collections of information that require approval of the Office of Management and Budget (''OMB'') under the PRA.

The Commission invites the public and other interested parties to comment on any aspect of the reporting burdens. Pursuant to 44 U.S.C. 3506(c)(2)(B), the Commission generally solicits comments in order to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) evaluate the accuracy of the Commission's estimate of the burden of the proposed collection of information; (3) determine whether there are ways to enhance the quality, utility, and clarity of the information to be collected; and (4) mitigate the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology. The Commission specifically invites public comment on the accuracy of its estimate that no additional information collection requirements or changes to existing collection requirements would result from the rules proposed herein.

Comments may be submitted directly to the Office of Information and Regulatory Affairs, by fax at (202) 395–6566 or by email at *OIRAsubmissions@omb.eop.gov.* Please provide the Commission with a copy of submitted comments so that all comments can be summarized and addressed in the final rule preamble. Refer to the **ADDRESSES** section of this proposed rule for comment submission instructions to the Commission. A copy of the supporting statement for the collection of information discussed above may be obtained by visiting *http://reginfo.gov/.* OMB is required to make a decision concerning 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.

C. Cost-Benefit Analysis

Section 15(a) of the CEA requires the Commission to consider the costs and benefits of its actions before issuing new regulations under the Act.[14] By its terms, it does not require the Commission to quantify the costs and benefits of new rules or to determine whether the benefits of the proposed rules outweigh their costs; it requires the Commission to ''consider'' the cost and benefits of its actions. Section 15(A) of the CEA further specifies that the costs and benefits of the proposed rules shall be evaluated in light of five broad areas of market public concern: (1) Protection of market participants and the public; (2) efficiency, competitiveness and financial integrity of the futures markets; (3) price discovery; (4) sound risk management practices; and (5) other public interest considerations. The Commission may, in its discretion, give greater weight to any of the five enumerated areas of concern and may, in its discretion, determine that, notwithstanding its costs, a particular rule is necessary or appropriate to protect the public interest or to effectuate any of the provisions or to accomplish any of the purposes of the CEA.

The proposed regulation should foster: (1) The protection of market participants and the public by providing greater legal certainty to the commodity interest activities of persons located outside the U.S.; and (2) greater efficiency, competitiveness and financial integrity of financial markets; price discovery; and sound risk management practices by ensuring greater depth in swaps markets accessed by U.S. persons. The Commission invites public comment on its cost-benefit considerations.

List of Subjects in 17 CFR Part 3

Definitions, Consumer protection, Foreign futures, Foreign options, Registration requirements.

For the reasons set forth in the preamble, the Commodity Futures Trading Commission proposes to amend 17 CFR part 3 as follows:

PART 3—REGISTRATION

■ 1. The authority citation for part 3 continues to read as follows:

Authority: 5 U.S.C. 552, 552b; 7 U.S.C. 1a, 2, 6a, 6b, 6b–1, 6c, 6d, 6e, 6f, 6g, 6h, 6i, 6k, 6m, 6n, 6o, 6p, 6s, 8, 9, 9a, 12, 12a, 13b, 13c, 16a, 18, 19, 21, 23.

■ 2. Amend § 3.10 as follows:

■ a. Revise paragraphs (c)(2)(i) and (c)(3)(i); and

■ b. Add paragraph (c)(6).

The revisions and addition to read as follows:

§ 3.10 Registration of futures commission merchants, retail foreign exchange dealers, introducing brokers, commodity trading advisors, commodity pool operators, swap dealers, major swap participants and leverage transaction merchants.

* * * * *

(c) * * *

(2)(i) A person located outside the United States, its territories, or possessions (a ''foreign located person'') engaged in activity that meets the definition of a futures commission merchant in the Act and § 1.3(p) of this chapter is not required to register as a futures commission merchant if such activity is either solely that of a foreign broker as defined in § 1.3(xx) of this chapter or solely on behalf of international financial institutions.

* * * * *

(3)(i) A foreign located person engaged in activity that meets the definition of an introducing broker, commodity trading advisor, or commodity pool operator, as defined in the Act and in § 1.3(mm), (bb), and (nn) of this chapter, respectively, is not required to register as an introducing broker, commodity trading advisor, or commodity pool operator if such activity is either solely on behalf of foreign located persons or international financial institutions.

* * * * *

(6) For the purposes of this section, ''international financial institution'' means each of the following and any other international financial institution that the Commission may designate: Int'l Monetary Fund, Int'l Bank for Reconstruction and Development, European Bank for Reconstruction and Development, Int'l Development Association, Int'l Finance Corp., Multilateral Investment Guarantee Agency, African Development Bank, African Development Fund, Asian Development Bank, Inter-American Development Bank, Bank for Economic Cooperation and Development in the Middle East and North Africa, Inter-American Investment Corp., Council of Europe Development Bank, Nordic Investment Bank, Caribbean Development Bank, European

[13] 44 U.S.C. 3501 *et seq.*

[14] 7 U.S.C. 19(a).

Investment Bank and European Investment Fund.

* * * * *

Issued in Washington, DC, on July 27, 2016, by the Commission.

Christopher J. Kirkpatrick,

Secretary of the Commission.

Note: The following appendix will not appear in the Code of Federal Regulations.

Appendix to Amendment to Commission Regulation 3.10(c): Exemption From Registration for Certain Foreign Persons—Commission Voting Summary

On this matter, Chairman Massad and Commissioners Bowen and Giancarlo voted in the affirmative. No Commissioner voted in the negative.

[FR Doc. 2016–18210 Filed 8–4–16; 8:45 am]

BILLING CODE 6351–01–P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 4

RIN 3038–AE47

Commodity Pool Operator Annual Report

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Commodity Futures Trading Commission (Commission or CFTC) is proposing to amend certain of its regulations applicable to the Annual Report that each person registered or required to be registered as a commodity pool operator (CPO) must distribute for each commodity pool that it operates (Proposal). Specifically, the Proposal addresses the use of additional alternative generally accepted accounting principles, standards or practices, and the Annual Report audit requirement where the first fiscal year of a pool consists of a period of three months or less from the date of formation of the pool.

DATES: Comments must be received on or before September 6, 2016.

ADDRESSES: You may submit comments, identified by RIN 3038–AE47 and ''Commodity Pool Operator Annual Report,'' by any of the following methods:

- *CFTC Web site: http://comments.cftc.gov.* Follow the instructions for submitting comments through the Comments Online process on the Web site.
- *Mail:* Send to Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581.
- *Hand Delivery/Courier:* Same as Mail, above.
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Please submit your comments using only one of these methods.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *http://www.cftc.gov.* You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that may be exempt from disclosure under the Freedom of Information Act (FOIA), a petition for confidential treatment of the exempt information may be submitted according to the procedures established in Commission Regulation 145.9.[1]

The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from *www.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the rulemaking will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the FOIA.

FOR FURTHER INFORMATION CONTACT: Christopher W. Cummings, Special Counsel, 202–418–5445, *ccummings@cftc.gov* or Barbara S. Gold, Associate Director, 202–418–5441, *bgold@cftc.gov,* Division of Swap Dealer and Intermediary Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st NW., Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

I. Background

A. Part 4 of the Commission's Regulations

Part 4 of the Commission's regulations governs the operations and activities of CPOs.[2] It requires each CPO registered or required to be registered with the Commission: To deliver to each participant in its commodity pool a Disclosure Document for the pool containing specified information (Regulations 4.21, 4.24, 4.25 and 4.26); to distribute to each participant periodic unaudited Account Statements for the pool (Regulation 4.22(a)) and an audited Annual Report for the pool (Regulation 4.22(c)); and to make and keep specified books and records (Regulation 4.23). Additionally, Part 4 prohibits certain activities on the part of all CPOs (Regulations 4.20 and 4.41) and provides for various CPO definitional exclusions (Regulation 4.5), CPO registration exemptions (Regulation 4.13), and compliance exemptions from otherwise applicable CPO requirements (Regulations 4.7, 4.12(b), and 4.12(c)).[3]

Over the past years, and pursuant to authority delegated to it by Regulation 140.93, Commission staff has provided exemptive relief from specific Part 4 requirements on a case-by-case basis.[4] By this **Federal Register** release, the Commission is proposing to codify certain of these exemptions as applicable to the Annual Report.

B. Regulation 4.22: The Annual Report Requirement

Regulation 4.22 requires, in general, that each CPO registered or required to be registered with the Commission to distribute to each participant in each commodity pool it operates, and to submit to the National Futures Association (NFA),[5] an Annual Report for the pool within 90 calendar days after the end of the pool's fiscal year.[6]

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[1] 17 CFR 145.9 (2016). The Commission's regulations are found at 17 CFR Ch. I (2016). They are accessible through the Commission's Web site.

[2] Section 1a(11) of the Commodity Exchange Act (Act or CEA), 7 U.S.C. 1a(11) (2012), defines the term ''commodity pool operator'' and CEA Section 4m(1) generally requires each person who comes within the CPO definition to register as a CPO with the Commission. The Act is found at 7 U.S.C. *et seq.* (2012). It similarly is accessible through the Commission's Web site.

[3] Part 4 contains many similar provisions applicable to commodity trading advisors (CTAs). The Proposal does not pertain to CTAs, however, because CTAs do not operate commodity pools (CPOs do) and therefore there is no Annual Report requirement applicable to them.

[4] These were issued by the Commission's Division of Swap Dealer and Intermediary Oversight (''DSIO'') and its predecessors, the Division of Clearing and Intermediary Oversight and the Division of Trading and Markets.

Regulation 140.93 currently delegates to the Director of DSIO ''all functions reserved to the Commission'' in Regulation 4.12(a)—which provides that the Commission ''may exempt any person or any class or classes of persons from any provision of this Part 4 if it finds that the exemption is not contrary to the public interest and the purposes of the provisions from which the exemption is sought'' and, further, that the Commission ''may grant the exemption subject to such terms and conditions as it may find appropriate.''

[5] NFA is registered as a futures association in accordance with CEA Section 17. It is the only futures association registered as such.

[6] Regulation 4.22(c) further requires the CPO to submit to NFA certain key financial balances from the Annual Report.

The regulation: Specifies the financial statements and related information that the Annual Report must contain (Regulation 4.22(c)); requires that the financial statements must be presented and computed in accordance with generally accepted accounting principles consistently applied (U.S. GAAP) and that they must be audited by an independent public accountant (Regulation 4.22(d)); includes specific provisions applicable to the Statement of Operations (Regulation 4.22(e)); provides for an extension of an otherwise applicable distribution deadline (Regulation 4.22(f)); governs fiscal year election (Regulation 4.22(g)); mandates that the Annual Report be accompanied by a prescribed oath or affirmation of the CPO (Regulation 4.22(h)); and permits electronic distribution of the Annual Report to a participant if the participant consents to that method of distribution (Regulation 4.22(*i*)).

In connection with the adoption of the Annual Report requirement, the Commission explained that the purpose of the Annual Report is to provide pool participants ''with the information necessary to assess the overall trading performance and financial condition of the pool'' and that the purpose of the requirement that the Annual Report be audited is to ''promote greater accuracy in financial statements and provide an independent review of the pool's activities.'' [7] The Commission believes that the amendments it is proposing today to Regulation 4.22 are consistent with these purposes.

II. The Proposal

A. Proposed Amendment to Regulation 4.22(d)(2): Use of Additional Alternative Generally Accepted Accounting Principles, Practices or Standards

Regulation 4.22(d) specifies how the financial statements in the Annual Report must be presented and computed. Currently, paragraph (d)(1) of the regulation requires that these financial statements must be presented and computed in accordance with generally accepted accounting principles consistently applied, and paragraph (d)(2) of the regulation makes available an exception to this requirement by permitting the use of International Financial Reporting Standards (IFRS) where certain criteria are met. A CPO seeking to avail itself of Regulation 4.22(d)(2) must claim the relief by filing a signed notice with NFA representing that: (1) The pool is organized under the laws of a foreign jurisdiction; (2) the Annual Report will include a schedule of investments (condensed unless a full schedule is required under IFRS); (3) the use of IFRS to prepare the Annual Report is not inconsistent with representations set forth in the pool's disclosures to participants; (4) any special allocations of ownership equity will be reported in accordance with Regulation 4.22(e); and (5) in the event that IFRS requires consolidated financial statements for the pool (*e.g.,* in a master-feeder fund structure), all applicable disclosures required by U.S. GAAP will be provided.

At the time that the Commission proposed to amend Regulation 4.22(d) to permit the use of IFRS, it acknowledged that its staff had also been granting relief on a case-by-case basis to allow CPOs operating commodity pools located outside the United States to use accounting standards established in certain other jurisdictions, and it invited such CPOs if they otherwise met the criteria of Regulation 4.22(d)(2) to continue requesting such relief from staff on a case-by-case basis.[8] The Commission now believes that staff's experience with providing relief to use the accounting principles, standards or practices followed in the U.K., Ireland, Luxembourg, and Canada warrants extending relief comparable to that which Regulation 4.22(d) provides for the use of IFRS. Accordingly, the Commission is proposing to amend Regulation 4.22(d)(2) so that it would also permit the use of generally accepted accounting principles, standards or practices followed in the U.K., Ireland, Luxembourg, or Canada.[9] A CPO desiring to avail itself of any of these additional alternative accounting principles, standards or practices would be required to claim this relief by filing a notice with NFA containing the same representations required for CPOs desiring to use IFRS.

B. Proposed Amendment to Regulation 4.22(g)(2): Audit Requirement Where the First Fiscal Year Is a Period of Three Months or Less From the Date of Formation of the Pool

As stated above, Regulation 4.22(g) governs the election of a fiscal year by a CPO. It: Permits the CPO to initially elect any fiscal year for its pool, provided that the pool's first fiscal year does not end more than one year after the pool's formation; [10] requires notice to participants and NFA if the CPO elects other than a calendar year for the pool's fiscal year; and requires notice to participants and NFA prior to changing the previously-elected fiscal year (paragraphs (g)(1), (g)(2), and (g)(3), respectively).

Because Regulation 4.22(c) requires that an Annual Report be distributed to pool participants and submitted to NFA within 90 calendar days after the end of the pool's fiscal year, and because Regulation 4.22(d) requires that the Annual Report be audited by an independent public accountant, the CPO of a pool that was formed, for example, two months before the end of the pool's first fiscal year would be required to distribute and submit an audited Annual Report for that two-month fiscal year, regardless of particular circumstances—for example, where there are a limited number of participants in the pool and a limited amount of funds have been contributed to the pool. In those circumstances, the cost of an audit for the short period of time of the pool's operation would likely be unduly burdensome relative to the size of the pool.[11] Over the past years, in circumstances such as the foregoing, Commission staff has issued exemptions from the requirement that a separate audited Annual Report be distributed and submitted for the pool's first fiscal year.[12]

The Commission is now proposing to amend Regulation 4.22(g)(2) to provide for an exemption from the audit requirement applicable to the Annual Report for a pool's first fiscal year when the period from formation of the pool to the end of the pool's first fiscal year is

As noted above, Regulation 4.22 also requires each CPO registered or required to be registered to distribute to each participant in each commodity pool it operates an unaudited periodic Account Statement for the pool. Specifically, Regulation 4.22(a) prescribes the financial information the Account Statement must contain, and Regulation 4.22(b) prescribes the frequency of distribution of the Account Statement (quarterly or monthly, depending on the size of the pool).

[7] 44 FR 1918, 1922 (Jan. 8, 1979).

[8] *See* 74 FR 8220, 8224 (Feb. 24, 2009). Subsequent to the Commission amending Regulation 4.22(d) to permit the use of IFRS, Commission staff has granted relief to use accounting principles, standards or practices established in the United Kingdom (U.K.), Ireland, Luxembourg and Canada. *See, e.g.,* CFTC Staff Letter 09–42 (U.K.) and CFTC Staff Letters 15–57 and 14–10 (Luxembourg). Staff Letters are accessible through the Commission's Web site.

[9] In order to clarify the existing text, the Commission is also proposing to specify in Regulation 4.22(d)(1) that the regulatory norm is that ''[t]he financial statements in the Annual Report must be presented and computed in accordance with *United States* generally accepted accounting principles. . . .'' (Emphasis supplied.)

[10] Regulation 4.22(g)(1) provides that for these purposes, a pool is deemed to be formed as of the date the pool operator first receives funds, securities or other property for the purchase of an interest in the pool.

[11] *See* CFTC Staff Letter 01–13.

[12] *See, e.g.,* CFTC Staff Letters 16–50 and 15–10.

a short period of time.[13] The existing text of the regulation would be found in new paragraph (g)(2)(i) of Regulation 4.22 and the proposed exemption would be contained in new paragraph (g)(2)(ii) of Regulation 4.22. As discussed below, the proposed exemption would specify the criteria for eligibility and the procedure to be followed to claim the exemption. It would also be subject to compliance with the condition that the next Annual Report the CPO distributes and submits is audited and covers the time period from the formation of the pool to the end of the pool's first 12-month fiscal year. Under the Proposal, a CPO could claim this relief where: (1) The time period from the formation of the pool to the end of the pool's first fiscal year is three months or less; (2) from the formation of the pool to the end of the pool's first fiscal year the pool had no more than fifteen participants; and (3) from the formation of the pool to the end of the pool's first fiscal year the total gross capital contributions received by the CPO for units of participation in the pool did not exceed $1,500,000. The Commission is proposing to use the formation of the pool as the starting point of the stub period, and thus the point for determining eligibility for relief, to ensure that all CPOs and their pool participants are on a level playing field with respect to both what information the Annual Report must contain for the pool's first fiscal year, and the requirement that such information be audited.

For the purpose of determining eligibility for relief, the following persons and their capital contributions would not be counted: (1) The pool's CPO, its CTA, and any of their principals; (2) a child, sibling, or parent of the participants described in category (1); (3) the spouse of any of the participants described in category (1) or (2); (4) any relative of one of the participants described in categories (1) through (3); and (5) an entity that is wholly-owned by one or more of the participants described in categories (1) through (4). In this regard, the Commission notes that the CPO could count a non-natural person as a single participant. But if that non-natural person was also a commodity pool, its CPO would have to separately qualify for relief under (proposed) Regulation 4.22(g)(2)(ii) in order for that (second) CPO to claim the relief. The 15-participant limit and the categories of participants and respective contributions that need not be counted are taken from Regulation 4.13(a)(2), which makes available a CPO registration exemption for the operator of a family, club or small pool.[14] The Commission believes that structuring the proposed exemption in this way would avoid unnecessary burdens while maintaining customer protections.

To avail itself of the relief, a CPO would be required to obtain, prior to the date on which the Annual Report for the pool's first fiscal year is due, a specified written waiver of the right to receive an audited Annual Report for that fiscal year from each person who has been a participant in the pool during the first fiscal year. The CPO would be required to retain the waiver in accordance with Regulation 4.23. Then, on or before the date on which the Annual Report for the pool's first fiscal year is due, the CPO would be required to file a notice of claim with NFA, along with a certification that the CPO had received the specified written waiver from each of the pool's participants. This notice would be based on the notice required to claim relief to present and compute an Annual Report in accordance with IFRS, under existing Regulation 4.22(d)(2)(ii). Finally, the CPO would be required to include on the cover of each Annual Report for which relief had been claimed under Regulation 4.22(g)(2) a prescribed statement that provided information on whether the Annual Report was unaudited or audited and the period of time that the Annual Report covered.

C. Proposed Amendment to Regulation 4.22(c)(7): Unavailability of Audit Requirement Exception

Regulation 4.22(c)(7) makes available various exceptions to Annual Report requirements to the CPO of a pool that ceases operation prior to, or at the end of, the pool's fiscal year. In particular, paragraph (c)(7)(iii) provides that a report distributed and submitted pursuant to Regulation 4.22(c)(7) is not required to be audited if the CPO complies with the conditions stated in the regulation. To ensure that an audit is conducted at least once in the life of a commodity pool, the Commission is proposing an amendment to paragraph (c)(7)(iii) of Regulation 4.22 that would make the audit requirement relief under that paragraph unavailable where a CPO has not previously distributed an audited Annual Report to pool participants or submitted the audited Annual Report to NFA—*e.g.,* where the CPO has claimed relief pursuant to (proposed) Regulation 4.22(g)(2) and the pool has ceased operations before the end of its first twelve-month fiscal year.

III. Request for Comments

The Commission requests comment generally on all aspects of the Proposal. In particular, the Commission requests comment on the following:

1. Is there any information required to be included in an Annual Report prepared in accordance with U.S. GAAP that would not be included under generally accepted accounting principles, standards or practices in the U.K., Ireland, Luxembourg or Canada? If so, what is that information and should the Commission require that such information be separately presented in an Annual Report prepared under any such alternative accounting principles, standards or practices? Are there, for example, any specific line items where treatment under one of the referenced sets of accounting principles, standards or practices (or under IFRS) differs from the treatment under U.S. GAAP and for which reconciliation to U.S. GAAP should be required?

2. Should the Commission adopt a provision whereby a CPO could claim relief from the Annual Report audit requirement for a pool in which the only participants were the CPO and one or more other ''insiders'' (*i.e.,* the persons identified in proposed Regulation 4.22(g)(2)(ii)), regardless of the amount of capital contributed to the pool? What other criteria, if any, should be required?

3. Are there any other issues relevant to the Proposal that the Commission should consider?

IV. Related Matters

A. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires Federal agencies to consider whether the rules they propose will have a significant economic impact on a substantial number of small entities and, if so, to provide a regulatory flexibility analysis regarding the

[13] In addition to the substantive changes described below, because the Proposal would add another exception to the general Annual Report audit requirement, the introductory text of Regulation 4.22(d)(1) would be revised to read ''Subject to the provisions of paragraphs (d)(2) and (g)(2) of this section.''

[14] Briefly stated, Regulation 4.13(a)(2) provides that a person is not required to register as a CPO if: (1) None of the commodity pools operated by it has more than 15 participants; and (2) the total gross capital contributions it receives from participants in all of its pools does not in the aggregate exceed $400,000. The regulation further provides that for the purpose of determining eligibility for the exemption, the person may exclude, among others, the following participants and their contributions: The pool's CPO, the pool's CTA, and the principals thereof.

The Commission explained that it had adopted this registration exemption ''because the costs of compliance with the Part 4 rules outweighs the benefits to be gained from regulating family, club and small pools.'' 44 FR 1918, 1919 (Jan. 8, 1979).

economic impact on those entities. The Commission previously has established certain definitions of ''small entities'' to be used by the Commission in evaluating the impact of its rules on such entities in accordance with the requirements of the RFA.[15] With respect to CPOs, the Commission previously has determined that a CPO is a small entity for the purpose of the RFA if it meets the criteria for an exemption from registration under Regulation 4.13(a)(2).[16] Thus, because the Proposal applies to persons registered or required to be registered as a CPO with the Commission, the RFA is not applicable to it.

Accordingly, the Chairman, on behalf of the Commission, hereby certifies pursuant to 5 U.S.C. 6065(b) that the Proposal, if adopted, will not have a significant economic impact on a substantial number of small entities.

B. Paperwork Reduction Act

1. Overview

The Paperwork Reduction Act of 1995 (PRA)[17] imposes certain requirements on Federal agencies (including the Commission) in connection with conducting or sponsoring any collection of information as defined by the PRA. If adopted, the Proposal would result in a collection of information within the meaning of the PRA, as discussed below. The Commission therefore is submitting the Proposal to the Office of Management and Budget (OMB) for review.

The Proposal contains collections of information for which the Commission has previously received control numbers from OMB. The title for these collections of information is ''Registration under the Commodity Exchange Act, OMB control number 3038–0005.''

The responses to these collections of information are mandatory. 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 control number issued by OMB.

The collections of information in this Proposal would provide to eligible CPOs: (1) An optional alternative to complying with the requirement to compute and present the financial statements in a pool Annual Report in accordance with U.S. GAAP (or in accordance with IFRS); and (2) an optional alternative to complying with the audit requirement for the Annual Report for a pool's first fiscal year, all as described above. In each case, eligible persons would have the option to elect the alternative, but no obligation to do so. For this reason, except to the extent that the Commission is amending the subject OMB control number for PRA purposes to reflect these alternatives, the Proposal is not expected to impose any new burdens on CPOs. Rather, to the extent that the Proposal provides alternative means to comply with existing requirements, and an alternative is elected by a CPO, it is reasonable for the Commission to infer that the alternative is less burdensome to such CPO.

2. Revisions to Collection 3038–0005

Collection 3038–0005 is currently in force with its control number having been provided by OMB. As discussed above, the Proposal would add a new exemption to permit a CPO to use accounting principles, standards or practices established in the U.K., Ireland, Luxembourg or Canada. In order to qualify for this exemption, an eligible CPO would be required to take the steps stated in the Proposal, including providing appropriate notification in the pool's Disclosure Document and submitting the required notice to NFA. The Proposal would further add a new exemption to permit a CPO to distribute and submit an unaudited Annual Report for its pool's first (partial) fiscal year and an audited Annual Report for the combined period covered by the pool's first (partial) fiscal year plus the pool's first twelve-month fiscal year. In order to qualify for this exemption, an eligible CPO would be required to take the steps stated in the Proposal, including obtaining waivers from pool participants, submitting the required notice and certification to NFA, providing appropriate notification in the Annual Report, and maintaining the waivers as records. Requiring such actions on the part of an eligible CPO would result in revisions to collection 3038–0005. Therefore, the Commission proposes to revise collection 3038–0005.

Commission staff has received approximately 8 requests in each of 2014 and 2015 from CPOs asking for relief from the requirement to prepare the pool's financial statements in accordance with U.S. GAAP. If the same relief can be claimed with a notice filing (without submitting a request for an individual exemptive letter) additional CPOs are likely to apply. Therefore, the Commission estimates that CPOs will submit 10 notices per year to take advantage of the alternative provided in this Proposal. Similarly, because staff has received approximately 10 requests in each of 2014 and 2015 from CPOs asking for relief from the requirement to distribute and submit an audited Annual Report for a pool's first fiscal year, the Commission estimates that CPOs will submit 12 notices per year to take advantage of the alternative provided in this Proposal.

Collection 3038–0005 relates to collections of information from CPOs and other Commission registrants. Based on the above, the estimated additional hour burden for collection 3038–0005 of 34 hours is calculated as follows:

a. Estimated Additional Hour Burden for Collection 3038–0005 Due to Proposed Alternative to Complying With Requirement To Present and Compute a Pool's Financial Statements According to U.S. GAAP

Anticipated number of claimants: 10.
Frequency of collection: As needed (initial filing and subsequent compliance).
Estimated annual responses per claimant: 1.
Estimated aggregate number of annual responses: 10.
Estimated annual hour burden per registrant: 1 hr.
Estimated aggregate annual hour burden: 10 (10 claimants × 1 hour per claimant).

b. Estimated Additional Hour Burden for Collection 3038–0005 Due to Proposed Alternative to Complying With Requirement To Distribute and Submit an Audited Annual Report for a Pool's First Fiscal Year

Number of claimants: 12.
Frequency of collection: As needed (initial filing and subsequent compliance and recordkeeping).
Estimated annual responses per claimant: 1.
Estimated aggregate number of annual responses: 12.
Estimated annual hour burden per claimant: 2.[18]
Estimated aggregate annual hour burden: 24 (12 claimants × 2 hours per claimant).

3. Information Collection Comments

The Commission invites the public and other Federal agencies to comment on any aspect of the proposed information collection requirements discussed above. Pursuant to 44 U.S.C. 3506(c)(2)(B), the Commission solicits comments in order to: (1) Evaluate whether the proposed collection of information is necessary for the proper

[15] *See, e.g.,* 47 FR 18618 (Apr. 30, 1982).
[16] *Id.* at 18619–20.
[17] 44 U.S.C. 3501 *et seq.*
[18] This figure for annual hour burden per claimant includes one hour for reporting and one hour for recordkeeping.

performance of the functions of the Commission, including whether the information will have practical utility; (2) evaluate the accuracy of the Commission's estimate of the burden of the proposed collection of information; (3) determine whether there are ways to 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 automated collection techniques or other forms of information technology.

Comments may be submitted directly to the Office of Information and Regulatory Affairs, by fax at (202) 395–6566, or by email at *OIRAsubmissions@omb.eop.gov.* Please provide the Commission with a copy of submitted comments so that all comments can be summarized and addressed in the preamble of the adopting **Federal Register** release. Refer to the **ADDRESSES** section of this notice of proposed rulemaking for instructions on submitting comments to the Commission. A copy of the supporting statements for the collection of information discussed above may be obtained by visiting *http://RegInfo.gov.* OMB is required to make a decision concerning 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.

C. Cost-Benefit Considerations

Section 15(a) of the Act [19] requires the Commission to consider the costs and benefits of its actions before promulgating a regulation or issuing certain orders under the Act. Section 15(a) further requires the Commission to evaluate the costs and benefits of any such proposed action in light of five specified areas of consideration, discussed below. The baseline against which the Proposal is compared is the *status quo, i.e.,* current Regulations 4.22(c)(7), 4.22(d)(2) and 4.22(g).

1. Summary of the Proposal

The Proposal would require a CPO to make a notice filing in order to be able either to use alternative accounting principles, standards or practices other than U.S. GAAP or IFRS, or to distribute and submit an unaudited Annual Report for its pool's first (partial-year) fiscal year and an audited Annual Report that combines information for the pool's first (partial-year) fiscal year with information for the following, first twelve-month fiscal year. In either case, the required filing is patterned after that required by existing Regulation 4.22(d)(2) that a CPO must submit in order to use IFRS. Thus, the notice would contain such information as the CPO's name, address and telephone number, the NFA identification numbers of the CPO and the pool, and representations that the CPO complies with the requisite criteria. Additionally, in the second case, the notice would include a certification that the CPO had obtained written waivers from pool participants of their right to receive an audited Annual Report for the pool's first (partial-year) fiscal year. Finally, the Proposal makes unavailable the audit requirement exemption in Regulation 4.22(c)(7), such that the CPO of a pool that is opened and closed in the same fiscal year must distribute and submit audited financial statements.

2. Costs

The Commission believes that the differences in the costs of compliance between the Proposal and existing Regulations 4.22(d)(2) and 4.22(g) would be small because the notice filing is designed to mimic the relevant features of existing Regulation 4.22(d)(2). Nevertheless, the Commission believes that the Proposal will lower costs to CPOs relative to a case-by-case staff-issued exemption, because the Proposal is more standardized. In addition, due to the unavailability of the audit requirement exemption, there is a small cost to the CPO of a pool that is opened and closed in the same fiscal year, because the CPO would now have to distribute and submit audited financial statements for the pool.

There may also be some cost savings if the conditions of the exemption are met, because a CPO who operated a pool that met those conditions would be allowed to distribute to shareholders and submit to NFA an unaudited Annual Report for its pool's first (partial-year) fiscal year and an audited Annual Report that combines information for the pool's first (partial-year) fiscal year with information for the following, first twelve-month fiscal year. The Commission believes that the envisioned costs savings would be due to the independent public accountant only needing to conduct an audit of the pool once and only issuing one opinion on the pool's financial statements. The Commission seeks comment concerning whether or not the Proposal will reduce costs for CPOs relative to existing Regulations 4.22(d)(2) and 4.22(g).

3. Benefits

An advantage of a notice filing over a Commission staff-processed exemption is timeliness. For instance, a CPO that filed a notice under the Proposal would not have to wait for Commission staff to process a request for an individual exemption letter. There is also the benefit that pool participants would receive financial statements for the pool's first fiscal year.

The Commission believes there will be no net benefit from the Proposal as compared to existing Regulations 4.22(d)(2) and 4.22(g) with respect to financial disclosures. By codifying exemptions previously provided by Commission staff on a case-by-case basis, the Proposal would continue to assist pool participants by providing them the information necessary to assess the overall trading performance and financial condition of their pool, but with a lower overall burden to certain CPOs. The Commission believes that pool participants are knowledgeable enough to evaluate financial statements prepared under principles, standards or practices established in the U.K., Ireland, Luxembourg or Canada, provided that the relevant accounting principles, standards or practices are properly disclosed to them. The Commission seeks public comment concerning whether or not use of the specified different systems of accounting principles, standards and practices might lead to material differences in financial statements that pool participants might not be able to understand. For example, should the Commission require CPOs to disclose in the footnotes to the pool's financial statements when material difference exist between U.S. GAAP and alternative accounting principles, standards or practices? Additionally, the Commission believes that there will be minimal loss in the level of confidence of pool participants in their pool's financial statements, because an independent public accountant will still have to issue an opinion on an audited Annual Report that combines information for the pool's first (partial-year) fiscal year with information for the following, first twelve-month fiscal year. The Commission seeks public comment concerning whether this belief is correct or not.

4. Section 15(a) Factors

As noted above, Section 15(a) of the Commodity Exchange Act (CEA or Act) requires the Commission to consider the costs and benefits of its actions before promulgating a regulation or issuing

[19] 7 U.S.C. 19(a).

certain orders. As also noted above, CEA Section 15(a) further specifies that the Commission shall evaluate the costs and benefits of its actions in light of five specific concerns. Those concerns relate to: (i) Protection of market participants and the public; (ii) efficiency, competitiveness, and financial integrity of futures markets; (iii) price discovery; (iv) sound risk management practices; and (v) other public interest considerations.

i. Protection of Market Participants and the Public

The Commission believes that the Proposal will provide the same level of protection to commodity pool participants through the disclosure of financial statements as do existing Regulations 4.22(d)(2) and 4.22(g). The Commission believes that pool participants are knowledgeable enough to evaluate financial statements prepared under accounting principles, standards and practices established in the U.K., Ireland, Luxembourg or Canada, provided that the relevant accounting principles, standards and practices are properly disclosed to them. By codifying exemptions previously provided by Commission staff on a case-by-case basis, the Proposal would continue to assist pool participants by providing them the information necessary to assess the overall trading performance and financial condition of their pool, but with a lower overall burden to certain CPOs. Additionally, the Commission believes that there will be minimal loss in the level of confidence of pool participants in their pool's financial statements, because an independent public accountant will still have to issue an opinion on the financial statements included in an Annual Report that combines information for the pool's first (partial-year) fiscal year with information for the following, first twelve-month fiscal year.

ii. Efficiency, Competitiveness, and Financial Integrity of Markets

The Commission has not identified any impact that the Proposal would have on efficiency, competitiveness, and financial integrity of markets.

iii. Price Discovery

The Commission has not identified any impact that the Proposal would have on price discovery.

iv. Sound Risk Management Practices

The Commission has not identified any impact that the Proposal would have on sound risk management practices.

v. Other Public Interest Considerations

The Commission has not identified any impact on any other public interest considerations that the Proposal would have, but seeks public comment on any public interest the Commission should consider in this rulemaking.

5. Request for Comments

The Commission invites public comment on its cost-benefit considerations, including the Section 15(a) factors described above. Commenters are invited to submit with their comment letters any data or other information that they may have that quantifies or qualifies the costs and benefits of the Proposal.

List of Subjects in 17 CFR Part 4

Advertising, Brokers, Commodity futures, Commodity pool operators, Commodity trading advisors, Consumer protection, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Commodity Futures Trading Commission proposes to amend 17 CFR part 4 as follows:

PART 4—COMMODITY POOL OPERATORS AND COMMODITY TRADING ADVISORS

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

Authority: 7 U.S.C. 1a, 2, 6(c), 6b, 6c, 6l, 6m, 6n, 6o, 12a, and 23.

■ 2. Amend § 4.22 as follows:
■ a. Revise paragraphs (c)(7)(iii) and (d);
■ b. Redesignate paragraph (g)(2) as paragraph (g)(2)(i); and
■ c. Add paragraph (g)(2)(ii).

The revisions and addition to read as follows:

§ 4.22 Reporting to pool participants.

* * * * *

(c) * * *

(7) * * *

(iii) A report filed pursuant to paragraph (c)(7) of this section that would otherwise be required by paragraph (c) of this section is not required to be audited in accordance with paragraph (d) of this section if the commodity pool operator obtains from all participants written waivers of their rights to receive an audited Annual Report, and at the time of filing the Annual Report with the National Futures Association, certifies that it has received waivers from all participants. The commodity pool operator must maintain the waivers in accordance with § 1.31 of this chapter and must make the waivers available to the Commission or National Futures Association upon request. Notwithstanding the provisions of paragraph (g)(2)(ii) of this section, the relief made available by this paragraph (c)(7)(iii) shall not be available where the commodity pool operator has not previously distributed an audited Annual Report to pool participants and submitted an audited Annual Report to the National Futures Association.

* * * * *

(d)(1) Subject to the provisions of paragraphs (d)(2) and (g)(2) of this section, the financial statements in the Annual Report required by this section or by § 4.7(b)(3) must be presented and computed in accordance with United States generally accepted accounting principles consistently applied and must be audited by an independent public accountant. The requirements of § 1.16(g) of this chapter shall apply with respect to the engagement of such independent public accountants, except that any related notifications to be made may be made solely to the National Futures Association, and the certification must be in accordance with § 1.16 of this chapter, except that the following requirements of that section shall not apply:

* * * * *

(2)(i) Where a commodity pool is organized in a jurisdiction other than the United States, the financial statements in the Annual Report required by this section or by § 4.7(b)(3) may be presented and computed in accordance with the generally accepted accounting principles, standards or practices followed in such other jurisdiction; *Provided,* That:

(A) The other jurisdiction follows accounting principles, standards or practices set forth in paragraph (d)(2)(ii) of this section and the Annual Report presents and computes the financial statements of the pool in accordance with the applicable accounting principles, standards or practices followed by such other jurisdiction;

(B) The Annual Report includes a condensed schedule of investments, or, if required by the applicable accounting principles, standards or practices followed by such other jurisdiction, a full schedule of investments;

(C) The Annual Report reports special allocations of ownership equity in accordance with paragraph (e)(2) of this section;

(D) The Disclosure Document or offering memorandum for the pool identifies the accounting principles, standards or practices of the other jurisdiction pursuant to which the Annual Report presents and computes the financial statements of the pool; and

(E) Where the accounting principles, standards or practices of the other jurisdiction require consolidated financial statements for the pool, such as a feeder fund consolidating with its master fund, all applicable disclosures required by United States generally accepted accounting principles for the feeder fund must be presented with the reporting pool's consolidated financial statements.

(ii) For purposes of paragraph (d)(2)(i) of this section, the following alternative accounting principles, standards or practices may be employed in the preparation and computation of the financial statements in the Annual Report of the commodity pool; *Provided,* That any such alternative accounting principles, standards or practices so employed are those followed by the jurisdiction other than the United States in which the commodity pool is organized:

(A) International Financial Reporting Standards;

(B) Generally Accepted Accounting Practice in the United Kingdom;

(C) New Irish Generally Accepted Accounting Practice;

(D) Luxembourg Generally Accepted Accounting Principles; or

(E) Canadian Generally Accepted Accounting Principles.

(iii) To claim the relief available under this paragraph (d)(2), a commodity pool operator must file a notice with the National Futures Association within 90 calendar days after the end of the pool's first fiscal year.

(A) The notice must contain: The name, main business address, main telephone number and National Futures Association registration identification number of the commodity pool operator; the name and identification number of the commodity pool for which the pool operator is claiming relief; and the alternative accounting principles, standards or practices pursuant to which the financial statements in the Annual Report will be presented and computed;

(B) The notice must include a representation that the commodity pool operator complies with each of the conditions specified in paragraphs (d)(2)(i)(A) through (D) of this section and, if applicable, paragraph (d)(2)(i)(E) of this section; and

(C) The notice must be signed by the commodity pool operator in accordance with paragraph (h) of this section.

* * * * *

(g) * * *

(2)(i) If a commodity pool operator elects a fiscal year other than the calendar year, it must give written notice of the election to all participants and must file the notice with the National Futures Association within 90 calendar days after the date of the pool's formation. If this notice is not given, the pool operator will be deemed to have elected the calendar year as the pool's fiscal year.

(ii) If the time period from the formation of the pool to the end of the pool's first fiscal year is three months or less, the first Annual Report for the pool may be unaudited; *Provided,* That:

(A) Throughout the period of formation through the end of the pool's first fiscal year, the pool had no more than fifteen participants and no more than $1,500,000 in aggregate gross capital contributions. For the purpose of satisfying these criteria, the commodity pool operator may exclude the following persons and their contributions:

(*1*) The pool operator, the pool's commodity trading advisor, and any principal thereof;

(*2*) A child, sibling, or parent of any of these participants;

(*3*) The spouse of any participant specified in paragraph (g)(2)(i)(A)(*1*) or (*2*) of this section;

(*4*) Any relative of a participant specified in paragraph (g)(2)(i)(A)(*1*), (*2*) or (*3*) of this section, its spouse or a relative of its spouse, who has the same principal residence as such participant; and

(*5*) An entity that is wholly-owned by one or more participants specified in paragraph (g)(2)(ii)(A)(*1*), (*2*), (*3*) or (*4*) of this section; and

(B) The next Annual Report for the pool is audited and covers the time period from the formation of the pool to the end of the pool's first 12-month fiscal year.

(C) To claim the relief available under paragraph (g)(2)(ii) of this section, a commodity pool operator must:

(*1*) Prior to the date upon which it is required to distribute and submit an audited Annual Report for the pool's first fiscal year, obtain from each pool participant who otherwise would have been entitled to such an Annual Report a written waiver of the participant's right to receive an audited Annual Report for the pool's first fiscal year. The waiver must be signed by the pool participant and must state as follows: ''[Name of participant], a participant in [Name of pool], voluntarily waives the right under CFTC Regulation 4.22(d) to receive an audited Annual Report for the fiscal year ended [end date of the pool's first fiscal year] and will accept in lieu thereof an unaudited Annual Report covering the period [date of formation of the pool] through [end of the pool's first fiscal year] and an audited Annual Report covering the period [date of formation of the pool] through [end date of the pool's first twelve-month fiscal year].''; and

(*2*) On or before the date upon which it is required to distribute and submit the Annual Report for the pool's first fiscal year, file a notice with the National Futures Association, along with a certification that it has received the required written waiver from each person who has been a participant in the pool for its first fiscal year.

(*i*) The notice must contain: The name, main business address, main telephone number and National Futures Association registration identification number of the commodity pool operator; the name and identification number of the commodity pool for which the pool operator is claiming relief; and the dates of formation of the pool and the first fiscal year end of the pool;

(*ii*) The notice must include a representation that the commodity pool operator meets the criteria of paragraph (g)(2)(ii)(A) of this section and that it will comply with the condition of paragraph (g)(2)(ii)(B) of this section; and

(*iii*) The notice must be signed by the commodity pool operator in accordance with paragraph (h) of this section.

(D)(*1*) Each unaudited Annual Report for which the relief available under paragraph (g)(2)(ii) of this section has been claimed must prominently disclose on the cover page thereof: ''Pursuant to an exemption from the Commodity Futures Trading Commission, this unaudited Annual Report covers the period from the date of formation of the pool to the end of the pool's first fiscal year, a period of [number] months.''

(*2*) The next Annual Report for the pool must prominently disclose on the cover page thereof: ''Pursuant to an exemption from the Commodity Futures Trading Commission, this audited Annual Report covers the period from the date of formation of the pool to the end of the pool's first 12-month fiscal year, a period of [number] months.''

(E) The commodity pool operator must maintain in accordance with § 4.23 of this chapter each waiver it has obtained to claim the relief available under paragraph (g)(2)(ii) of this section.

* * * * *

Issued in Washington, DC, on July 29, 2016, by the Commission.

Christopher J. Kirkpatrick,

Secretary of the Commission.

Note: The following appendix will not appear in the Code of Federal Regulations.

Appendix to Commodity Pool Operator Annual Report—Commission Voting Summary

On this matter, Chairman Massad and Commissioners Bowen and Giancarlo voted in the affirmative. No Commissioner voted in the negative.

[FR Doc. 2016–18400 Filed 8–4–16; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[REG–105005–16]

RIN 1545–BN33

Election Into the Partnership Audit Regime Under the Bipartisan Budget Act of 2015

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations.

SUMMARY: This document contains proposed regulations pursuant to section 1101(g)(4) of the Bipartisan Budget Act of 2015 regarding an election to apply the new partnership audit regime enacted by that act to certain returns of a partnership. The regulations provide the time, form, and manner for making this election. The regulations affect any partnership that wishes to elect to have the new partnership audit regime apply to its returns filed for certain taxable years beginning before January 1, 2018.

DATES: Written or electronic comments and requests for a public hearing must be received by October 4, 2016.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–105005–16), Room 5207, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG–105005–16), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC 20224, or sent electronically via the Federal eRulemaking Portal at *http://www.regulations.gov* (IRS REG–105005–16). The public hearing will be held in the Auditorium, Internal Revenue Service Building, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Jenni M. Black at (202) 317–6834 (not a toll-free number).

Background and Explanation of Provisions

This notice of proposed rulemaking cross-references to temporary regulations published in the Rules and Regulations section of this issue of the **Federal Register**. The temporary regulations amend the Procedure and Administration Regulations (26 CFR part 301) to provide rules for the time, form, and manner of making the election under section 1101(g)(4) of the Bipartisan Budget Act of 2015, Public Law 114–74 (BBA) for taxable years beginning after November 2, 2015 and before January 1, 2018. The BBA was enacted on November 2, 2015, and was amended by the Protecting Americans from Tax Hikes Act of 2015, Public Law 114–113, div. Q (PATH Act) on December 18, 2015.

The text of the temporary regulations also serves as the text of these proposed regulations. The Background and Explanation of Provisions contained in the preamble to the temporary regulations explains these proposed regulations.

Special Analyses

Certain IRS regulations, including this one, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory impact assessment is not required.

Pursuant to the Regulatory Flexibility Act (5 U.S.C. chapter 6), it is hereby certified that the collection of information contained in this regulation will not have a significant economic impact on a substantial number of small entities. This certification is based on the fact that the collection of information contained in this regulation is voluntary and will only occur if a partnership elects into the new partnership audit regime enacted by the BBA for taxable years beginning after November 2, 2015 and before January 1, 2018. In addition, the new partnership audit regime is new, and the IRS has yet to provide guidance on the application of the new partnership audit regime generally. As a result, the IRS estimates that there will not be a substantial number of small entities that elect into the regime for an eligible taxable year. However, even if a substantial number of small entities elect into the new BBA regime for an eligible taxable year, the election under this regulation requires only a short statement containing limited and readily available information. Therefore, the IRS estimates that the economic impact on electing small entities will not be significant. Accordingly, a regulatory flexibility analysis is not required.

Pursuant to section 7805(f) of the Code, these regulations were submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Request for a Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any electronic and written comments (a signed original and eight (8) copies) that are submitted timely to the IRS. The IRS and Treasury request comments on all aspects of the proposed rules. All comments will be available for public inspection and copying. A public hearing may be scheduled if requested in writing by a person that timely submits written comments. If a public hearing is scheduled, notice of the date, time, and place of the hearing will be published in the **Federal Register**.

Drafting Information

The principal author of these proposed regulations is Jenni M. Black of the Office of the Associate Chief Counsel (Procedure and Administration). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 301

Income taxes, Penalties, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 301 is amended as follows:

PART 301—PROCEDURE AND ADMINISTRATION

■ **Paragraph 1.** The authority citation for part 301 is amended by adding an entry in numerical order to read as follows:

Authority: 26 U.S.C. 7805 * * *

* * * * *

Section 301.9100–22 also issued under section 1101(g)(4) of Pub. L. 114–74.

* * * * *

■ **Par. 2.** Section 301.9100–22 is added to read as follows:

§ 301.9100–22 Time, form, and manner of making the election under section 1101(g)(4) of the Bipartisan Budget Act of 2015 for taxable years beginning after November 2, 2015 and before January 1, 2018.

[The text of this proposed section is the same as the text of § 301.9100–22T

published elsewhere in this issue of the **Federal Register**].

John Dalrymple,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2016–18632 Filed 8–4–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AP73

Release of VA Records Relating to HIV

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) proposes to amend its medical regulations governing the release of VA medical records. Specifically, VA proposes to eliminate the restriction on protecting a negative test result for the human immunodeficiency virus (HIV). HIV testing is a common practice today in healthcare and the stigma of testing that may have been seen in the 1980s when HIV was first discovered is no longer prevalent. Continuing to protect negative HIV tests causes delays and an unnecessary burden to veterans when VA tries to share electronic medical information with the veterans' outside providers for their treatment through health information exchange efforts. For this same reason, VA would also eliminate negative test results of sickle cell anemia as protected medical information. This proposed rule would eliminate the current barriers to electronic medical information exchange.

DATES: Comments must be received on or before October 4, 2016.

ADDRESSES: Written comments may be submitted through *www.Regulations.gov;* by mail or hand-delivery to Director, Regulation Policy and Management (00REG), Department of Veterans Affairs, 810 Vermont Avenue NW., Room 1068, Washington, DC 20420; or by fax to (202) 273–9026. Comments should indicate that they are submitted in response to ''RIN 2900–AP73—Release of VA Records Relating to HIV.'' Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1068, between the hours of 8 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461–4902 for an appointment. (This is not a toll-free number.) In addition, during the comment period, comments may be viewed online through the Federal Docket Management System at *www.Regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Stephania H. Griffin, Director, Information Access and Privacy Office (10P2C), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420; (704) 245–2492. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: The Veterans Omnibus Health Care Act of 1976, Public Law 94–581, codified at 38 U.S.C. 7332, ensured confidentiality of medical records relating to drug abuse, alcoholism, and sickle cell anemia by establishing sanctions for unauthorized disclosure of information while meeting the legitimate needs for disclosure under certain conditions. In 1988, Public Law 100–322 added to this list the confidentiality of medical records relating to infection with the human immunodeficiency virus (HIV). Section 7332 states that records of the identity, diagnosis, prognosis, or treatment of any patient or subject which are maintained in connection with the performance of any program or activity (including education, training, treatment, rehabilitation, or research) of any patient or subject relating to drug abuse, alcoholism or alcohol abuse, infection with the human immunodeficiency virus (HIV), or sickle cell anemia shall only be disclosed under certain circumstances. The intent of section 7332 is to protect the medical records of those veterans who are undergoing treatment or have a positive diagnosis for the conditions stated in this section. Due to the stigma associated with HIV and HIV testing at the time, VA determined that the results of HIV testing should be protected regardless of the outcome of the test. However, HIV testing is common practice today. In the past, VA required health care providers to counsel patients as part of the informed consent process prior to ordering HIV testing. Currently, HIV testing is considered part of routine health care under VA policy, similar to other types of diagnostic laboratory testing, and while oral informed consent is still required no pre-testing counseling is required.

The continued protection of negative HIV tests has posed significant obstacles to the sharing of medical information between VA and non-VA medical providers, and also places an undue burden on veterans. If VA conducts an HIV test on a veteran, VA is prevented from electronically disclosing the veteran's medical information to the veteran's non-VA medical provider, even if the test result is negative, unless VA first obtains a specific written authorization that meets title 38 regulatory requirements from the veteran to share the medical information. Medical information sharing is crucial to treating a veteran who has outside medical providers and is significant in making certain that a veteran is not prescribed a medication that may negatively interact with other medications. Under section 7332, sickle cell anemia is also considered protected medical information. As with negative HIV test results, the prohibition on sharing negative test results for sickle cell anemia has posed challenges for the timely provision of medical care. This rulemaking would eliminate the current restrictions on sharing negative test results of veterans for HIV and sickle cell anemia and would be in line with the intent of the statute. As for positive HIV or sickle cell anemia test results, VA would continue to require a qualifying written authorization from the veteran prior to disclosure of such information.

Section 1.460 Definitions

Section 1.460 defines terms that apply to §§ 1.460 through 1.499, which cover the release of information from VA records relating to drug abuse, alcoholism or alcohol abuse, infection with HIV, or sickle cell anemia. The term ''HIV'' is defined as the presence of laboratory evidence for human immunodeficiency virus infection. The definition for ''HIV'' also states that ''[f]or the purposes of §§ 1.460 through 1.499 of this part, the term includes the testing of an individual for the presence of the virus or antibodies to the virus and information related to such testing (including tests with negative results).'' We propose to modify this definition because VA would only restrict the release of health information for positive results. The proposed definition would define ''HIV'' to mean ''the presence of laboratory evidence for human immunodeficiency virus infection. The term does not include negative results from the testing of an individual for the presence of the virus or antibodies to the virus, or such testing of an individual where the results are negative.'' As previously stated in this rulemaking, negative results are not protected under this provision.

The term ''patient'' is defined in part in § 1.460 to state that it includes an individual or subject who is tested for infection with HIV or sickle cell anemia. We propose to amend this definition to state that the term 'patient' for purpose of infection with the human immune

deficiency virus or sickle cell anemia, includes one tested positive for the disease even if no treatment is provided. The term does not include a patient who has tested negative for the disease. We would make this amendment to clarify that VA would only protect the medical information of a patient who tested positive for HIV or sickle cell anemia and not all individuals who were tested for these diseases. Although section 7332 considers sickle cell anemia as protected health information, it is silent on the protection of a negative test for sickle cell anemia. We would treat an individual who tested negative for sickle cell anemia in the same manner as an individual who tested negative for HIV. For this same reason, we propose to modify the last sentence in the definition of the term ''treatment'' to state the term does not include testing for the human immunodeficiency virus or sickle cell anemia where the results of such tests are negative. We would also amend the definition of ''treatment'' by stating that ''treatment'' means the diagnosis, management and care of a patient for infection with the human immunodeficiency virus or sickle cell anemia. This proposed addition would clarify what VA considers 7332-protected medical information.

Section 1.461 Applicability

Paragraph (a)(1)(i) of 38 CFR 1.461 states the restrictions on disclosure of medical information, specifically information that would identify a patient as an alcohol or drug abuser, an individual tested for or infected with the human immunodeficiency virus (HIV), hereafter referred to as HIV, or an individual with sickle cell anemia, either directly, by reference to other publicly available information, or through verification of such an identification by another person. As previously stated in this rulemaking, we would no longer consider 7332-protected medical information to include a negative test for HIV or sickle cell anemia. Therefore, we propose to amend § 1.461(a)(1)(i) by removing the restriction on disclosure of medical information for an individual who has tested negative for HIV or sickle cell anemia. Paragraph (a)(1)(i) would only protect medical information for individuals who have tested positive for or are infected with HIV, or have tested positive for or have sickle cell anemia.

Effect of Rulemaking

The Code of Federal Regulations, as proposed to be revised by this proposed rulemaking, would represent the exclusive legal authority on this subject. No contrary rules or procedures would be authorized. All VA guidance would be read to conform with this proposed rulemaking if possible or, if not possible, such guidance would be superseded by this rulemaking.

Paperwork Reduction Act

This proposed rule contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521).

Regulatory Flexibility Act

The Secretary hereby certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. This proposed rule would directly affect only individuals and would not directly affect small entities. Therefore, pursuant to 5 U.S.C. 605(b), this rulemaking would be exempt from the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604.

Executive Order 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a ''significant regulatory action,'' requiring review by the Office of Management and Budget (OMB), unless OMB waives such review, as ''any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.''

The economic, interagency, budgetary, legal, and policy implications of this regulatory action have been examined, and it has been determined not to be a significant regulatory action under Executive Order 12866. VA's impact analysis can be found as a supporting document at *http://www.regulations.gov,* usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA's Web site at *http://www.va.gov/orpm/,* by following the link for ''VA Regulations Published From FY 2004 Through Fiscal Year to Date.''

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. This proposed rule would have no such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are 64.007, Blind Rehabilitation Centers; 64.008, Veterans Domiciliary Care; 64.009, Veterans Medical Care Benefits; 64.010, Veterans Nursing Home Care; 64.011, Veterans Dental Care; 64.012, Veterans Prescription Service; 64.014, Veterans State Domiciliary Care; 64.015, Veterans State Nursing Home Care; 64.018, Sharing Specialized Medical Resources; 64.019, Veterans Rehabilitation Alcohol and Drug Dependence; 64.022, Veterans Home Based Primary Care; and 64.024, VA Homeless Providers Grant and Per Diem Program.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Gina S. Farrisee, Deputy Chief of Staff, Department of Veterans Affairs, approved this document on August 1, 2016, for publication.

List of Subjects in 38 CFR Part 1

Administrative practice and procedure, Archives and records, Cemeteries, Claims, Courts, Crime, Flags, Freedom of information, Government contracts, Government employees, Government property, Infants and children, Inventions and patents, Parking, Penalties, Postal Service, Privacy, Reporting and recordkeeping requirements, Seals and insignia, Security measures, Wages.

Dated: August 2, 2016.

Janet J. Coleman,

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

For the reasons set out in the preamble, Department of Veterans Affairs proposes to amend 38 CFR part 1 as follows:

PART 1—GENERAL PROVISIONS

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

Authority: 38 U.S.C. 501(a), and as noted in specific sections.

■ 2. Amend § 1.460 by:
■ a. Revising the last sentence of the definition of ''Infection with the human immunodeficiency virus (HIV).''
■ b. Revising the definition of ''Patient.''
■ c. Revising the definition of ''Treatment.''

The revisions read as follows:

§ 1.460 Definitions.

* * * * *

Infection with the human immunodeficiency virus (HIV). * * * The term does not include negative results from the testing of an individual for the presence of the virus or antibodies to the virus, or such testing of an individual where the results are negative.

* * * * *

Patient. The term ''patient'' means any individual or subject who has been given a diagnosis or treatment for drug abuse, alcoholism or alcohol abuse, infection with the human immunodeficiency virus, or sickle cell anemia and includes any individual who, after arrest on a criminal charge, is interviewed and/or tested in connection with drug abuse, alcoholism or alcohol abuse, infection with the human immunodeficiency virus, or sickle cell anemia in order to determine that individual's eligibility to participate in a treatment or rehabilitation program if the result of such testing is positive. The term ''patient'' includes an individual who has been diagnosed or treated for alcoholism, drug abuse, HIV infection, or sickle cell anemia for purposes of participation in a VA program or activity relating to those four conditions, including a program or activity consisting of treatment, rehabilitation, education, training, evaluation, or research. For the purpose of infection with the human immunodeficiency virus or sickle cell anemia, the term ''patient'' includes one tested positive for the disease even if no treatment is provided, offered, or requested. The term does not include a patient who has tested negative for the disease.

* * * * *

Treatment. The term ''treatment'' means the management and care of a patient for drug abuse, alcoholism or alcohol abuse, or the diagnosis, management and care of a patient for infection with the human immunodeficiency virus, or sickle cell anemia, or a condition which is identified as having been caused by one or more of these conditions, in order to reduce or eliminate the adverse effects upon the patient. The term does not include negative test results for the human immunodeficiency virus, antibodies to the virus, or sickle cell anemia, or such testing of an individual where the results are negative.''

* * * * *

■ 3. Revising § 1.461(a)(1)(i) to read as follows.

§ 1.461 Applicability.

(a) * * *

(1) * * *

(i) Would identify a patient as an alcohol or drug abuser, an individual who tested positive for or is infected with the human immunodeficiency virus (HIV), hereafter referred to as HIV, or an individual who tested positive for or has sickle cell anemia, either directly, by reference to other publicly available information, or through verification of such an identification by another person; and

* * * * *

[FR Doc. 2016–18660 Filed 8–4–16; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 257

[EPA–HQ–OLEM–2016–0274; FRL–9949–43–OLEM]

Hazardous and Solid Waste Management System: Disposal of Coal Combustion Residuals From Electric Utilities; Extension of Compliance Deadlines for Certain Inactive Surface Impoundments; Response to Partial Vacatur

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA or the Agency) is proposing to extend for certain inactive coal combustion residuals (CCR) surface impoundments the compliance deadlines established by the regulations for the disposal of CCR under subtitle D of the Resource Conservation and Recovery Act (RCRA). These revisions are being proposed in response to a partial vacatur ordered by the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit) on June 14, 2016.

DATES: Written comments must be received by August 22, 2016. Comments postmarked after the close of the comment period will be stamped ''late'' and may or may not be considered by the Agency.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OLEM–2016–0274, at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit

https://www.epa.gov/dockets/commenting-epa-dockets.

FOR FURTHER INFORMATION CONTACT: For information concerning this proposed rule, contact Steve Souders, Office of Resource Conservation and Recovery, Environmental Protection Agency, 5304P, Washington, DC 20460; telephone number: (703) 308–8431; email address: *souders.steve@epa.gov.* For more information on this rulemaking please visit *https://www.epa.gov/coalash.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This proposed rule applies only to those owners or operators of inactive CCR surface impoundments that meet all three of the following conditions: (1) Complied with the requirement at 40 CFR 257.105(i)(1) by placing in their facility's written operating record a notification of intent to initiate closure of the CCR unit as required by 40 CFR 257.100(c)(1), no later than December 17, 2015; (2) complied with the requirement at 40 CFR 257.106(i)(1) by providing notification to the relevant State Director and/or appropriate Tribal authority by January 19, 2016, of the intent to initiate closure of the CCR unit; and (3) complied with the requirement at 40 CFR 257.107(i)(1) by placing the notification of intent to initiate closure of the CCR unit on the owner or operator's publicly accessible CCR Web site no later than January 19, 2016.

If you have any questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

B. Why is EPA issuing this proposed rule?

This action proposes to extend the deadlines for the owners and operators of those inactive CCR surface impoundments that had taken advantage of the ''early closure'' provisions of 40 CFR 257.100, who became newly subject to the rule's requirements for existing CCR surface impoundments on June 14, 2016 when the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit) ordered the vacatur of those provisions. This proposed rule provides time for these owners and operators to bring their units into compliance with the rule's substantive requirements, but does not otherwise amend the rule or otherwise impose new requirements on those units. In the ''Rules and Regulations'' section of this **Federal Register**, we have also published a direct final rule for this same action because we view this as a noncontroversial action and anticipate no adverse comment. We have explained our reason for this in the preamble to the direct final rule.

If we receive no adverse comment, we will not take further action on this proposed rule and the direct final rule will become effective as provided in that action. If we do receive adverse comment, we will publish a timely notice in the **Federal Register** withdrawing the direct final rule and it will not take effect. We will address all public comments in any subsequent final rule based on this proposed rule. We do not intend to institute a second comment period on this action. Any parties interested in commenting must do so at this time, for further information about commenting on this rule see the **ADDRESSES** section of this document.

C. Where is the location of regulatory text for this proposal?

The regulatory text for this proposal is identical to that for the direct final rule published in the Rules and Regulations section of the **Federal Register**. For further supplemental information, the detailed rationale for the proposal, and the regulatory revisions, see the information provided in the direct final rule published in the Rules and Regulations section of this **Federal Register**.

II. Statutory Authority

These regulations are established under the authority of sections 1006(b), 1008(a), 2002(a), 4004, and 4005(a) of the Solid Waste Disposal Act of 1970, as amended by the Resource Conservation and Recovery Act of 1976 (RCRA), as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA), 42 U.S.C. 6906(b), 6907(a), 6912(a), 6944, and 6945(a).

III. Statutory and Executive Order (EO) Reviews

For a complete discussion of all of the administrative requirements applicable to this action, see the direct final rule in the Rules and Regulations section of this **Federal Register**.

List of Subjects in 40 CFR Part 257

Environmental protection, Beneficial use, Coal combustion products, Coal combustion residuals, Coal combustion waste, Disposal, Hazardous waste, Landfill, Surface impoundment.

Dated: July 26, 2016.

Gina McCarthy,

Administrator.

[FR Doc. 2016–18325 Filed 8–4–16; 8:45 am]

BILLING CODE 6560–50–P

Notices

Federal Register
Vol. 81, No. 151
Friday, August 5, 2016

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

Office of the Secretary

Request for Nominations of Members for the National Agricultural Research, Extension, Education, and Economics Advisory Board and Specialty Crop Committee

AGENCY: Research, Education, and Economics, USDA.

ACTION: Solicitation for membership.

SUMMARY: In accordance with the Federal Advisory Committee Act, 5 U.S.C. App., the United States Department of Agriculture announces the solicitation for nominations to fill vacancies on the National Agricultural Research, Extension, Education, and Economics Advisory Board and its subcommittees. There are 7 vacancies on the NAREEE Advisory Board, 3 vacancies on the Specialty Crop Committee, 4 vacancies on the National Genetics Advisory Council, and 6 vacancies on the Citrus Disease Committee.

SUPPLEMENTARY INFORMATION: Correction.

In the Federal Register of July 29, 2016 in FR Doc. 146, on page 49922, of the date section should read as follows:

DATES: All nomination materials should be mailed in a single, complete package and postmarked by August 12, 2016.

Yvette Anderson,

Federal Register Liaison Officer for ARS, ERS, and NASS.

[FR Doc. 2016–18607 Filed 8–4–16; 8:45 am]

BILLING CODE 3410–03–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Child and Adult Care Food Program: National Average Payment Rates, Day Care Home Food Service Payment Rates, and Administrative Reimbursement Rates for Sponsoring Organizations of Day Care Homes for the Period, July 1, 2016 Through June 30, 2017

AGENCY: Food and Nutrition Service, USDA.

ACTION: Notice.

SUMMARY: This notice announces the annual adjustments to the national average payment rates for meals and snacks served in child care centers, outside-school-hours care centers, at-risk afterschool care centers, and adult day care centers; the food service payment rates for meals and snacks served in day care homes; and the administrative reimbursement rates for sponsoring organizations of day care homes, to reflect changes in the Consumer Price Index. Further adjustments are made to these rates to reflect the higher costs of providing meals in the States of Alaska and Hawaii. The adjustments contained in this notice are made on an annual basis each July, as required by the laws and regulations governing the Child and Adult Care Food Program.

DATES: These rates are effective from July 1, 2016 through June 30, 2017.

FOR FURTHER INFORMATION CONTACT: Jessica Saracino, Branch Chief, Program Monitoring and Operational Support Division, Child Nutrition Programs, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Room 640, Alexandria, Virginia 22302–1594; phone 703–457–7743.

SUPPLEMENTARY INFORMATION:

Definitions

The terms used in this notice have the meanings ascribed to them in the Child and Adult Care Food Program regulations, 7 CFR part 226.

Background

Pursuant to sections 4, 11, and 17 of the Richard B. Russell National School Lunch Act (42 U.S.C. 1753, 1759a and 1766), section 4 of the Child Nutrition Act of 1966 (42 U.S.C. 1773) and 7 CFR 226.4, 226.12 and 226.13 of the Program regulations, notice is hereby given of the new payment rates for institutions participating in the Child and Adult Care Food Program (CACFP). These rates are in effect during the period, July 1, 2016 through June 30, 2017.

As provided for under the law, all rates in the CACFP must be revised annually, on July 1, to reflect changes in the Consumer Price Index (CPI), published by the Bureau of Labor Statistics of the United States Department of Labor, for the most recent 12-month period. In accordance with this mandate, the United States Department of Agriculture (USDA) last published the adjusted national average payment rates for centers, the food service payment rates for day care homes, and the administrative reimbursement rates for sponsoring organizations of day care homes, for the period from July 1, 2015 through June 30, 2016, on July 17, 2015, in the **Federal Register** at 80 FR 42474.

Adjusted Payments

The following national average payment factors and food service payment rates for meals and snacks are in effect from July 1, 2016 through June 30, 2017. All amounts are expressed in dollars or fractions thereof. Due to a higher cost of living, the reimbursements for Alaska and Hawaii are higher than those for all other States. The District of Columbia, Virgin Islands, Puerto Rico, and Guam use the figures specified for the contiguous States. These rates do not include the value of USDA Foods or cash-in-lieu of USDA Foods which institutions receive as additional assistance for each lunch or supper served to participants under the Program. A notice announcing the value of USDA Foods and cash-in-lieu of USDA Foods is published separately in the **Federal Register**.

National Average Payment Rates for Centers

Payments for breakfasts served are: *Contiguous States*—paid rate—29 cents (no change from 2015–2016 annual level), reduced price rate—141 cents (5 cents increase), free rate—171 cents (5 cents increase); *Alaska*—paid rate—44 cents (1 cent increase), reduced price rate—243 cents (7 cents increase), free rate—273 cents (7 cents increase); *Hawaii*—paid rate—33 cents (no change), reduced price rate—169 cents

(5 cents increase), free rate—199 cents (5 cents increase).

Payments for lunch or supper served are: *Contiguous States*—paid rate—30 cents (1 cent increase from 2015–2016 annual level), reduced price rate—276 cents (9 cents increase), free rate—316 cents (9 cents increase); *Alaska*—paid rate—49 cents (1 cent increase), reduced price rate—472 cents (13 cents increase), free rate—512 cents (13 cents increase); *Hawaii*—paid rate—35 cents (1 cent increase), reduced price rate—329 cents (9 cents increase), free rate—369 cents (9 cents increase).

Payments for snack served are: *Contiguous States*—paid rate—7 cents (no change from 2015–2016 annual level), reduced price rate—43 cents (1 cent increase), free rate—86 cents (2 cents increase); *Alaska*—paid rate—12 cents (no change), reduced price rate—70 cents (2 cents increase), free rate—140 cents (3 cents increase); *Hawaii*—paid rate—9 cents (no change), reduced price rate—50 cents (1 cent increase), free rate—101 cents (2 cents increase).

Food Service Payment Rates for Day Care Homes

Payments for breakfast served are: *Contiguous States*—tier I—131 cents (1 cent decrease from 2015–2016 annual level) and tier II—48 cents (no change); *Alaska*—tier I—209 cents (2 cents decrease) and tier II—74 cents (1 cent decrease); *Hawaii*—tier I—153 cents (1 cent decrease) and tier II—55 cents (no change).

Payments for lunch and supper served are: *Contiguous States*—tier I—246 cents (2 cent decrease from 2015–2016 annual level) and tier II—149 cents (1 cent decrease); *Alaska*—tier I—399 cents (3 cents decrease) and tier II—241 cents (2 cents decrease); *Hawaii*—tier I—288 cents (2 cents decrease) and tier II—174 cents (1 cent decrease).

Payments for snack served are: *Contiguous States*—tier I—73 cents (1 cent decrease from 2015–2016 annual level) and tier II—20 cents (no change); *Alaska*—tier I—119 cents (1 cent decrease) and tier II—33 cents (no change); *Hawaii*—tier I—86 cents (no change) and tier II—23 cents (1 cent decrease).

Administrative Reimbursement Rates for Sponsoring Organizations of Day Care Homes

Monthly administrative payments to sponsors for each sponsored day care home are: *Contiguous States*—initial 50 homes—112 dollars (1 dollar increase from 2015–2016 annual level), next 150 homes—86 dollars (1 dollar increase), next 800 homes—67 dollars (1 dollar increase), each additional home—59 dollars (1 dollar increase); *Alaska*—initial 50 homes—182 dollars (2 dollar increase), next 150 homes—139 dollars (2 dollar increase), next 800 homes—108 dollars (1 dollar increase), each additional home—95 dollars (1 dollar increase); *Hawaii*—initial 50 homes—131 dollars (1 dollar increase), next 150 homes—100 dollars (1 dollar increase), next 800 homes—78 dollars (1 dollar increase), each additional home—69 dollars (1 dollar increase).

Payment Chart

The following chart illustrates the national average payment factors and food service payment rates for meals and snacks in effect from July 1, 2016, through June 30, 2017.

CHILD AND ADULT CARE FOOD PROGRAM (CACFP)

[Per meal rates in whole or fractions of U.S. dollars effective from July 1, 2016–June 30, 2017]

Centers	Breakfast	Lunch and supper [1]	Supplement
Contiguous States:			
Paid	0.29	0.30	0.07
Reduced Price	1.41	2.76	0.43
Free	1.71	3.16	0.86
Alaska:			
Paid	0.44	0.49	0.12
Reduced Price	2.43	4.72	0.70
Free	2.73	5.12	1.40
Hawaii:			
Paid	0.33	0.35	0.09
Reduced Price	1.69	3.29	0.50
Free	1.99	3.69	1.01

[1] These rates do not include the value of USDA Foods or cash-in-lieu of USDA Foods which institutions receive as additional assistance for each CACFP lunch or supper served to participants. A notice announcing the value of USDA Foods and cash-in-lieu of USDA Foods is published separately in the **Federal Register**.

Day care homes	Breakfast		Lunch and supper		Supplement	
	Tier I	Tier II	Tier I	Tier II	Tier I	Tier II
Contiguous States	1.31	0.48	2.46	1.49	0.73	0.20
Alaska	2.09	0.74	3.99	2.41	1.19	0.33
Hawaii	1.53	0.55	2.88	1.74	0.86	0.23

ADMINISTRATIVE REIMBURSEMENT RATES FOR SPONSORING ORGANIZATIONS OF DAY CARE HOMES

[Per home/per month rates in U.S. dollars]

	Initial 50	Next 150	Next 800	Each additional
Contiguous States	112	86	67	59
Alaska	182	139	108	95
Hawaii	131	100	78	69

The changes in the national average payment rates for centers reflect a 2.64 percent increase during the 12-month period, May 2015 to May 2016, (from 255.322 in May 2015, as previously published in the **Federal Register**, to 262.074 in May 2016) in the food away from home series of the CPI for All Urban Consumers.

The changes in the food service payment rates for day care homes reflect a 0.69 percent decrease during the 12-month period, May 2014 to May 2015, (from 241.019 in May 2015, as previously published in the **Federal Register**, to 239.354 in May 2016) in the food at home series of the CPI for All Urban Consumers.

The changes in the administrative reimbursement rates for sponsoring organizations of day care homes reflect a 1.02 percent increase during the 12-month period, May 2015 to May 2016 (from 237.805 in May 2015, as previously published in the **Federal Register**, to 240.236 in May 2016) in the series for all items of the CPI for All Urban Consumers.

The total amount of payments available to each State agency for distribution to institutions participating in CACFP is based on the rates contained in this notice.

This action is not a rule as defined by the Regulatory Flexibility Act (5 U.S.C. 601–612) and thus is exempt from the provisions of that Act. This notice has been determined to be exempt under Executive Order 12866.

CACFP is listed in the Catalog of Federal Domestic Assistance under No. 10.558 and is subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 2 CFR 415.3–415.6).

This notice has been determined to be not significant and was reviewed by the Office of Management and Budget (OMB) in conformance with Executive Order 12866.

This notice imposes no new reporting or recordkeeping provisions that are subject to OMB review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3518).

Authority: Sections 4(b)(2), 11, 17(c) and 17(f)(3)(B) of the Richard B. Russell National School Lunch Act (42 U.S.C. 1753(b)(2), 1759a, 1766(f)(3)(B)) and section 4(b)(1)(B) of the Child Nutrition Act of 1966 (42 U.S.C. 1773(b)(1)(B)).

Dated: August 2, 2016.

Yvette S. Jackson,

Acting Administrator, Food and Nutrition Service.

[FR Doc. 2016–18646 Filed 8–4–16; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

National School Lunch, Special Milk, and School Breakfast Programs, National Average Payments/Maximum Reimbursement Rates

AGENCY: Food and Nutrition Service, USDA.

ACTION: Notice.

SUMMARY: This Notice announces the annual adjustments to the ''national average payments,'' the amount of money the Federal Government provides States for lunches, afterschool snacks and breakfasts served to children participating in the National School Lunch and School Breakfast Programs; to the ''maximum reimbursement rates,'' the maximum per lunch rate from Federal funds that a State can provide a school food authority for lunches served to children participating in the National School Lunch Program; and to the rate of reimbursement for a half-pint of milk served to non-needy children in a school or institution which participates in the Special Milk Program for Children. The payments and rates are prescribed on an annual basis each July. The annual payments and rates adjustments for the National School Lunch and School Breakfast Programs reflect changes in the Food Away From Home series of the Consumer Price Index for All Urban Consumers. Food and Nutrition Service has approved a 17-percent increase in school meal reimbursement rates for Puerto Rico to reflect their higher cost of providing school meals. The rate adjustment will take effect beginning July 1, 2016, for school year 2016–2017. This increase is based on data indicating that the cost of producing school lunches, breakfasts, and snacks are higher than those in the continental United States, as well as other factors impacting Puerto Rico's school meal program. The annual rate adjustment for the Special Milk Program reflects changes in the Producer Price Index for Fluid Milk Products.

DATES: These rates are effective from July 1, 2016 through June 30, 2017

FOR FURTHER INFORMATION CONTACT: Jessica Saracino, Branch Chief, Program Monitoring and Operational Support Division, Child Nutrition Programs, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Room 640, Alexandria, Virginia 22302–1594; phone 703–457–7743.

SUPPLEMENTARY INFORMATION:

Background

Special Milk Program for Children—Pursuant to section 3 of the Child Nutrition Act of 1966, as amended (42 U.S.C. 1772), the Department announces the rate of reimbursement for a half-pint of milk served to non-needy children in a school or institution that participates in the Special Milk Program for Children. This rate is adjusted annually to reflect changes in the Producer Price Index for Fluid Milk Products, published by the Bureau of Labor Statistics of the Department of Labor.

For the period July 1, 2016 through June 30, 2017, the rate of reimbursement for a half-pint of milk served to a non-needy child in a school or institution which participates in the Special Milk Program is 19.75 cents. This reflects a decrease of .25 cents from the School Year (SY) 2015–16 level, based on the 1.32 percent decrease in the Producer Price Index for Fluid Milk Products from May 2015 to May 2016 (from a level of 219.0 in May 2015, as previously published in the **Federal Register**, to 216.1 in May 2016).

As a reminder, schools or institutions with pricing programs that elect to serve milk free to eligible children continue to receive the average cost of a half-pint of milk (the total cost of all milk purchased during the claim period divided by the total number of purchased half-pints) for each half-pint served to an eligible child.

National School Lunch and School Breakfast Programs—Pursuant to sections 11 and 17A of the Richard B. Russell National School Lunch Act, (42 U.S.C. 1759a and 1766a), and section 4 of the Child Nutrition Act of 1966 (42 U.S.C. 1773), the Department annually announces the adjustments to the National Average Payment Factors and to the maximum Federal reimbursement rates for lunches and afterschool snacks served to children participating in the National School Lunch Program and breakfasts served to children participating in the School Breakfast Program. Adjustments are prescribed each July 1, based on changes in the Food Away From Home series of the Consumer Price Index for All Urban Consumers, published by the Bureau of Labor Statistics of the Department of Labor. The changes in the national average payment rates for schools and residential child care institutions for the period July 1, 2016 through June 30, 2017 reflect a 2.64 percent increase in the Consumer Price Index for All Urban Consumers during the 12-month period May 2015 to May 2016 (from a level of 255.322 in May 2015, as previously published in the **Federal Register**, to

262.074 in May 2016). Adjustments to the national average payment rates for all lunches served under the National School Lunch Program, breakfasts served under the School Breakfast Program, and afterschool snacks served under the National School Lunch Program are rounded down to the nearest whole cent.

Lunch Payment Levels—Section 4 of the Richard B. Russell National School Lunch Act (42 U.S.C. 1753) provides general cash for food assistance payments to States to assist schools in purchasing food. The Richard B. Russell National School Lunch Act provides two different section 4 payment levels for lunches served under the National School Lunch Program. The lower payment level applies to lunches served by school food authorities in which less than 60 percent of the lunches served in the school lunch program during the second preceding school year were served free or at a reduced price. The higher payment level applies to lunches served by school food authorities in which 60 percent or more of the lunches served during the second preceding school year were served free or at a reduced price.

To supplement these section 4 payments, section 11 of the Richard B. Russell National School Lunch Act (42 U.S.C. 1759a) provides special cash assistance payments to aid schools in providing free and reduced price lunches. The section 11 National Average Payment Factor for each reduced price lunch served is set at 40 cents less than the factor for each free lunch.

As authorized under sections 8 and 11 of the Richard B. Russell National School Lunch Act (42 U.S.C. 1757 and 1759a), maximum reimbursement rates for each type of lunch are prescribed by the Department in this Notice. These maximum rates are to ensure equitable disbursement of Federal funds to school food authorities.

Section 201 of the Healthy, Hunger-Free Kids Act of 2010—Section 201 of the Healthy, Hunger-Free Kids Act of 2010 made significant changes to the Richard B. Russell National School Lunch Act. On January 3, 2014, the final rule entitled, ''Certification of Compliance With Meal Requirements for the National School Lunch Program Under the Healthy, Hunger-Free Kids Act of 2010'' (79 FR 325), was published and provides eligible school food authorities with performance-based cash reimbursement in addition to the general and special cash assistance described above. The final rule requires that school food authorities be certified by the State agency as being in compliance with the updated meal pattern and nutrition standard requirements set forth in amendments to 7 CFR parts 210 and 220 on January 26, 2012, in the final rule entitled ''Nutrition Standards in the National School Lunch and School Breakfast Programs'' (77 FR 4088). Certified school food authorities are eligible to receive performance-based cash assistance for each reimbursable lunch served (an additional six cents per lunch available beginning October 1, 2012, and adjusted annually thereafter).

Afterschool Snack Payments in Afterschool Care Programs—Section 17A of the Richard B. Russell National School Lunch Act (42 U.S.C. 1766a) establishes National Average Payments for free, reduced price and paid afterschool snacks as part of the National School Lunch Program.

Breakfast Payment Factors—Section 4 of the Child Nutrition Act of 1966 (42 U.S.C. 1773) establishes National Average Payment Factors for free, reduced price and paid breakfasts served under the School Breakfast Program and additional payments for free and reduced price breakfasts served in schools determined to be in ''severe need'' because they serve a high percentage of needy children.

Revised Payments

The following specific section 4, section 11 and section 17A National Average Payment Factors and maximum reimbursement rates for lunch, the afterschool snack rates, and the breakfast rates are in effect from July 1, 2016 through June 30, 2017. Beginning July 1, 2016, Puerto Rico will receive a 17-percent increase adjustment to these rates due to the higher cost of producing a meal in Puerto Rico. In addition, the average payments and maximum reimbursements for Alaska and Hawaii are higher due to the higher cost of living in these States. The District of Columbia, Virgin Islands, and Guam use the figures specified for the contiguous States.

National School Lunch Program Payments

Section 4 National Average Payment Factors—In school food authorities which served less than 60 percent free and reduced price lunches in School Year (SY) 2014–2015, the payments for meals served are: *Contiguous States*—paid rate—30 cents (1 cent increase from the SY 2015–2016 level), free and reduced price rate—30 cents (1 cent increase), maximum rate—38 cents (1 cent increase); *Alaska*—paid rate—49 cents (1 cent increase), free and reduced price rate—49 cents (1 cent increase), maximum rate—60 cents (2 cent increase); *Hawaii* and *Puerto Rico*—paid rate—35 cents (1 cent increase), free and reduced price rate—35 cents (1 cent increase), maximum rate—44 cents (2 cent increase).

In school food authorities which served 60 percent or more free and reduced price lunches in School Year 2014–2015, payments are: *Contiguous States*—paid rate—32 cents (1 cent increase from the SY 2015–2016 level), free and reduced price rate—32 cents (1 cent increase), maximum rate—38 cents (1 cent increase); *Alaska*—paid rate—51 cents (1 cent increase), free and reduced price rate—51 cents (1 cents increase), maximum rate—60 cents (2 cent increase); *Hawaii* and *Puerto Rico*—paid rate—37 cents (1 cent increase), free and reduced price rate—37 cents (1 cent increase), maximum rate—44 cents (2 cent increase).

School food authorities certified to receive the performance-based cash assistance will receive an additional 6 cents (adjusted annually) added to the above amounts as part of their section 4 payments.

Section 11 National Average Payment Factors—Contiguous States—free lunch—286 cents (8 cent increase from the SY 2015–2016 level), reduced price lunch—246 cents (8 cent increase); *Alaska*—free lunch—463 cents (12 cent increase), reduced price lunch—423 cents (12 cent increase); *Hawaii* and *Puerto Rico*—free lunch—334 cents (8 cent increase), reduced price lunch—294 cents (8 cent increase).

Afterschool Snacks in Afterschool Care Programs—The payments are: *Contiguous States*—free snack—86 cents (2 cent increase from the SY 2015–2016 level), reduced price snack—43 cents (1 cent increase), paid snack—07 cents (no change); *Alaska*—free snack—140 cents (3 cent increase), reduced price snack—70 cents (2 cent increase), paid snack—12 cents (no change); *Hawaii* and *Puerto Rico*—free snack—101 cents (2 cent increase), reduced price snack—50 cents (1 cent increase), paid snack—09 cents (no change).

School Breakfast Program Payments

For schools ''not in severe need'' the payments are: *Contiguous States*—free breakfast—171 cents (5 cent increase from the SY 2015–2016 level), reduced price breakfast—141 cents (5 cent increase), paid breakfast—29 cents (no change); *Alaska*—free breakfast—273 cents (7 cent increase), reduced price breakfast—243 cents (7 cent increase), paid breakfast—44 cents (1 cent increase); *Hawaii* and *Puerto Rico*—free breakfast—199 cents (5 cent increase), reduced price breakfast—169 cents (5

cent increase), paid breakfast—33 cents (no change).

For schools in ''severe need'' the payments are: *Contiguous States*—free breakfast—204 cents (5 cent increase from the SY 2015–2016 level), reduced price breakfast—174 cents (5 cent increase), paid breakfast—29 cents (no change); *Alaska*—free breakfast—327 cents (8 cent increase), reduced price breakfast—297 cents (8 cent increase), paid breakfast—44 cents (1 cent increase); *Hawaii* and *Puerto Rico*—free breakfast—238 cents (6 cent increase), reduced price breakfast—208 cents (6 cent increase), paid breakfast—33 cents (no change).

Payment Chart

The following chart illustrates the lunch National Average Payment Factors with the sections 4 and 11 already combined to indicate the per lunch amount; the maximum lunch reimbursement rates; the reimbursement rates for afterschool snacks served in afterschool care programs; the breakfast National Average Payment Factors including ''severe need'' schools; and the milk reimbursement rate. All amounts are expressed in dollars or fractions thereof. The payment factors and reimbursement rates used for the District of Columbia, Virgin Islands, and Guam are those specified for the contiguous States.

SCHOOL PROGRAMS—MEAL, SNACK AND MILK PAYMENTS TO STATES AND SCHOOL FOOD AUTHORITIES—EXPRESSED IN DOLLARS OR FRACTIONS THEREOF

[Effective from: July 1, 2016–June 30, 2017]

National School Lunch Program [1]	Less than 60%	Less than 60% + 6 cents [2]	60% or more	60% or more + 6 cents [2]	Maximum rate	Maximum rate + 6 cents [2]
Contiguous States:						
Paid	0.30	0.36	0.32	0.38	0.38	0.44
Reduced price	2.76	2.82	2.78	2.84	2.93	2.99
Free	3.16	3.22	3.18	3.24	3.33	3.39
Alaska:						
Paid	0.49	0.55	0.51	0.57	0.60	0.66
Reduced price	4.72	4.78	4.74	4.80	4.98	5.04
Free	5.12	5.18	5.14	5.20	5.38	5.44
Hawaii:						
Paid	0.35	0.41	0.37	0.43	0.44	0.50
Reduced price	3.29	3.35	3.31	3.37	3.49	3.55
Free	3.69	3.75	3.71	3.77	3.89	3.95
Puerto Rico: [3]						
Paid	0.35	0.41	0.37	0.43	0.44	0.50
Reduced Price	3.29	3.35	3.31	3.37	3.49	3.55
Free	3.69	3.75	3.71	3.77	3.89	3.95

School breakfast program	Non-severe need	Severe need
Contiguous States:		
Paid	0.29	0.29
Reduced price	1.41	1.74
Free	1.71	2.04
Alaska:		
Paid	0.44	0.44
Reduced price	2.43	2.97
Free	2.73	3.27
Hawaii:		
Paid	0.33	0.33
Reduced price	1.69	2.08
Free	1.99	2.38
Puerto Rico: [3]		
Paid	0.33	0.33
Reduced price	1.69	2.08
Free	1.99	2.38

Special milk program	All milk	Paid milk	Free milk
Pricing Programs without Free Option	0.1975	N/A	N/A.
Pricing Programs with Free Option	N/A	0.1975	Average Cost Per 1/2 Pint of Milk.
Nonpricing Programs	0.1975	N/A	N/A.

Afterschool Snacks Served in Afterschool Care Programs	
Contiguous States:	
Paid	0.07
Reduced price	0.43
Free	0.86
Alaska:	
Paid	0.12
Reduced price	0.70
Free	1.40
Hawaii:	
Paid	0.09
Reduced price	0.50
Free	1.01
Puerto Rico: [3]	
Paid	0.09
Reduced price	0.50
Free	1.01

[1] Payment listed for Free and Reduced Price Lunches include both section 4 and section 11 funds.

[2] Performance-based cash reimbursement (adjusted annually for inflation).

[3] Beginning July 1, 2016, FNS approved Puerto Rico to receive a 17-percent increase in school meal reimbursement rates.

This action is not a rule as defined by the Regulatory Flexibility Act (5 U.S.C. 601–612) and thus is exempt from the provisions of that Act.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), no new recordkeeping or reporting requirements have been included that are subject to approval from the Office of Management and Budget.

This notice has been determined to be not significant and was reviewed by the Office of Management and Budget in conformance with Executive Order 12866.

National School Lunch, School Breakfast and Special Milk Programs are listed in the Catalog of Federal Domestic Assistance under No. 10.555, No. 10.553 and No. 10.556, respectively, and are subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 2 CFR 415.3–415.6).

Authority: Sections 4, 8, 11 and 17A of the Richard B. Russell National School Lunch Act, as amended, (42 U.S.C. 1753, 1757, 1759a, 1766a) and sections 3 and 4(b) of the Child Nutrition Act, as amended, (42 U.S.C. 1772 and 42 U.S.C. 1773(b)).

Dated: August 2, 2016.

Yvette S. Jackson,

Acting Administrator, Food and Nutrition Service.

[FR Doc. 2016–18650 Filed 8–4–16; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Forest Service

Information Collection; Cooperative Wildland Fire Management and Stafford Act Response Agreements

AGENCY: Forest Service USDA, Bureau of Land Management DOI, Fish and Wildlife Service DOI, National Park Service DOI, and Bureau of Indian Affairs DOI.

ACTION: Notice and request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Forest Service is seeking comments from all interested individuals and organizations on the new information collection, Cooperative Wildland Fire Management and Stafford Act Response Agreements.

DATES: Comments must be received in writing on or before October 4, 2016 to be assured of consideration. Comments received after that date will be considered to the extent practicable.

ADDRESSES: Comments concerning this notice should be addressed to Tim Melchert, Cooperative Fire Specialist, USDA Forest Service, 1400 Independence Avenue SW., Washington, DC 20250.

Comments also may be submitted via facsimile to 208–387–5398 or by email to: *CoopFire_Agreements@fs.fed.us.*

The public may inspect comments received at Forest Service, U.S. Department of Agriculture, 1400 Independence Avenue SW., Washington, DC 20250 during normal business hours. Visitors are encouraged to call ahead to 202–205–1637 to facilitate entry to the building.

FOR FURTHER INFORMATION CONTACT: Tim Melchert, Cooperative Fire Specialist, at USDA Forest Service, 208–387–5887.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 twenty-four hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, Forest Service will submit a request for a new information collection to Office of Management and Budget.

Title: Cooperative Wildland Fire Management and Stafford Act Response Agreements.

OMB Number: 0596—NEW.

Type of Request: New.

Abstract: To allow the performance of specific activities in cooperation with Federal, State, local, and Tribal governments, Congress enacted authorities allowing the U.S. Department of Agriculture (USDA) and U.S. Department of the Interior (DOI) to enter into cooperative agreements with fire organizations to improve efficiency by facilitating the coordination and exchange of personnel, equipment, supplies, services, and funds among the parties in sustaining wildland fire management activities, such as prevention, preparedness, communication and education, fuels treatment and hazard mitigation, fire planning, response strategies, tactics and alternatives, suppression, and post-fire rehabilitation and restoration. In addition, agreements allow for the parties to respond to presidentially declared emergencies or disasters. The primary authorities allowing for the agreements are the Reciprocal Fire Protection Act, 42 U.S.C. 1856, and the Stafford Act, 42 U.S.C. 5121. The proposed Cooperative Wildland Fire Management and Stafford Act Response Agreement template will allow authorized agencies to streamline coordination with other Federal, State, local, and Tribal governments in wildland fire protection activities, and to document in an agreement the roles and responsibilities among the parties, ensuring maximum protection of resources.

To negotiate, develop, and administer Cooperative Wildland Fire Management and Stafford Act Response Agreements, the USDA Forest Service, DOI Bureau of Land Management, DOI Fish and Wildlife Service, DOI National Park Service, and DOI Bureau of Indian Affairs DOI must collect information from willing State, local, and Tribal governments from the pre-agreement to the closeout stage via telephone calls, emails, postal mail, and person-to-person meetings. There are multiple means for cooperators to communicate responses, which include forms, optional forms, templates, electronic documents, in person, telephone, and email. The scope of information collected includes the project type, project scope, financial plan, statement of work, and cooperator's business information. Without the collected information, authorized Federal agencies would not be able to negotiate, create, develop, and administer cooperative agreements with cooperators for to wildland fire protection, approved severity activities, and presidentially declared emergencies or disasters. Authorized Federal agencies would be unable to develop or monitor projects, make payments, or identify financial and accounting errors.

The regulations governing Federal financial assistance relationships are not applicable to agreement templates under this information collection request. The regulations in 2 CFR 200 set forth the general rules that are applicable to all grants and cooperative agreements made by the USDA and DOI. Because the Federal Government's use of Cooperative Wildland Fire Management and Stafford Act Response Agreements entered into under cited Federal statutes are not financial assistance for the benefit of the recipient but instead are entered into for the mutual benefit of the Federal government and the non-Federal cooperators, the assistance regulations in 2 CFR 200, as adopted and supplemented by the USDA and DOI, are not applicable to such agreements.

This is a new information collection request. The Cooperative Wildland Fire Management and Stafford Act Response Agreement template can be viewed at *www.fs.fed.us/managing-land/fire/master-agreement-template.*

Estimate of Annual Burden: 4 to 24 hours annually per respondent.

Type of Respondents: State, local, and Tribal governments.

Estimated Annual Number of Respondents: 320.

Estimated Annual Number of Responses per Respondent: 1 to 4.

Estimated Total Annual Burden on Respondents: 47,040 hours.

Comment is invited on: (1) Whether this collection of information is necessary for the stated purposes and the proper performance of the functions of the Agency, including whether the information will have practical or scientific utility; (2) the accuracy of the Agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used; (3) 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 the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments received in response to this notice, including names and addresses when provided, will be a matter of public record. Comments will be summarized and included in the submission request toward Office of Management and Budget approval.

Dated: August 1, 2016.

James E. Hubbard,

Deputy Chief State and Private Forestry.

[FR Doc. 2016–18685 Filed 8–4–16; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Siskiyou County Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Siskiyou County Resource Advisory Committee (RAC) will meet in Yreka, California. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act. RAC information can be found at the following Web site: *http://cloudapps-usda-gov.force.com/FSSRS/RAC_Meeting_Page?id=a2zt00000004CyPAAU.*

DATES: The meeting will be held September 6, 2016, at 5:00 p.m.

All RAC meetings are subject to cancellation. For status of meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

ADDRESSES: The meeting will be held at the Klamath National Forest (NF) Supervisor's Office, Conference Room, 1711 South Main Street, Yreka, California.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION.** All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at Klamath NF Supervior's Office. Please call ahead to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Natalie Stovall, RAC Coordinator, by phone at 530–841–4411 or via email at *nstovall@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to:

1. Approve prior meeting notes,
2. Update on ongoing projects,
3. Public comment period,
4. Review meeting schedule,
5. Proposal reviews, and
6. Vote on proposals.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments may be sent to Natalie Stovall, RAC Coordinator, 1711 S. Main Street, Yreka, California 96097; by email to *nstovall@fs.fed.us* or via facsimile to 530–841–4571.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices, or other reasonable accommodation. For access to the facility or proceedings, please contact the person listed in the section titled **FOR FURTHER INFORMATION CONTACT.** All reasonable accommodation requests are managed on a case by case basis.

Dated: July 29, 2016.

Christine Frisbee,

Acting Forest Supervisor.

[FR Doc. 2016–18608 Filed 8–4–16; 8:45 am]

BILLING CODE 3411–15–P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the South Dakota Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that a briefing meeting of the South Dakota Advisory Committee to the Commission will convene at 1:00 p.m. (CDT) on Thursday, August 25, 2016, in the Community Room on the 1st Floor of the Aberdeen Public Safety Building, 114 2nd Avenue SE., Aberdeen, SD 57401.

The purpose of the briefing meeting is to examine the subtle effects of racism in South Dakota. The briefing topics will include the value of the use of body-worn cameras in law enforcement, and minority policing that impacts Native Americans and immigrant communities. The South Dakota Advisory Committee will hear from law enforcement, tribal officials, advocacy groups, community organizations, representatives of local, state, and Federal agencies, and the public.

If other persons who plan to attend the meeting require other accommodations, please contact Evelyn Bohor at ebohor@*usccr.gov* at the Rocky Mountain Regional Office at least ten (10) working days before the scheduled date of the meeting.

Time will be set aside at the end of the briefing so that members of the public may address the Committee after the formal presentations have been completed. Persons interested in the issue are also invited to submit written comments; the comments must be received in the regional office by Monday, September 26. Written comments may be mailed to the Rocky Mountain Regional Office, U.S. Commission on Civil Rights, 1961 Stout Street, Suite 13–201, Denver, CO 80294, faxed to (303) 866–1050, or emailed to Evelyn Bohor at *ebohor@usccr.gov.* Persons who desire additional information may contact the Rocky Mountain Regional Office at (303) 866–1040.

Records and documents discussed during the meeting will be available for public viewing as they become available at *https://database.faca.gov/committee/meetings.aspx?cid=274* and clicking on the ''Meeting Details'' and ''Documents'' links. Records generated from this meeting may also be inspected and reproduced at the Rocky Mountain Regional Office, as they become available, both before and after the meeting. Persons interested in the work of this advisory committee are advised to go to the Commission's Web site, *www.usccr.gov,* or to contact the Rocky Mountain Regional Office at the above phone number, email or street address.

Agenda

Welcome and Introductions
Richard Braunstein, Chair, South Dakota Advisory Committee
Malee V. Craft, Regional Director, RMRO–USCCR, Denver, CO
Briefing
South Dakota Advisory Committee
Government and Tribal Officials, Advocates, Experts, Law Enforcement

DATE: Thursday, August 25, 2016 (CDT).
TIME:

1:00 p.m.–5:00 p.m.—Briefing Meeting
5:00 p.m.–6:00 p.m.—Public Session

ADDRESSES: Aberdeen Public Safety Building, Community Room, 1st Floor, 114 2nd Avenue SE., Aberdeen, SD 57401.

FOR FURTHER INFORMATION CONTACT: Malee Craft at *mcraft@usccr.gov,* or 303–866–1040.

Dated: August 2, 2016.

David Mussatt,

Chief, Regional Programs Unit.

[FR Doc. 2016–18644 Filed 8–4–16; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Vermont Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA) that an orientation and planning meeting of the Vermont Advisory Committee to the Commission will convene at 12:00 p.m. (EDT) on Friday, August 19, 2016, at Community College of Vermont, 660 Elm St., Montpelier, 05602. The purpose of the orientation meeting is to inform the newly appointed Committee members about the rules of operation of federal advisory committees and to select additional officers, as determined by the Committee. The purpose of the planning meeting is to discuss potential topics that the Committee may wish to study. The Committee will also review draft reports on Housing Discrimination and Racial Profiling and vote on submission of these reports to the Commission.

Persons who plan to attend the meeting and who require other accommodations, please contact Evelyn Bohor at *ebohor@usccr.gov* at the Rocky Mountain Regional Office at least ten (10) working days before the scheduled date of the meeting.

Members of the public are invited to submit written comments; the comments must be received in the regional office by Monday, September 19, 2016. Written comments may be mailed to the Eastern Regional Office, U.S. Commission on Civil Rights, 1331 Pennsylvania Avenue, Suite 1150, Washington, DC 20425, faxed to (202) 376–7548, or emailed to Evelyn Bohor at *ero@usccr.gov.* Persons who desire additional information may contact the Eastern Regional Office at (202) 376–7533.

The activities of this advisory committee, including records and documents discussed during the meeting, will be available for public viewing, as they become available at: *https://database.faca.gov/committee/meetings.aspx?cid=239.* Records generated from this meeting may also be inspected and reproduced at the Eastern Regional Office, as they become available, both before and after the meeting. Persons interested in the work of this advisory committee are advised to go to the Commission's Web site, *www.usccr.gov,* or to contact the Eastern Regional Office at the above phone number, email or street address.

Agenda

Orientation and Administrative Matters
Barbara de La Viez, Deputy Director, Eastern Regional Office and Designated Federal Official
Discussion of Potential Civil Rights topics
Diane Snelling, Chair
Discussion of Potential Topics of Study
VT State Advisory Committee
Review of Draft Reports
VT State Advisory Committee

DATES: Friday, August 19, 2016, at 1:30 p.m. (EDT).

ADDRESSES: Community College of Vermont, 660 Elm St., Montpelier, 05602

FOR FURTHER INFORMATION CONTACT: Ivy L. Davis at *ero@usccr.gov,* or 202–376–7533

Dated: August 1, 2016.

David Mussatt,

Chief, Regional Programs Unit.

[FR Doc. 2016–18538 Filed 8–4–16; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Georgia Advisory Committee for an Orientation and Planning Meeting

AGENCY: U.S. Commission on Civil Rights.

ACTION: Notice of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Georgia (State) Advisory Committee will hold a meeting on Wednesday, August 31, 2016, for the purpose of welcoming the new committee.

DATES: The meeting will be held on Wednesday, August 31, 2016 12:00 p.m. EST.

ADDRESSES: The meeting will be by teleconference. Toll-free call-in number: 888–487–0360, conference ID: 4411088.

Members of the public can listen to the discussion. This meeting is available to the public through the following toll-free call-in number: 888–487–0360, conference ID: 4411088. Any interested member of the public may call this number and listen to the meeting. Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–977–8339 and providing the Service with the conference call number and conference ID number.

FOR FURTHER INFORMATION CONTACT: Members of the public are also entitled speak at the open session at the end of the meeting. In addition, members of the public may submit written comments; the comments must be received in the regional office by September 25, 2016. Written comments may be mailed to the Southern Regional Office, U.S. Commission on Civil Rights, 61 Forsyth Street, Suite 16T126, Atlanta, GA 30303. They may also be faxed to the Commission at (404) 562–7005, or

emailed to Regional Director, Jeffrey Hinton at *jhinton@usccr.gov.* Persons who desire additional information may contact the Southern Regional Office at (404) 562–7000.

Records generated from this meeting may be inspected and reproduced at the Southern Regional 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, North Carolina Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's Web site, *http://www.usccr.gov,* or may contact the Southern Regional Office at the above email or street address.

SUPPLEMENTARY INFORMATION:

Agenda

Welcome and Introductions
Jeff Hinton, Regional Director; Jerry Gonzalez, Chair Georgia SAC
Regional Update—Jeff Hinton
Member Introduction/Open Comment—Jerry Gonzalez
Staff/Advisory Committee
Public Participation
Adjournment

Dated: July 29, 2016.

David Mussatt,

Chief, Regional Programs Unit.

[FR Doc. 2016–18443 Filed 8–4–16; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Wisconsin Advisory Committee To Discuss Preparations for a Hearing on Hate Crimes in the State

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Wisconsin Advisory Committee (Committee) will hold a meeting on Monday, August 22, 2016, at 2:00 p.m. CDT for the purpose of discussing final preparations for a hearing on hate crime in the state.

DATES: The meeting will be held on Monday, August 22, 2016, at 2:00 p.m. CDT.

ADDRESSES: *Public Call Information:* Dial: 888–312–9841; Conference ID: 4502335.

This meeting is open to the public through the following toll-free call-in number: 888–312–9841, conference ID: 4502335. Any interested member of the public may call this number and listen to the meeting. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–977–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are invited to make statements to the Committee during the scheduled open comment period. In addition, members of the public may submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be mailed to the Regional Programs Unit, U.S. Commission on Civil Rights, 55 W. Monroe St., Suite 410, Chicago, IL 60615. They may also be faxed to the Commission at (312) 353–8324, or emailed to Carolyn Allen at *callen@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (312) 353–8311.

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at *https://database.faca.gov/committee/meetings.aspx?cid=282.* Click on the ''Meeting Details'' and ''Documents'' links to download. Records generated from this meeting may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's Web site, *http://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

FOR FURTHER INFORMATION CONTACT: Melissa Wojnaroski, DFO, at 312–353–8311 or *mwojnaroski@usccr.gov.*

SUPPLEMENTARY INFORMATION:

Agenda

I. Welcome and Introductions—Naheed Bleecker, Chair
II. Hearing Preparation: Hate Crimes and Civil Rights in Wisconsin
- Panelists
- Logistics (schedule, location, date)

III. Open Comment—Public Participation
IV. Adjournment

Dated July 29, 2016.

David Mussatt,

Chief, Regional Programs Unit.

[FR Doc. 2016–18441 Filed 8–4–16; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Wisconsin Advisory Committee To Hear Testimony Regarding Civil Rights and Hate Crimes in Wisconsin

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Wisconsin Advisory Committee (Committee) will hold a meeting on Monday, July 29, 2016, from 1:00 p.m.–4:30 p.m. CDT. The Committee will hear testimony regarding civil rights and hate crimes in the state.

DATES: The meeting will be held on Monday August 29, 2016, from 1:00 p.m.–4:30 p.m. CDT.

ADDRESSES: This meeting is open to the public, and will take place at the Hampton Inn and Suites Conference Center, 8201 W. Greenfield Avenue, West Allis, WI 53214. Members of the public are invited to make statements during the open comment period beginning at 4:00 p.m. In addition, members of the public may submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be mailed to the Regional Programs Unit, U.S. Commission on Civil Rights, 55 W. Monroe St., Suite 410, Chicago, IL 60615. They may also be faxed to the Commission at (312) 353–8324, or emailed to Carolyn Allen at *callen@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (312) 353–8311.

Records and documents discussed during the meeting will be available for public viewing priorto and following the meeting at *https://database.faca.gov/committee/meetings.aspx?cid=282* and following the links for ''Meeting Details'' and then ''Documents.'' Records generated from this meeting may also be inspected and reproduced

at the Regional Programs Unit, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's Web site, *http://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

FOR FURTHER INFORMATION CONTACT: Melissa Wojnaroski, DFO, at 312–353–8311 or *mwojnaroski@usccr.gov.*

SUPPLEMENTARY INFORMATION:

Agenda

Opening Remarks and Introductions (1:00 p.m.–1:10 p.m.)
Panel 1: Academic (1:10 p.m.–2:25 p.m.)
Panel 2: Community (2:40 p.m.–3:55 p.m.)
Open Forum * (4:00 p.m.–4:30 p.m.)
Closing Remarks (4:30 p.m.)
* *Open forum may be extended as necessary to accommodate additional testimony.*

Dated July 29, 2016.

David Mussatt,

Chief, Regional Programs Unit.

[FR Doc. 2016–18442 Filed 8–4–16; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Bureau of the Census

[Docket Number 160725648–6648–01]

2020 Census Tribal Consultation Meetings

AGENCY: Bureau of the Census, Department of Commerce.

ACTION: Notice of 2020 Census tribal consultation meetings.

SUMMARY: Pursuant to Executive Order 13175, the Bureau of the Census (Census Bureau) is continuing tribal consultation meetings through calendar year 2016 with federally recognized tribes across the country as part of our ongoing government-to-government relations. The Census Bureau is planning to conduct tribal consultation meetings with federally recognized tribes across the country between September 2016 and December 2016. These meetings will provide a forum for tribes to share insights, make recommendations and discuss concerns related to the 2020 Census. The Census Bureau's procedures for outreach, notice and consultation will ensure involvement of tribes, to the extent practicable and permitted by law, before making decisions or implementing policies, rules or programs that affect federally recognized tribal governments. The Census Bureau requests that interested members of the public comment with any questions or topics they would like to see considered in these meetings. For a list of dates, locations and times please check *http://www.census.gov/aian/census_2020/.* These meetings are open to members of federally recognized tribes by invitation.

DATES: Any questions or topics to be considered in the tribal consultation meetings must be received in writing by September 9, 2016.

ADDRESSES: Please direct all comments on this notice to Dee Alexander, Tribal Affairs Coordinator, Office of Congressional and Intergovernmental Affairs, Intergovernmental Affairs Office, U.S. Census Bureau Washington, DC 20233; telephone (301) 763–9335 or fax (301) 763–3780 or by email *Dee.A.Alexander@census.gov.*

FOR FURTHER INFORMATION CONTACT: Dee Alexander, Tribal Affairs Coordinator, Office of Congressional and Intergovernmental Affairs, Intergovernmental Affairs Office, U.S. Census Bureau, at the above listed address and telephone number.

SUPPLEMENTARY INFORMATION:

Background

The Census Bureau's Decennial Directorate and the Intergovernmental Affairs Office is responsible for the development and implementation of outreach and promotion activities to assist in obtaining a complete and accurate census count in 2020 among all residents including the American Indian and Alaska Native (AIAN) populations. This program is one part of the overall outreach and promotion efforts directed at building awareness about the importance of the census and motivating response to the census in communities all across the country.

In accordance with Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, issued November 6, 2000, the Census Bureau will be adhering to its tribal consultation policy by seeking the input of tribal governments in the planning and implementation of the 2020 Census with the goal of ensuring the most accurate counts and data for the American Indian and Alaska Native population. In that regard, we are seeking comments with regard to the following operational topics:

Enumeration—Enumeration is the process of collecting data, and is the central focus of the decennial census operation. Most successful enumeration occurs at the respondent's domicile either through self-response, or through some method of non-response follow-up. The Census Bureau is exploring ways to increase its self-response rates, and is developing tools to ease the burden of responding by leveraging technology, and exploring new modalities to promote Internet response.

Demographic Statistics—Demographic statistics provide information that is used to develop an understanding of the age, sex, and racial composition of a population and how it has changed over time through the basic demographic processes of birth, death, and migration.

Geography—Geography is a determinative part of the decennial census operation because it provides meaning and context to decennial census counts. Geographic planning provides the framework for census design, data collection, tabulation, and data dissemination. The Census Bureau seeks to use the latest and best geographic methodologies available to support the decennial census.

2020 Census Field Partnerships and Recruitment—Partnership efforts focus on maximizing public engagement in the decennial census process in an effort to keep the public informed, encourage self-response, and assist with recruiting the workforce necessary to complete the decennial census. Partnership efforts are directed at individuals from all walks of life, as well as the widest variety of public, private and governmental organizations.

2020 Census Communications and Planning—Communications planning seeks to motivate the entire population of the 50 states and its territories to participate in the decennial census and its partnership activities. Communications planning will culminate in a communications campaign that will focus on increasing participation in self-response options, improving accuracy, reducing the differential undercount and improving cooperation with enumerators and field operations.

For additional information on the tribal consultation sessions please visit: *http://www.census.gov/aian/census_2020/.*

Dated: July 29, 2016.

John H. Thompson,

Director, Bureau of the Census.

[FR Doc. 2016–18645 Filed 8–4–16; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 2007]

Reorganization of Foreign-Trade Zone 70 (Expansion of Service Area) Under Alternative Site Framework; Detroit, Michigan

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Board adopted the alternative site framework (ASF) (15 CFR Sec. 400.2(c)) as an option for the establishment or reorganization of zones;

Whereas, the Greater Detroit Foreign-Trade Zone, Inc., grantee of Foreign-Trade Zone 70, submitted an application to the Board (FTZ Docket B–10–2016, docketed February 18, 2016, amended June 9, 2016) for authority to expand the service area of the zone to include Livingston County and a portion of Lenawee County, as described in the application, adjacent to the Detroit Customs and Border Protection port of entry;

Whereas, notice inviting public comment was given in the **Federal Register** (81 FR 9168, February 24, 2016) and the application has been processed pursuant to the FTZ Act and the Board's regulations; and,

Whereas, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and the Board's regulations are satisfied;

Now, Therefore, the Board hereby orders:

The amended application to reorganize FTZ 70 to expand the service area under the ASF to include Livingston County and a portion of Lenawee County is approved, subject to the FTZ Act and the Board's regulations, including Section 400.13, and to the Board's standard 2,000-acre activation limit for the zone.

Signed at Washington, DC, July 29, 2016.

Ronald K. Lorentzen,

Acting Assistant Secretary of Commerce for Enforcement and Compliance, Alternate Chairman, Foreign-Trade Zones Board.

ATTEST:

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2016–18658 Filed 8–4–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 2006]

Reorganization of Foreign-Trade Zone 172 Under Alternative Site Framework, Oneida County, New York

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Board adopted the alternative site framework (ASF) (15 CFR Sec. 400.2(c)) as an option for the establishment or reorganization of zones;

Whereas, the County of Oneida, grantee of Foreign-Trade Zone 172, submitted an application to the Board (FTZ Docket B–19–2016, docketed April 12, 2016) for authority to reorganize under the ASF with a service area of Oneida County, New York, adjacent to the Syracuse Customs and Border Protection port of entry, FTZ 172's existing Site 2a would be renumbered as Site 6 and included as a magnet site, Sites 1, 2, 3, 4, 5 and Subzone 172A would be removed from the zone, and the grantee proposes an additional magnet site (Site 7);

Whereas, notice inviting public comment was given in the **Federal Register** (81 FR 22210–22211, April 15, 2016) and the application has been processed pursuant to the FTZ Act and the Board's regulations; and,

Whereas, the Board adopts the findings and recommendation of the examiner's report, and finds that the requirements of the FTZ Act and the Board's regulations are satisfied;

Now, Therefore, the Board hereby orders:

The application to reorganize FTZ 172 under the ASF is approved, subject to the FTZ Act and the Board's regulations, including Section 400.13, to the Board's standard 2,000-acre activation limit for the zone, and to an ASF sunset provision for magnet sites that would terminate authority for Site 7 if not activated within five years from the month of approval.

Signed at Washington, DC, this 29th day of July 2016.

Ronald K. Lorentzen,

Acting Assistant Secretary of Commerce for Enforcement and Compliance, Alternate Chairman, Foreign-Trade Zones Board.

Attest:

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2016–18667 Filed 8–4–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–18–2016]

Authorization of Limited Production Activity; Foreign-Trade Zone (FTZ) 186—Waterville, Maine; Flemish Master Weavers; Subzone 186A (Area Rugs) Sanford, Maine

On March 31, 2016, the City of Waterville, Maine, grantee of FTZ 186, submitted a notification of proposed production activity to the FTZ Board on behalf of Flemish Master Weavers, within Subzone 186A, in Sanford, Maine.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (81 FR 22210, April 15, 2016). The FTZ Board has determined that further review of part of the proposed activity is warranted at this time. The production activity described in the notification is authorized on a limited basis, subject to the FTZ Act and the Board's regulations, including Section 400.14, and further subject to a restriction requiring that foreign-status polypropylene and polyester yarns (HTSUS Subheadings 5402.59 and 5402.33) be admitted to the subzone in privileged foreign status (19 CFR 146.41).

Dated: July 29, 2016.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2016–18539 Filed 8–4–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review

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

FOR FURTHER INFORMATION CONTACT: Brenda E. Waters, Office of AD/CVD Operations, Customs Liaison Unit, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230, telephone: (202) 482–4735.

Background

Each year during the anniversary month of the publication of an

antidumping or countervailing duty order, finding, or suspended investigation, an interested party, as defined in section 771(9) of the Tariff Act of 1930, as amended (''the Act''), may request, in accordance with 19 CFR 351.213, that the Department of Commerce (''the Department'') conduct an administrative review of that antidumping or countervailing duty order, finding, or suspended investigation.

All deadlines for the submission of comments or actions by the Department discussed below refer to the number of calendar days from the applicable starting date.

Respondent Selection

In the event the Department limits the number of respondents for individual examination for administrative reviews initiated pursuant to requests made for the orders identified below, the Department intends to select respondents based on U.S. Customs and Border Protection (''CBP'') data for U.S. imports during the period of review. We intend to release the CBP data under Administrative Protective Order (''APO'') to all parties having an APO within five days of publication of the initiation notice and to make our decision regarding respondent selection within 21 days of publication of the initiation **Federal Register** notice. Therefore, we encourage all parties interested in commenting on respondent selection to submit their APO applications on the date of publication of the initiation notice, or as soon thereafter as possible. The Department invites comments regarding the CBP data and respondent selection within five days of placement of the CBP data on the record of the review.

In the event the Department decides it is necessary to limit individual examination of respondents and conduct respondent selection under section 777A(c)(2) of the Act:

In general, the Department finds that determinations concerning whether particular companies should be ''collapsed'' (*i.e.,* treated as a single entity for purposes of calculating antidumping duty rates) require a substantial amount of detailed information and analysis, which often require follow-up questions and analysis. Accordingly, the Department will not conduct collapsing analyses at the respondent selection phase of this review and will not collapse companies at the respondent selection phase unless there has been a determination to collapse certain companies in a previous segment of this antidumping proceeding (*i.e.,* investigation, administrative review, new shipper review or changed circumstances review). For any company subject to this review, if the Department determined, or continued to treat, that company as collapsed with others, the Department will assume that such companies continue to operate in the same manner and will collapse them for respondent selection purposes. Otherwise, the Department will not collapse companies for purposes of respondent selection. Parties are requested to (a) identify which companies subject to review previously were collapsed, and (b) provide a citation to the proceeding in which they were collapsed. Further, if companies are requested to complete the Quantity and Value Questionnaire for purposes of respondent selection, in general each company must report volume and value data separately for itself. Parties should not include data for any other party, even if they believe they should be treated as a single entity with that other party. If a company was collapsed with another company or companies in the most recently completed segment of this proceeding where the Department considered collapsing that entity, complete quantity and value data for that collapsed entity must be submitted.

Deadline for Withdrawal of Request for Administrative Review

Pursuant to 19 CFR 351.213(d)(1), a party that requests a review may withdraw that request within 90 days of the date of publication of the notice of initiation of the requested review. The regulation provides that the Department may extend this time if it is reasonable to do so. In order to provide parties additional certainty with respect to when the Department will exercise its discretion to extend this 90-day deadline, interested parties are advised that, with regard to reviews requested on the basis of anniversary months on or after August 2016, the Department does not intend to extend the 90-day deadline unless the requestor demonstrates that an extraordinary circumstance prevented it from submitting a timely withdrawal request. Determinations by the Department to extend the 90-day deadline will be made on a case-by-case basis.

The Department is providing this notice on its Web site, as well as in its ''Opportunity to Request Administrative Review'' notices, so that interested parties will be aware of the manner in which the Department intends to exercise its discretion in the future.

Opportunity to request a review: Not later than the last day of August 2016,[1] interested parties may request administrative review of the following orders, findings, or suspended investigations, with anniversary dates in August for the following periods:

	Period of review
Antidumping Duty Proceedings	
GERMANY:	
Seamless Line and Pressure Pipe A–428–820	8/1/15–7/31/16
Sodium Nitrite A–428–841	8/1/15–7/31/16
ITALY: Granular Polytetrafluorethylene Resin A–475–703	8/1/15–7/31/16
JAPAN:	
Brass Sheet & Strip A–588–704	8/1/15–7/31/16
Tin Mill Products A–588–854	8/1/15–7/31/16
MALAYSIA: Polyethylene Retail Carrier Bags A–557–813	8/1/15–7/31/16
MEXICO: Light-Walled Rectangular Pipe and Tube A–201–836	8/1/15–7/31/16
REPUBLIC OF KOREA:	
Large Power Transformers A–580–867	8/1/15–7/31/16
Light-Walled Rectangular Pipe and Tube A–580–859	8/1/15–7/31/16
ROMANIA: Carbon and Alloy Seamless Standard, Line, and Pressure Pipe (under 4½ inches) A–485–805	8/1/15–7/31/16
SOCIALIST REPUBLIC OF VIETNAM: Frozen Fish Fillets A–552–801	8/1/15–7/31/16

[1] Or the next business day, if the deadline falls on a weekend, federal holiday or any other day when the Department is closed.

	Period of review
THAILAND: Polyethylene Retail Carrier Bags A–549–821	8/1/15–7/31/16
THE PEOPLE'S REPUBLIC OF CHINA:	
Floor-Standing, Metal-Top Ironing Tables and Parts Thereof A–570–888	8/1/15–7/31/16
Laminated Woven Sacks A–570–916	8/1/15–7/31/16
Light-Walled Rectangular Pipe and Tube A–570–914	8/1/15–7/31/16
Passenger Vehicle and Light Truck Tires A–570–016	1/27/15–7/31/16
Petroleum Wax Candles A–570–504	8/1/15–7/31/16
Polyethylene Retail Carrier Bags A–570–886	8/1/15–7/31/16
Sodium Nitrate A–570–925	8/1/15–7/31/16
Steel Nails A–570–909	8/1/15–7/31/16
Sulfanilic Acid A–570–815	8/1/15–7/31/16
Tetrahydrofurfuryl Alcohol A–570–887	8/1/15–7/31/16
Tow-Behind Lawn Groomers and Parts Thereof A–570–939	8/1/15–7/31/16
UKRAINE: Silicomanganese A–823–805	8/1/15–7/31/16
Countervailing Duty Proceedings	
REPUBLIC OF KOREA: Stainless Steel Sheet and Strip in Coil C–580–835	1/1/15–12/31/15
THE PEOPLE'S REPUBLIC OF CHINA:	
Laminated Woven Sacks C–570–917	1/1/15–12/31/15
Light-Walled Rectangular Pipe and Tube C–570–915	1/1/15–12/31/15
Passenger Vehicle and Light Truck Tires C–570–017	12/1/14–12/31/15
Sodium Nitrite C–570–926	1/1/15–12/31/15
Suspension Agreements	
None	

In accordance with 19 CFR 351.213(b), an interested party as defined by section 771(9) of the Act may request in writing that the Secretary conduct an administrative review. For both antidumping and countervailing duty reviews, the interested party must specify the individual producers or exporters covered by an antidumping finding or an antidumping or countervailing duty order or suspension agreement for which it is requesting a review. In addition, a domestic interested party or an interested party described in section 771(9)(B) of the Act must state why it desires the Secretary to review those particular producers or exporters. If the interested party intends for the Secretary to review sales of merchandise by an exporter (or a producer if that producer also exports merchandise from other suppliers) which was produced in more than one country of origin and each country of origin is subject to a separate order, then the interested party must state specifically, on an order-by-order basis, which exporter(s) the request is intended to cover.

Note that, for any party the Department was unable to locate in prior segments, the Department will not accept a request for an administrative review of that party absent new information as to the party's location. Moreover, if the interested party who files a request for review is unable to locate the producer or exporter for which it requested the review, the interested party must provide an explanation of the attempts it made to locate the producer or exporter at the same time it files its request for review, in order for the Secretary to determine if the interested party's attempts were reasonable, pursuant to 19 CFR 351.303(f)(3)(ii).

As explained in *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003), and *Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011) the Department clarified its practice with respect to the collection of final antidumping duties on imports of merchandise where intermediate firms are involved. The public should be aware of this clarification in determining whether to request an administrative review of merchandise subject to antidumping findings and orders.[2]

Further, as explained in *Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963 (November 4, 2013), the Department clarified its practice with regard to the conditional review of the non-market economy (NME) entity in administrative reviews of antidumping duty orders. The Department will no longer consider the NME entity as an exporter conditionally subject to administrative reviews. Accordingly, the NME entity will not be under review unless the Department specifically receives a request for, or self-initiates, a review of the NME entity.[3] In administrative reviews of antidumping duty orders on merchandise from NME countries where a review of the NME entity has not been initiated, but where an individual exporter for which a review was initiated does not qualify for a separate rate, the Department will issue a final decision indicating that the company in question is part of the NME entity. However, in that situation, because no review of the NME entity was conducted, the NME entity's entries were not subject to the review and the rate for the NME entity is not subject to change as a result of that review (although the rate for the individual exporter may change as a function of the finding that the exporter is part of the NME entity). Following initiation of an antidumping administrative review when there is no review requested of the NME entity, the Department will instruct CBP to liquidate entries for all exporters not named in the initiation notice, including those that were suspended at the NME entity rate.

[2] *See also* the Enforcement and Compliance Web site at *http://trade.gov/enforcement/.*

[3] In accordance with 19 CFR 351.213(b)(1), parties should specify that they are requesting a review of entries from exporters comprising the entity, and to the extent possible, include the names of such exporters in their request.

All requests must be filed electronically in Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (''ACCESS'') on Enforcement and Compliance's ACCESS Web site at *http://access.trade.gov.*[4] Further, in accordance with 19 CFR 351.303(f)(l)(i), a copy of each request must be served on the petitioner and each exporter or producer specified in the request.

The Department will publish in the **Federal Register** a notice of ''Initiation of Administrative Review of Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation'' for requests received by the last day of August 2016. If the Department does not receive, by the last day of August 2016, a request for review of entries covered by an order, finding, or suspended investigation listed in this notice and for the period identified above, the Department will instruct CBP to assess antidumping or countervailing duties on those entries at a rate equal to the cash deposit of (or bond for) estimated antidumping or countervailing duties required on those entries at the time of entry, or withdrawal from warehouse, for consumption and to continue to collect the cash deposit previously ordered.

For the first administrative review of any order, there will be no assessment of antidumping or countervailing duties on entries of subject merchandise entered, or withdrawn from warehouse, for consumption during the relevant provisional-measures ''gap'' period of the order, if such a gap period is applicable to the period of review.

This notice is not required by statute but is published as a service to the international trading community.

Dated: July 28, 2016.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2016–18540 Filed 8–4–16; 8:45 am]

BILLING CODE 3510–DS–P

[4] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–992]

Monosodium Glutamate From the People's Republic of China: Preliminary Results of the Antidumping Duty Administrative Review; 2014–2015

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

SUMMARY: The Department of Commerce (the ''Department'') is conducting the first administrative review of the antidumping duty order on monosodium glutamate (''MSG'') from the People's Republic of China (''PRC'') covering the period of review (''POR'') May 8, 2014 through October 31, 2015. This review covers 38 manufacturers/exporters (''the companies'') of the subject merchandise. None of these companies have filed a separate rate application (''SRA'') and/or a separate rate certification (''SRC'') to establish its separate rate status. Therefore, the Department preliminarily finds that the companies are part of the PRC-wide entity. We invite interested parties to comment on these preliminary results.

DATES: Effective August 5, 2016.

FOR FURTHER INFORMATION CONTACT: Kathryn Wallace or Alexander Cipolla, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–6251 or (202) 482–4956, respectively.

SUPPLEMENTARY INFORMATION:

Background

On November 3, 2015, the Department published a notice of opportunity to request an administrative review of the antidumping duty order on MSG from the PRC.[1] In response, on November 30, 2015, Ajinomoto North America, Inc. (''Petitioner'' or ''Ajinomoto'') requested a review of 38 companies.[2] Also on November 20, 2015, Neimenggu Fufeng Biotechnologies Co., Ltd. and its affiliate, Hulunbeier Northeast Fufeng Biotechnologies Co., Ltd. (collectively, ''Fufeng'') requested a review.[3] The Department initiated a review of all 38 companies, which included Fufeng, on January 7, 2016.[4] On February 8, 2016, Fufeng timely withdrew its request for review.[5] No party timely submitted an SRA or an SRC.[6] Thereafter, Petitioner submitted comments on the Department's selection of respondents, encouraging the Department to employ its customary policy to treat companies as a part of the country-wide entity in reviews where no party submits an SRA or SRC.[7]

Scope of the Order

The product covered by this order is MSG, whether or not blended or in solution with other products. Specifically, MSG that has been blended or is in solution with other product(s) is included in this scope when the resulting mix contains 15 percent or more of MSG by dry weight. Products with which MSG may be blended include, but are not limited to, salts, sugars, starches, maltodextrins, and various seasonings. Further, MSG is included in this order regardless of physical form (including, but not limited to, in monohydrate or anhydrous form, or as substrates, solutions, dry powders of any particle size, or unfinished forms such as MSG slurry), end-use application, or packaging. MSG in monohydrate form has a molecular formula of $C5H8NO4Na\text{-}H_2O$, a Chemical Abstract Service (CAS) registry number of 6106–04–3, and a Unique Ingredient Identifier (UNII) number of W81N5U6R6U. MSG in anhydrous form has a molecular formula of C5H8NO4Na, a CAS registry number of l42–47–2, and a UNII number of C3C196L9FG. Merchandise covered by the scope of this order is currently

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review,* 80 FR 67706 (November 3, 2015).

[2] *See* Letter from Ajinomoto to the Department of Commerce, Re: ''Monosodium Glutamate from China: Request for Administrative Review,'' dated November 30, 2015, at footnote 1 which lists 38 companies for which Ajinomoto sought review.

[3] *See* Letter from Fufeng to the Department of Commerce, Re: ''Request for the First Administrative Review of the Antidumping Duty Order on Monosodium Glutamate from the People's Republic of China,'' dated November 30, 2015.

[4] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 81 FR 736 (January 7, 2016) (''Initiation Notice'').

[5] *See* Letter from Fufeng to the Department of Commerce, Re: ''Withdrawal of Review Request: First Administrative Review of the Antidumping Duty Order on Monosodium Glutamate from the People's Republic of China,'' dated February 8, 2016. Because the Petitioner's request for review included Fufeng, it was not removed from the administrative review.

[6] Because of tolling, the deadline for SRAs and SRCs was extended four business days until February 12, 2016. *See* Memorandum from Ron Lorentzen, Acting Assistant Secretary for Enforcement and Compliance, Re: ''Tolling of Administrative Deadlines as a Result of the Government Closure during Snowstorm 'Jonas,' '' dated January 27, 2016.

[7] *See* Letter from Ajinomoto to the Department of Commerce, Re: ''MSG from China: Comments on Respondent Selection,'' dated February 29, 2016.

classified in the Harmonized Tariff Schedule of the United States (''HTSUS'') at subheading 2922.42.10.00. Merchandise subject to the order may also enter under HTS subheadings 2922.42.50.00, 2103.90.72.00, 2103.90.74.00, 2103.90.78.00, 2103.90.80.00, and 2103.90.90.91. The tariff classifications, CAS registry numbers, and UNII numbers are provided for convenience and customs purposes; however, the written description of the scope is dispositive.[8]

Methodology

The Department is conducting this review in accordance with section 751(a)(1)(B) of the Tariff Act of 1930, as amended (''the Act''), and 19 CFR 351.213.[9]

Preliminary Results of Review

The Department's policy regarding conditional review of the PRC-wide entity applies to this administrative review.[10] Under this policy, the PRC-wide entity will not be under review unless a party specifically requests, or the Department self-initiates, a review of the entity.

The Department preliminarily determines that the 38 companies subject to review are part of the PRC-wide entity. None of the 38 companies filed an SRA or an SRC. No review has been requested for the PRC-wide entity. Therefore, the Department preliminarily determines that these companies have not demonstrated their eligibility for separate rate status and are part of the PRC-wide entity. The PRC-wide entity rate is 40.41 percent.[11]

Public Comment

Interested parties are invited to comment on the preliminary results and may submit case briefs and/or written comments, filed electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS), within 30 days after the date of publication of these preliminary results of review.[12] ACCESS is available to registered users at *http://access.trade.gov* and is available to all parties in the Central Records Unit in Room B8024 of the main Commerce building. Rebuttal briefs, limited to issues raised in the case briefs, must be filed within five days after the time limit for filing case briefs.[13] Parties who submit case or rebuttal briefs in this proceeding are requested to submit with each argument a statement of the issue, a brief summary of the argument, and a table of authorities.[14]

Interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request to the Department within 30 days of the date of publication of this notice.[15] Requests should contain: (1) The party's name, address and telephone number; (2) The number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs. If a request for a hearing is made, parties will be notified of the time and date for the hearing to be held at the U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230.[16] The Department intends to issue the final results of this administrative review, which will include the results of our analysis of all issues raised in the case briefs, within 120 days of publication of these preliminary results in the **Federal Register**, unless extended, pursuant to section 751(a)(3)(A) of the Act.

Assessment Rates

Upon issuance of the final results of this review, the Department will determine, and U.S. Customs and Border Protection (''CBP'') shall assess, antidumping duties on all appropriate entries of subject merchandise covered by this review.[17] We intend to instruct CBP to liquidate entries containing subject merchandise exported by the companies under review that we determine in the final results to be part of the PRC-wide entity at the PRC-wide rate of 40.41 percent. The Department intends to issue assessment instructions to CBP 15 days after the date of publication of this review in the **Federal Register**.[18]

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this review for shipments of the subject merchandise from the PRC entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by sections 751(a)(2)(C) of the Act: (1) For companies that have a separate rate, the cash deposit rate will be that established in the final results of this review (except, if the rate is zero or *de minimis,* then zero cash deposit will be required); (2) for previously investigated or reviewed PRC and non-PRC exporters not listed above that received a separate rate in a prior segment of this proceeding, the cash deposit rate will continue to be the existing exporter-specific rate; (3) for all PRC exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be that for the PRC-wide entity (*i.e.,* 40.41 percent); and (4) for all non-PRC exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporter that supplied that non-PRC exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a reminder to importers of their responsibility under 19 CFR 315.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Department's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

We are issuing and publishing these preliminary results in accordance with sections 751(a)(1) and 777(i) of the Act, and 19 CFR 351.213(h) and 351.221(b)(4).

[8] *See Monosodium Glutamate From the People's Republic of China: Second Amended Final Determination of Sales at Less Than Fair Value and Amended Antidumping Order,* 80 FR 487 (January 6, 2015).

[9] For a complete description of the methodology underlying this preliminary result, *see* ''Decision Memorandum for the Preliminary Results of the Antidumping Duty Administrative Review of Monosodium Glutamate from the People's Republic of China; 2014–2015,'' at 3–4 (dated concurrently with this notice).

[10] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963, 65970 (November 4, 2013).

[11] *See Monosodium Glutamate From the People's Republic of China: Second Amended Final Determination of Sales at Less Than Fair Value and Amended Antidumping Duty Order,* 80 FR 487 (January 6, 2015).

[12] *See* 19 CFR 351.309(c)(1)(ii).

[13] *See* 19 CFR 351.309(d)(1) and (2).

[14] *See* 19 CFR 351.309(c) and (d); *see also* 19 CFR 351.303 (for general filing requirements).

[15] *See* 19 CFR 351.310(c)

[16] *See* 19 CFR 310(d).

[17] *See* 19 CFR 351.212(b)(1).

[18] For a full discussion of this practice, *see Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011).

Dated: August 1, 2016.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

1. Summary
2. Background
3. Scope of the Order
4. Non-Market Economy Country Status
5. PRC-Wide Entity

[FR Doc. 2016–18669 Filed 8–4–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Advance Notification of Sunset Reviews

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

Background

Every five years, pursuant to section 751(c) of the Tariff Act of 1930, as amended (''the Act''), the Department of Commerce (''the Department'') and the International Trade Commission automatically initiate and conduct a review to determine whether revocation of a countervailing or antidumping duty order or termination of an investigation suspended under section 704 or 734 of the Act would be likely to lead to continuation or recurrence of dumping or a countervailable subsidy (as the case may be) and of material injury.

Upcoming Sunset Reviews for September 2016

The following Sunset Reviews are scheduled for initiation in September 2016 and will appear in that month's Notice of Initiation of Five-Year Sunset Review (''Sunset Review'').

	Department Contact
Antidumping Duty Proceedings	
Sulfanilic Acid from China (A–570–815) (4th Review)	David Goldberger: (202) 482–4136.
Sulfanilic Acid from India (A–533–806) (4th Review)	David Goldberger: (202) 482–4136.
Carbon and Alloy Seamless Standard, Line, and Pressure Pipe (A–588–850) (Over 4½ Inches) from Japan (3rd Review).	David Goldberger: (202) 482–4136.
Carbon and Alloy Seamless Standard, Line, and Pressure Pipe (A–588–851) (Under 4½ Inches) from Japan (3rd Review).	David Goldberger: (202) 482–4136.
Carbon and Alloy Seamless Standard, Line, and Pressure Pipe (A–485–805) (Under 4½ Inches) from Romania (3rd Review).	David Goldberger: (202) 482–4136.
Countervailing Duty Proceedings	
Sulfanilic Acid from India (C–533–807) (4th Review)	David Goldberger: (202) 482–4136.
Suspended Investigations	
No Sunset Review of suspended investigations is scheduled for initiation in September 2016.	

The Department's procedures for the conduct of Sunset Reviews are set forth in 19 CFR 351.218. The Notice of Initiation of Five-Year (''Sunset'') Reviews provides further information regarding what is required of all parties to participate in Sunset Reviews.

Pursuant to 19 CFR 351.103(c), the Department will maintain and make available a service list for these proceedings. To facilitate the timely preparation of the service list(s), it is requested that those seeking recognition as interested parties to a proceeding contact the Department in writing within 10 days of the publication of the Notice of Initiation.

Please note that if the Department receives a Notice of Intent to Participate from a member of the domestic industry within 15 days of the date of initiation, the review will continue. Thereafter, any interested party wishing to participate in the Sunset Review must provide substantive comments in response to the notice of initiation no later than 30 days after the date of initiation.

This notice is not required by statute but is published as a service to the international trading community.

Dated: July 28, 2016.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2016–18537 Filed 8–4–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–967]

Aluminum Extrusions From the People's Republic of China: Final Results of Expedited First Sunset Review of the Antidumping Duty Order

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

SUMMARY: As a result of this sunset review, the Department of Commerce (the Department) finds that revocation of the antidumping duty order on aluminum extrusions from the People's Republic of China (PRC) would be likely to lead to continuation or recurrence of dumping at the levels indicated in the ''Final Results of Sunset Review'' section of this notice.

DATES: *Effective* August 5, 2016.

FOR FURTHER INFORMATION CONTACT: Deborah Scott or Robert James, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street & Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–2657 or (202) 482–0649, respectively.

SUPPLEMENTARY INFORMATION:

Background

On May 26, 2011, the Department published the notice of the antidumping duty order on aluminum extrusions from the PRC.[1] On April 1, 2016, the Department published the notice of initiation of the first sunset review of

[1] *See Aluminum Extrusions from the People's Republic of China: Antidumping Duty Order,* 76 FR 30650 (May 26, 2011) (*AD Order*).

the *AD Order,* pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] On April 18, 2016, the Department received a notice of intent to participate in this review from the Aluminum Extrusions Fair Trade Committee (Petitioner or Committee) within the deadline specified in 19 CFR 351.218(d)(1)(i).[3] Petitioner claimed interested party status under section 771(9)(E) of the Act and 19 CFR 351.102(b)(29)(vii) as a coalition of U.S. producers of the domestic like product, and the individual Committee members claimed interested party status under section 771(9)(C) of the Act and 19 CFR 351.102(b)(29)(v) as U.S. producers of the domestic like product. On May 2, 2016, the Department received a complete substantive response from Petitioner within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).[4] We received no substantive responses from respondent interested parties with respect to the *AD Order.* As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), the Department conducted an expedited (120-day) sunset review of the *AD Order.*

Scope of the Order

The merchandise covered by the order is aluminum extrusions which are shapes and forms, produced by an extrusion process, made from aluminum alloys having metallic elements corresponding to the alloy series designations published by The Aluminum Association commencing with the numbers 1, 3, and 6 (or proprietary equivalents or other certifying body equivalents).[5]

Imports of the subject merchandise are provided for under the following categories of the Harmonized Tariff Schedule of the United States (HTSUS): 8424.90.9080, 9405.99.4020, 9031.90.90.95, 7616.10.90.90, 7609.00.00, 7610.10.00, 7610.90.00, 7615.10.30, 7615.10.71, 7615.10.91, 7615.19.10, 7615.19.30, 7615.19.50, 7615.19.70, 7615.19.90, 7615.20.00, 7616.99.10, 7616.99.50, 8479.89.98, 8479.90.94, 8513.90.20, 9403.10.00, 9403.20.00, 7604.21.00.00, 7604.29.10.00, 7604.29.30.10, 7604.29.30.50, 7604.29.50.30, 7604.29.50.60, 7608.20.00.30, 7608.20.00.90, 8302.10.30.00, 8302.10.60.30, 8302.10.60.60, 8302.10.60.90, 8302.20.00.00, 8302.30.30.10, 8302.30.30.60, 8302.41.30.00, 8302.41.60.15, 8302.41.60.45, 8302.41.60.50, 8302.41.60.80, 8302.42.30.10, 8302.42.30.15, 8302.42.30.65, 8302.49.60.35, 8302.49.60.45, 8302.49.60.55, 8302.49.60.85, 8302.50.00.00, 8302.60.90.00, 8305.10.00.50, 8306.30.00.00, 8414.59.60.90, 8415.90.80.45, 8418.99.80.05, 8418.99.80.50, 8418.99.80.60, 8419.90.10.00, 8422.90.06.40, 8473.30.20.00, 8473.30.51.00, 8479.90.85.00, 8486.90.00.00, 8487.90.00.80, 8503.00.95.20, 8508.70.00.00, 8515.90.20.00, 8516.90.50.00, 8516.90.80.50, 8517.70.00.00, 8529.90.73.00, 8529.90.97.60, 8536.90.80.85, 8538.10.00.00, 8543.90.88.80, 8708.29.50.60, 8708.80.65.90, 8803.30.00.60, 9013.90.50.00, 9013.90.90.00, 9401.90.50.81, 9403.90.10.40, 9403.90.10.50, 9403.90.10.85, 9403.90.25.40, 9403.90.25.80, 9403.90.40.05, 9403.90.40.10, 9403.90.40.60, 9403.90.50.05, 9403.90.50.10, 9403.90.50.80, 9403.90.60.05, 9403.90.60.10, 9403.90.60.80, 9403.90.70.05, 9403.90.70.10, 9403.90.70.80, 9403.90.80.10, 9403.90.80.15, 9403.90.80.20, 9403.90.80.41, 9403.90.80.51, 9403.90.80.61, 9506.11.40.80, 9506.51.40.00, 9506.51.60.00, 9506.59.40.40, 9506.70.20.90, 9506.91.00.10, 9506.91.00.20, 9506.91.00.30, 9506.99.05.10, 9506.99.05.20, 9506.99.05.30, 9506.99.15.00, 9506.99.20.00, 9506.99.25.80, 9506.99.28.00, 9506.99.55.00, 9506.99.60.80, 9507.30.20.00, 9507.30.40.00, 9507.30.60.00, 9507.90.60.00, and 9603.90.80.50.

The subject merchandise entered as parts of other aluminum products may be classifiable under the following additional Chapter 76 subheadings: 7610.10, 7610.90, 7615.19, 7615.20, and 7616.99, as well as under other HTSUS chapters. In addition, fin evaporator coils may be classifiable under HTSUS numbers: 8418.99.80.50 and 8418.99.80.60. While HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this *AD Order* is dispositive.

Analysis of Comments Received

A complete discussion of all issues raised in this review, including the likelihood of continuation or recurrence of dumping in the event of revocation and the magnitude of the margins likely to prevail if the order were revoked, is provided in the accompanying Issues and Decision Memorandum, which is hereby adopted by this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov* and to all parties in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the Internet at *http://enforcement.trade.gov/frn/.* The signed Issues and Decision Memorandum and the electronic version of the Issues and Decision Memorandum are identical in content.

Final Results of Sunset Review

Pursuant to sections 751(c)(1) and 752(c)(1) and (3) of the Act, the Department determines that revocation of the *AD Order* would be likely to lead to continuation or recurrence of dumping, and that the magnitude of the dumping margins likely to prevail would be weighted-average margins up to 33.28 percent.

Notification to Interested Parties

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

We are issuing and publishing these results and notice in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act, 19 CFR 351.218, and 19 CFR 351.221(c)(5)(ii).

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[2] *See Initiation of Five-Year (''Sunset'') Review,* 81 FR 18829 (April 1, 2016).

[3] *See* Letter from Petitioner to the Department, ''Aluminum Extrusions from the People's Republic of China: Notice of Intent to Participate in Review,'' dated April 18, 2016.

[4] *See* Letter from Petitioner to the Department, ''Aluminum Extrusions from the People's Republic of China: AEFTC's Substantive Response to the Department's Notice of Initiation of its Five-Year (''Sunset'') Review,'' dated May 2, 2016 (Substantive Response).

[5] *See* Memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Ronald K. Lorentzen, Acting Assistant Secretary for Enforcement and Compliance, ''Issues and Decision Memorandum for the Final Results of the Expedited First Sunset Review of the Antidumping Duty Order on Aluminum Extrusions from the People's Republic of China,'' dated concurrently with this notice (Issues and Decision Memorandum) for a complete description of the scope of the *Order.*

Dated: July 29, 2016.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2016–18649 Filed 8–4–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–507–502]

Certain In-Shell (Raw) Pistachios From the Islamic Republic of Iran: Final Results of the Expedited Sunset Review of the Antidumping Duty Order

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

DATES: Effective August 5, 2016.

SUMMARY: As a result of this sunset review, the Department of Commerce (the Department) finds that revocation of the antidumping duty order on certain in-shell (raw) pistachios (pistachios) from the Islamic Republic of (Iran) would be likely to lead to continuation or recurrence of dumping at the rates identified in the ''Final Results of Review'' section of this notice.

FOR FURTHER INFORMATION CONTACT: Jacqueline Arrowsmith or Madeline Heeren, AD/CVD Operations, Offices VII and VI, respectively, Enforcement and Compliance, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone (202) 482–5255 and (202) 482–9179, respectively.

SUPPLEMENTARY INFORMATION:

Background

The Department published the antidumping duty order on pistachios from Iran on July 17, 1986.[1] On April 1, 2016, pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act), the Department initiated a sunset review of the antidumping duty order on pistachios from Iran.[2] On April 11, 2016, and April 13, 2016, the Department received notices of intent to participate from Wonderful Pistachios & Almonds LLC (WP&A) and American Pistachio Growers (APG), respectively (collectively, the Domestic Interested Parties), within the deadline specified in 19 CFR 351.218(d)(1)(i). The Domestic Interested Parties are manufacturers of a domestic like product in the United States and, accordingly, are domestic interested parties pursuant to section 771(9)(C) of the Act.

On April 29, 2016, and May 2, 2016, the Department received an adequate substantive response to the notice of initiation from WP&A and APG, respectively, within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i). The Department did not receive any timely filed responses from the respondent interested parties, *i.e.,* pistachio producers and exporters from Iran. The Department did receive an untimely substantive response from Tehran Negah Nima, trading as Nima Trading Company (Nima). As this response was untimely, the Department rejected the submission.[3] On the basis of the notices of intent to participate and adequate substantive responses filed by the Domestic Interested Parties and the inadequate response from any respondent interested party, the Department conducted an expedited sunset review of the order pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C).

Scope of the Order

The products covered by the order are raw,[4] in-shell pistachio nuts from which the hulls have been removed, leaving the inner hard shells, and edible meats from Iran. This merchandise is provided for in subheading 0802.51.00.00 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this order is dispositive.

Analysis of Comments Received

The issues discussed in the Decision Memorandum [5] are the likelihood of continuation or recurrence of dumping and the magnitude of the margins of dumping likely to prevail if this order was revoked. Parties can find a complete discussion of all issues raised in this review, and the corresponding recommendations, in the Decision Memorandum which is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov* and is available to all parties in the Central Records Unit in room B8024 of the main Commerce building. In addition, a complete version of the Decision Memorandum can be accessed directly on the Internet at *http://trade.gov/enforcement/.* The signed Decision Memorandum and electronic versions of the Decision Memorandum are identical in content.

Final Results of Review

Pursuant to sections 752(c)(1) and (3) of the Act, we determine that revocation of the antidumping duty order of pistachios from Iran would be likely to lead to continuation or recurrence of dumping at weighted average margins up to the following:

Exporter/producer	Margin (percent)
Rafsanjan Pistachios Cooperative	241.14
Tehran Negah Nima Trading Company, Inc./Maghsoudi Farms	241.14
Tehran Negah Nima Trading Company, Inc./Razi Domghan Agricultural and Animal Husbandry Company	241.14
All-Others Rate	241.14

[1] *See Antidumping Duty Order; Certain In-Shell Pistachios from Iran,* 51 FR 25922 (July 17, 1986) (*Iran Order*).

[2] *See Initiation of Five-Year* (''*Sunset*'') *Review,* 81 FR 18829 (April 1, 2016) (*Sunset Initiation*).

[3] *See* the memorandum to the file from Madeline Heeren entitled, ''Request to Take Action on Certain Barcodes,'' dated May 17, 2016 (Rejection Memo); *see also* letter from the Department to Nima, dated May 17, 2016 (Rejection Letter).

[4] *See Certain In-Shell Pistachios From Iran; Clarification of Scope in Antidumping Duty Investigation,* 51 FR 23254 (June 26, 1986).

[5] *See* Memorandum to Ronald K. Lorentzen, Acting Assistant Secretary for Enforcement and Compliance, from Christian Marsh, Deputy Assistant Secretary for Antidumping and Counter vailing Duty Operations, titled ''Issues and Decision Memorandum for the Expedited Sunset Review of the Antidumping Duty Order on Certain In-Shell (Raw) Pistachios from the Islamic Republic of Iran; Final Results,'' dated concurrently with this notice (Decision Memorandum).

Administrative Protective Order

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return of destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

The Department is issuing and publishing these final results and notice in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act and 19 CFR 351.218.

Dated: July 29, 2016.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2016–18673 Filed 8–4–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–885]

Phosphor Copper From the Republic of Korea: Postponement of Preliminary Determination of Antidumping Duty Investigation

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

DATES: Effective August 5, 2016.

FOR FURTHER INFORMATION CONTACT: Cindy Robinson at (202) 482–3797, AD/CVD Operations, Enforcement and Compliance, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On April 5, 2016, the Department of Commerce (the Department) initiated an antidumping duty investigation of imports of phosphor copper from the Republic of Korea.[1] The notice of initiation stated that, in accordance with section 733(b)(l)(A) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.205(b)(1), we would issue our preliminary determination no later than 140 days after the date of initiation, unless postposed. Currently, the preliminary determination is due no later than August 16, 2016.

Postponement of Preliminary Determination

Sections 733(c)(1)(B)(i) and (ii) of the Act permit the Department to postpone the time limit for the preliminary determination if it concludes that the parties concerned are cooperating and determines that the case is extraordinarily complicated by reason of the number and complexity of the transactions to be investigated or adjustments to be considered, the novelty of the issues presented, or the number of firms whose activities must be investigated, and additional time is necessary to make the preliminary determination. Under this section of the Act, the Department may postpone the preliminary determination until no later than 190 days after the date on which the Department initiated the investigation.

The Department determines that the parties involved in this phosphor copper investigation are cooperating, and that the investigation is extraordinarily complicated. Additional time is required to analyze the questionnaire responses and issue appropriate requests for clarification and additional information.

Therefore, in accordance with section 733(c)(1)(B) of the Act and 19 CFR 351.205(f)(1), the Department is postponing the time period for the preliminary determination of this investigation by 50 days, to October 5, 2016. Pursuant to section 735(a)(l) of the Act and 19 CFR 351.210(b)(1), the deadline for the final determination will continue to be 75 days after the date of the preliminary determination, unless postponed at a later date.

This notice is issued and published pursuant to section 733(c)(2) of the Act and 19 CFR 351.205(f)(1).

Dated: July 29, 2016.

Ronald Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2016–18544 Filed 8–4–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–968]

Aluminum Extrusions from the People's Republic of China: Final Results of Expedited First Sunset Review of the Countervailing Duty Order

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

SUMMARY: The Department of Commerce (the Department) finds that revocation of the countervailing duty (CVD) order on aluminum extrusions from the People's Republic of China (PRC) would likely lead to the continuation or recurrence of a countervailable subsidy at the levels indicated in the Final Results of Review section of this notice.

DATES: *Effective* August 5, 2016.

FOR FURTHER INFORMATION CONTACT: Tyler Weinhold, Office VI, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–1121.

SUPPLEMENTARY INFORMATION:

Background

On April 1, 2016, the Department initiated the first sunset review of the *Order*[1] on aluminum extrusions from the PRC, pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] The Aluminum Extrusions Fair Trade Committee and its constituent producers of aluminum extrusions (Petitioners) filed a timely notice of intent to participate on April 18, 2016, in accordance with 19 CFR 351.218(d)(1).[3] Petitioners claimed interested party status under section 771(9)(E) (covering trade and business associations) and individually under section 771(9)(C) (covering manufacturers, producers, and wholesalers) of the Act, respectively.

The Department received an adequate substantive response from Petitioners within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).[4] The

[1] *See Phosphor Copper from the Republic of Korea: Initiation of Less-Than-Fair-Value Investigation,* 81 FR 19552 (April 5, 2016).

[1] *See Aluminum Extrusions from the People's Republic of China: Countervailing Duty Order,* 76 FR 30653 (May 26, 2011) (the *Order*).

[2] *See Initiation of Five-Year (''Sunset'') Review,* 81 FR 18829 (April 1, 2016).

[3] *See* Letter from Petitioner to the Department, ''*Aluminum Extrusions from the People's Republic of China:* Notice of Intent to Participate in Review,'' dated April 18, 2016.

[4] *See* Letter to the Department, ''*Aluminum Extrusions from the People's Republic of China:* AEFTC's Substantive Response to the Department's

Department did not receive a substantive response from the Government of the PRC or any respondent interested party to the proceeding. Because the Department received no response from any respondent interested party, the Department conducted an expedited review of the *Order,* pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(l)(ii)(B)(2) and (C)(2).

Scope of the Order

The merchandise covered by the order{s} is aluminum extrusions which are shapes and forms, produced by an extrusion process, made from aluminum alloys having metallic elements corresponding to the alloy series designations published by The Aluminum Association commencing with the numbers 1, 3, and 6 (or proprietary equivalents or other certifying body equivalents). Specifically, the subject merchandise made from aluminum alloy with an Aluminum Association series designation commencing with the number 1 contains not less than 99 percent aluminum by weight. The subject merchandise made from aluminum alloy with an Aluminum Association series designation commencing with the number 3 contains manganese as the major alloying element, with manganese accounting for not more than 3.0 percent of total materials by weight. The subject merchandise is made from an aluminum alloy with an Aluminum Association series designation commencing with the number 6 contains magnesium and silicon as the major alloying elements, with magnesium accounting for at least 0.1 percent but not more than 2.0 percent of total materials by weight, and silicon accounting for at least 0.1 percent but not more than 3.0 percent of total materials by weight. The subject aluminum extrusions are properly identified by a four-digit alloy series without either a decimal point or leading letter. Illustrative examples from among the approximately 160 registered alloys that may characterize the subject merchandise are as follows: 1350, 3003, and 6060.

Aluminum extrusions are produced and imported in a wide variety of shapes and forms, including, but not limited to, hollow profiles, other solid profiles, pipes, tubes, bars, and rods. Aluminum extrusions that are drawn subsequent to extrusion (drawn aluminum) are also included in the scope.

Aluminum extrusions are produced and imported with a variety of finishes (both coatings and surface treatments), and types of fabrication. The types of coatings and treatments applied to subject aluminum extrusions include, but are not limited to, extrusions that are mill finished (*i.e.,* without any coating or further finishing), brushed, buffed, polished, anodized (including brightdip anodized), liquid painted, or powder coated. Aluminum extrusions may also be fabricated, *i.e.,* prepared for assembly. Such operations would include, but are not limited to, extrusions that are cut-to-length, machined, drilled, punched, notched, bent, stretched, knurled, swedged, mitered, chamfered, threaded, and spun. The subject merchandise includes aluminum extrusions that are finished (coated, painted, *etc.*), fabricated, or any combination thereof. Subject aluminum extrusions may be described at the time of importation as parts for final finished products that are assembled after importation, including, but not limited to, window frames, door frames, solar panels, curtain walls, or furniture. Such parts that otherwise meet the definition of aluminum extrusions are included in the scope. The scope includes the aluminum extrusion components that are attached *(e.g.,* by welding or fasteners) to form subassemblies, *i.e.,* partially assembled merchandise unless imported as part of the finished goods 'kit' defined further below. The scope does not include the non-aluminum extrusion components of subassemblies or subject kits.

Subject extrusions may be identified with reference to their end use, such as fence posts, electrical conduits, door thresholds, carpet trim, or heat sinks (that do not meet the finished heat sink exclusionary language below). Such goods are subject merchandise if they otherwise meet the scope definition, regardless of whether they are ready for use at the time of importation. The following aluminum extrusion products are excluded: Aluminum extrusions made from aluminum alloy with an Aluminum Association series designations commencing with the number 2 and containing in excess of 1.5 percent copper by weight; aluminum extrusions made from aluminum alloy with an Aluminum Association series designation commencing with the number 5 and containing in excess of 1.0 percent magnesium by weight; and aluminum extrusions made from aluminum alloy with an Aluminum Association series designation commencing with the number 7 and containing in excess of 2.0 percent zinc by weight.

The scope also excludes finished merchandise containing aluminum extrusions as parts that are fully and permanently assembled and completed at the time of entry, such as finished windows with glass, doors with glass or vinyl, picture frames with glass pane and backing material, and solar panels. The scope also excludes finished goods containing aluminum extrusions that are entered unassembled in a ''finished goods kit.'' A finished goods kit is understood to mean a packaged combination of parts that contains, at the time of importation, all of the necessary parts to fully assemble a final finished good and requires no further finishing or fabrication, such as cutting or punching, and is assembled ''as is'' into a finished product. An imported product will not be considered a ''finished goods kit'' and therefore excluded from the scope of the investigation merely by including fasteners such as screws, bolts, *etc.* in the packaging with an aluminum extrusion product.

The scope also excludes aluminum alloy sheet or plates produced by other than the extrusion process, such as aluminum products produced by a method of casting. Cast aluminum products are properly identified by four digits with a decimal point between the third and fourth digit. A letter may also precede the four digits. The following Aluminum Association designations are representative of aluminum alloys for casting: 208.0, 295.0, 308.0, 355.0, C355.0, 356.0, A356.0, A357.0, 360.0, 366.0, 380.0, A380.0, 413.0, 443.0, 514.0, 518.1, and 712.0. The scope also excludes pure, unwrought aluminum in any form. The scope also excludes collapsible tubular containers composed of metallic elements corresponding to alloy code 1080A as designated by the Aluminum Association where the tubular container (excluding the nozzle) meets each of the following dimensional characteristics: (1) Length of 37 millimeters (''mm'') or 62 mm, (2) outer diameter of 11.0 mm or 12.7 mm, and (3) wall thickness not exceeding 0.13 mm.

Also excluded from the scope of this order are finished heat sinks. Finished heat sinks are fabricated heat sinks made from aluminum extrusions the design and production of which are organized around meeting certain specified thermal performance requirements and which have been fully, albeit not necessarily individually, tested to comply with such requirements.

Notice of Initiation of its Five-Year (''Sunset'') Review,'' dated May 2, 2016.

Imports of the subject merchandise are provided for under the following categories of the Harmonized Tariff Schedule of the United States (HTSUS): 8424.90.9080, 9405.99.4020, 9031.90.90.95, 7616.10.90.90, 7609.00.00, 7610.10.00, 7610.90.00, 7615.10.30, 7615.10.71, 7615.10.91, 7615.19.10, 7615.19.30, 7615.19.50, 7615.19.70, 7615.19.90, 7615.20.00, 7616.99.10, 7616.99.50, 8479.89.98, 8479.90.94, 8513.90.20, 9403.10.00, 9403.20.00, 7604.21.00.00, 7604.29.10.00, 7604.29.30.10, 7604.29.30.50, 7604.29.50.30, 7604.29.50.60, 7608.20.00.30, 7608.20.00.90, 8302.10.30.00, 8302.10.60.30, 8302.10.60.60, 8302.10.60.90, 8302.20.00.00, 8302.30.30.10, 8302.30.30.60, 8302.41.30.00, 8302.41.60.15, 8302.41.60.45, 8302.41.60.50, 8302.41.60.80, 8302.42.30.10, 8302.42.30.15, 8302.42.30.65, 8302.49.60.35, 8302.49.60.45, 8302.49.60.55, 8302.49.60.85, 8302.50.00.00, 8302.60.90.00, 8305.10.00.50, 8306.30.00.00, 8414.59.60.90, 8415.90.80.45, 8418.99.80.05, 8418.99.80.50, 8418.99.80.60, 8419.90.10.00, 8422.90.06.40, 8473.30.20.00, 8473.30.51.00, 8479.90.85.00, 8486.90.00.00, 8487.90.00.80, 8503.00.95.20, 8508.70.00.00, 8515.90.20.00, 8516.90.50.00, 8516.90.80.50, 8517.70.00.00, 8529.90.73.00, 8529.90.97.60, 8536.90.80.85, 8538.10.00.00, 8543.90.88.80, 8708.29.50.60, 8708.80.65.90, 8803.30.00.60, 9013.90.50.00, 9013.90.90.00, 9401.90.50.81, 9403.90.10.40, 9403.90.10.50, 9403.90.10.85, 9403.90.25.40, 9403.90.25.80, 9403.90.40.05, 9403.90.40.10, 9403.90.40.60, 9403.90.50.05, 9403.90.50.10, 9403.90.50.80, 9403.90.60.05, 9403.90.60.10, 9403.90.60.80, 9403.90.70.05, 9403.90.70.10, 9403.90.70.80, 9403.90.80.10, 9403.90.80.15, 9403.90.80.20, 9403.90.80.41, 9403.90.80.51, 9403.90.80.61, 9506.11.40.80, 9506.51.40.00, 9506.51.60.00, 9506.59.40.40, 9506.70.20.90, 9506.91.00.10, 9506.91.00.20, 9506.91.00.30, 9506.99.05.10, 9506.99.05.20, 9506.99.05.30, 9506.99.15.00, 9506.99.20.00, 9506.99.25.80, 9506.99.28.00, 9506.99.55.00, 9506.99.60.80, 9507.30.20.00, 9507.30.40.00, 9507.30.60.00, 9507.90.60.00, and 9603.90.80.50.

The subject merchandise entered as parts of other aluminum products may be classifiable under the following additional Chapter 76 subheadings: 7610.10, 7610.90, 7615.19, 7615.20, and 7616.99, as well as under other HTSUS chapters. In addition, fin evaporator coils may be classifiable under HTSUS numbers: 8418.99.80.50 and 8418.99.80.60. While HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this *Order* is dispositive.

Analysis of Comments Received

All issues raised in this review are addressed in the Issues and Decision Memorandum, which is dated concurrently with and adopted by this notice.[5] The issues discussed in the Issues and Decision Memorandum include the likelihood of continuation or recurrence of a countervailable subsidy and the net countervailable subsidy likely to prevail if the *Order* were revoked. Parties can find a complete discussion of all issues raised in this expedited sunset review and the corresponding recommendations in this public memorandum, which is on file electronically *via* the Enforcement and Compliance Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov* and to all parties in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the Internet at *http://enforcement.trade.gov/frn/index.html*. The signed Issues and Decision Memorandum and the electronic versions of the Issues and Decision Memorandum are identical in content.

Final Results of Review

Pursuant to sections 752(b)(1) and (3) of the Act, we determine that revocation of the *Order* on aluminum extrusions from the PRC would be likely to lead to continuation or recurrence of a net countervailable subsidy at the rates listed below: [6]

Manufacturers/producers/exporters	Net countervailable subsidy rate (percent)
Dragonluxe Limited	374.15
Foshan Guangcheng Aluminum Co., Ltd., Guang Ya Aluminum Industries Co. Ltd., Guang Ya Aluminum Industries Hong Kong, and Yongji Guanghai Aluminum Industry Co., Ltd	12.05
Kong Ah International Company Limited	[7] 25.83
Karlton Aluminum Company Ltd., Zhaoqing New Zhongya Aluminum Co., Ltd., Zhongya Shaped Aluminum HK Holding Ltd	20.78
Liaoyang Zhongwang Aluminum Profile Co. Ltd./Liaoning Zhongwang Group	374.15
Miland Luck Limited	374.15
All-Others	23.26

[5] See Memorandum from Brian Davis, Program Manager, Office VI, to Gary Taverman, Associate Deputy Assistant Secretary for Enforcement and Compliance regarding: ''Issues and Decision Memorandum for the Final Results of the Expedited Sunset Review of the Countervailing Duty Order on Aluminum Extrusions from the People's Republic of China,'' dated concurrently with and adopted by this Notice (Issues and Decision Memorandum).

[6] *Id.*

[7] Kong Ah Kong Ah International Company Limited was included among the cross-owned companies comprising the Gyang Ya Group in the *Final Determination.* However, other members of the Gyang Ya Group were subsequently reviewed as mandatory respondents as cross-owned affiliates in the *Third (2013) Review,* while Kong Ah International Company Limited was not. Therefore, the rates for the additional programs found to be countervailable for the individually-examined Guang Ya Group Companies in the *Third (2013) Review* are not the rates for Kong Ah International Company Limited. Rather, for additional programs found to be countervailable in the *Third (2013) Review,* we have used the average of the rates of the companies individually examined.

Notification Regarding Administrative Protective Order

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

The Department is issuing and publishing these final results and this notice in accordance with sections 751(c), 752(b), and 777(i)(1) of the Act.

Dated: August 1, 2016.

Gary Taverman,

Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2016–18656 Filed 8–4–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–947]

Certain Steel Grating From the People's Republic of China: Final Results of the 2014–2015 Antidumping Administrative Review

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

SUMMARY: On April 13, 2016, the Department of Commerce (''Department'') published its *Preliminary Results* for the July 1, 2014, through June 30, 2015, administrative review of certain steel grating (''steel grating'') from the People's Republic of China (''PRC'').[1] Although invited to do so, interested parties did not comment on our *Preliminary Results.* We have adopted the *Preliminary Results* as the final results.

DATES: Effective August 5, 2016.

FOR FURTHER INFORMATION CONTACT: Lilit Astvatsatrian, AD/CVD Operations, Office IV, Enforcement & Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–6412.

[1] *See Certain Steel Grating From the People's Republic of China: Preliminary Results of Antidumping Administrative Review and Preliminary Determination of No Shipments; 2014–2015,* 81 FR 21843 (April 13, 2016) (''*Preliminary Results*'').

Background

On April 13, 2016, the Department published its *Preliminary Results* of the review of the antidumping duty order on steel grating from the PRC for Ningbo Haitian International Co., Ltd. (''Ningbo Haitian'') and Yantai Xinke Steel Structure Co., Ltd. (''Yantai Xinke'') covering the period July 1, 2014, through June 30, 2015 (the period of review (''POR'')). No parties commented on the *Preliminary Results.*

Scope of the Order

The products covered by this order are certain steel grating, consisting of two or more pieces of steel, including load-bearing pieces and cross pieces, joined by any assembly process, regardless of: (1) Size or shape; (2) method of manufacture; (3) metallurgy (carbon, alloy, or stainless); (4) the profile of the bars; and (5) whether or not they are galvanized, painted, coated, clad or plated. Steel grating is also commonly referred to as ''bar grating,'' although the components may consist of steel other than bars, such as hot-rolled sheet, plate, or wire rod.

The scope of this order excludes expanded metal grating, which is comprised of a single piece or coil of sheet or thin plate steel that has been slit and expanded, and does not involve welding or joining of multiple pieces of steel. The scope of this order also excludes plank type safety grating which is comprised of a single piece or coil of sheet or thin plate steel, typically in thickness of 10 to 18 gauge, that has been pierced and cold formed, and does not involve welding or joining of multiple pieces of steel.

Certain steel grating that is the subject of this order is currently classifiable in the Harmonized Tariff Schedule of the United States (''HTSUS'') under subheading 7308.90.7000. While the HTSUS subheading is provided for convenience and customs purposes, the written description of the scope of this order is dispositive.

Analysis

In the *Preliminary Results,* the Department determined that Ningbo Haitian was not eligible for separate rate status and was therefore part of the PRC-wide entity and that Yantai Xinke did not have reviewable transactions during the POR.[2] No parties commented on the *Preliminary Results.* Therefore, for these final results of review, we have continued to treat Ningbo Haitian as part of the PRC-wide entity and continued to find that Yantai Xinke did not have reviewable transactions during the POR. We are adopting the Preliminary Decision Memorandum for these final results of review.[3] The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (''ACCESS''). ACCESS is available to registered users at *http://access.trade.gov* and in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Results Decision Memorandum can be accessed directly on the Internet at *http://enforcement.trade.gov/frn/index.html.* The signed and the electronic versions of the Preliminary Decision Memorandum are identical in content.

[2] *See Preliminary Results,* at 21845.

Assessment Rates

Upon issuance of the final results, the Department will determine, and U.S. Customs and Border Protection (''CBP'') shall assess, antidumping duties on all appropriate entries covered by this review. The Department intends to issue assessment instructions to CBP 15 days after the publication date of the final results of this review. The Department intends to instruct CBP to liquidate any entries of subject merchandise from Ningbo Haitian at 145.18 percent (the PRC-wide rate).

Additionally, pursuant to the Department's practice in non-market economy cases, given that we have continued to find that Yantai Xinke had no shipments of subject merchandise during the POR, any suspended entries of subject merchandise from Yantai Xinke will be liquidated at the PRC-wide rate.[4]

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of review, as provided by section 751(a)(2)(C) of the Act: (1) For previously investigated or reviewed PRC and non-PRC exporters, which are not under review in this

[3] *See* Decision Memorandum for Preliminary Results of Antidumping Duty Administrative Review of Certain Steel Grating from the People's Republic of China (''Preliminary Decision Memorandum''), from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations to Ronald K. Lorentzen, Acting Assistant Secretary for Enforcement and Compliance.

[4] For a full discussion of this practice, *see NME AD Assessment,* 76 FR 65694 (October 24, 2011).

segment of the proceeding, but which have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recent period; (2) for all PRC exporters of subject merchandise that have not been found to be entitled to a separate rate, including Ningbo Haitian, the cash deposit rate will be the PRC-wide rate of 145.18 percent; and (3) for all non-PRC exporters of subject merchandise, which have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporter(s) that supplied that non-PRC exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification of Interested Parties

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of the antidumping duties occurred and the subsequent assessment of double antidumping duties.

This notice also serves as a reminder to parties subject to administrative protective orders (''APOs'') of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation that is subject to sanction.

This notice of the final results of this antidumping duty administrative review is issued and published in accordance with sections 751(a)(1) and 777(i) of the Act and 19 CFR 351.213 and 19 CFR 351.221(b)(5).

Dated: July 27, 2016.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2016–18541 Filed 8–4–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE765

New England Fishery Management Council; Public Meeting; Correction

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

ACTION: Correction of a public meeting notice.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Herring Advisory Panel on Tuesday, August 16, 2016 to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Tuesday, August 16, 2016 at 9:30 a.m.

ADDRESSES: The meeting will be held at the Holiday Inn, 31 Hampshire Street, Mansfield, MA 02048; telephone: (508) 339–2200; fax: (508) 339–1040.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION: The original notice published in the **Federal Register** on July 29, 2016 (81 FR 49958). The original notice stated that it was a Herring Committee meeting. It should have read that is was a Herring Advisory Panel meeting.

Agenda

The Advisory Panel will give a brief update on the next steps for Management Strategy Evaluation of Atlantic Herring Acceptable Biological Catch control rules being considered in Amendment 8 to the Atlantic Herring Fishery Management Plan (FMP). The Advisory Panel will also review preliminary PDT analysis and develop measures related to localized depletion to be considered in Amendment 8 to the Atlantic Herring FMP. The Advisory Panel will review progress and provide input on Framework Adjustment 5 to the Atlantic Herring FMP, an action considering modification of accountability measures (AMs) that trigger if the sub-ACL of Georges Bank haddock is exceeded by the midwater trawl herring fishery. Additionally, they will start initial discussions of work priorities for the Herring FMP in 2017. Other business may be discussed as necessary.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

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

Dated: August 2, 2016.

Tracey L. Thompson,

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

[FR Doc. 2016–18612 Filed 8–4–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE764

New England Fishery Management Council; Public Meeting; Correction

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

ACTION: Correction of a public meeting notice.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Herring Committee on Wednesday, August 17, 2016 to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Wednesday, August 17, 2016 at 9 a.m.

ADDRESSES: The meeting will be held at the Holiday Inn, 31 Hampshire Street, Mansfield, MA 02048; telephone: (508) 339–2200; fax: (508) 339–1040.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION: The original notice published in the **Federal Register** on July 29, 2016 (81 FR 49958). The original notice stated that it was a Herring Advisory Panel meeting. It should have read that is was a Herring Committee meeting.

Agenda

The Committee will give a brief update on the next steps for Management Strategy Evaluation of Atlantic Herring Acceptable Biological Catch control rules being considered in Amendment 8 to the Atlantic Herring Fishery Management Plan (FMP). The Committee will also review preliminary PDT analysis and develop measures related to localized depletion to be considered in Amendment 8 to the Atlantic Herring FMP. The Committee will review progress and provide input on Framework Adjustment 5 to the Atlantic Herring FMP, an action considering modification of accountability measures (AMs) that trigger if the sub-ACL of Georges Bank haddock is exceeded by the midwater trawl herring fishery. Additionally, they will also start initial discussions of work priorities for the Herring FMP in 2017. Other business may be discussed as necessary.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

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

Dated: August 2, 2016.

Tracey L. Thompson,

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

[FR Doc. 2016–18611 Filed 8–4–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE784

New England Fishery Management Council; Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a joint public meeting of its Monkfish Advisory Panel to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Wednesday, August 17, 2016 at 9 a.m.

ADDRESSES:

Meeting address: The meeting will be held at the Radisson Airport Hotel, 2081 Post Road, Warwick, RI 02886; telephone: (401) 739–3000; fax: (401) 732–9309.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

The Advisory Panel will meet to receive an update on the 2016 operational assessment. The Advisory Panel will discuss the SSC recommendations for Allowable Biological Catch (ABC) for FYs 2017–19, the potential range of alternatives for the specifications package, and priorities for 2017. The Advisory Panel will discuss other business, as needed.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

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

Dated: August 2, 2016.

Tracey L. Thompson,

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

[FR Doc. 2016–18613 Filed 8–4–16; 8:45 am]

BILLING CODE 3510–22–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to and Deletions from the Procurement List.

SUMMARY: This action adds products and services to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes products and a service from the Procurement List previously furnished by such agencies.

DATES: Effective on September 4, 2016.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov*.

SUPPLEMENTARY INFORMATION:

Additions

On 2/12/2016 (81 FR 7510–7511), 5/13/2016 (81 FR 29848), 5/20/2016 (81 FR 31917–31918), 5/27/2016 (81 FR 33665–33666), and 6/10/2016 (81 FR 37581–37582), the Committee for Purchase From People Who Are Blind or Severely Disabled published notices of proposed additions to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the products and services and impact of the additions on the current or most recent contractors, the Committee has determined that the products and services listed below are suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the products and services to the Government.

2. The action will result in authorizing small entities to furnish the products and services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the products and services proposed for addition to the Procurement List.

End of Certification

Accordingly, the following products and services are added to the Procurement List:

Products

NSN(s)—Product Name(s):

7490–00–NIB–0046—Label Printer, High Speed, PC and Mac, Black/Silver
7490–00–NIB–0047—Label Maker, Industrial, Handheld, Orange
7490–00–NIB–0050—Kit, Desktop Label Maker
7510–00–NIB–1081—Tape, Label, Black on White, ½″ x 24′
7510–00–NIB–1082—Cartridge, Label, Black on White, ¾″ x 26.2′
7510–01–NIB–1054—Cartridge, Label, Black on Clear, ½″ x 23′
7510–01–NIB–1055—Cartridge, Label, Black on Yellow, ½″ x 23′
7510–01–NIB–1056—Cartridge, Label, White on Black, ½″ x 23′
7510–01–NIB–1057—Cartridge, Label, Heat Shrink Tube, Black on White, ½″ x 5′
7530–00–NIB–1174—Labels, File Folder, Black on White, 9⁄16″ x 3 7⁄16″
7530–00–NIB–1175—Labels, Address, Black on White, 1⅛″ x 3½″
7530–00–NIB–1176—Labels, Shipping, Black on White, 2⅛″ x 4″
7530–00–NIB–1177—Labels, Name Badge, Clip Hole, Black on White 2¼″ x 4″
Mandatory for: Total Government Requirement
Mandatory Source(s) of Supply: Association for the Blind and Visually Impaired—Goodwill Industries of Greater Rochester, Rochester, NY
Contracting Activity: General Services Administration, New York, NY
Distribution: A-List
NSN(s)—Product Name(s): 8530–01–490–7372—Kit, Toiletries
Mandatory Purchase For: Total Government Requirement
Mandatory Source(s) of Supply: NewView Oklahoma, Inc., Oklahoma City, OK
Contracting Activity: General Services Administration, Fort Worth, TX
Distribution: B-List

NSN(s)—Product Name(s):

6650–00–NIB–0009—Complete Eyeglass CR–39 Single Vision, plastic, clr
6650–00–NIB–0010—Complete Eyeglass CR–39 Flat Top 28 Bifocal, clr
6650–00–NIB–0011—Complete Eyeglass CR–39 Flat Top 35 Bifocal, clr
6650–00–NIB–0012—Complete Eyeglass CR–39 Round 25 & 28, clr
6650–00–NIB–0013—Complete Eyeglass CR–39 Flat Top 7 x 28, clr
6650–00–NIB–0014—Complete Eyeglass CR–39 Flat Top 8 x 35, clr
6650–00–NIB–0015—Complete Eyeglass CR–39 Progressives, clr
6650–00–NIB–0016—Complete Eyeglass CR–39 SV Aspheric Lentic.
6650–00–NIB–0017—Complete Eyeglass CR–39 Flat Top-Round Asph Len
6650–00–NIB–0018—Complete Eyeglass CR–39 Exec. Bifocal, clr
6650–00–NIB–0019—Complete Eyeglass Glass Single Vision, clr
6650–00–NIB–0020—Complete Eyeglass Glass Flat Top 28 Bifocal, clr
6650–00–NIB–0021—Complete Eyeglass Glass Flat Top 35 Bifocal, clr
6650–00–NIB–0022—Complete Eyeglass Glass Flat Top 7 x 28, trifoc, clr
6650–00–NIB–0023—Complete Eyeglass Glass Flat Top 8 x 35, trifoc, clr
6650–00–NIB–0024—Complete Eyeglass Glass Progressives, clr
6650–00–NIB–0025—Complete Eyeglass Glass Executive Bifocal, clr
6650–00–NIB–0026—Complete Eyeglass Polycarb SV = Single Vision, clr
6650–00–NIB–0027—Complete Eyeglass Polycarb Flat Top 28, clr
6650–00–NIB–0028—Complete Eyeglass Polycarb Flat Top 35, clr
6650–00–NIB–0029—Complete Eyeglass Polycarb Flat Top 7 x 28, clr
6650–00–NIB–0030—Complete Eyeglass Polycarb Flat Top 8 x 35, clr
6650–00–NIB–0031—Complete Eyeglass Polycarb Progressives, clr
6650–00–NIB–0032—Lenses Only, 1 pair CR–39 Single Vision, plastic, clr
6650–00–NIB–0033—Lenses Only, 1 pair CR–39 Flat Top 28 Bifocal, clr
6650–00–NIB–0034—Lenses Only, 1 pair CR–39 Flat Top 35 Bifocal, clr
6650–00–NIB–0035—Lenses Only, 1 pair CR–39 Round 25 & 28, clr
6650–00–NIB–0036—Lenses Only, 1 pair CR–39 Flat Top 7 x 28, clr
6650–00–NIB–0037—Lenses Only, 1 pair CR–39 Flat Top 8 x 35, clr
6650–00–NIB–0038—Lenses Only, 1 pair CR–39 Progressives, clr
6650–00–NIB–0039—Lenses Only, 1 pair CR–39 SV Aspheric Lentic.
6650–00–NIB–0040—Lenses Only, 1 pair CR–39 Flat Top/Round Asph Len
6650–00–NIB–0041—Lenses Only, 1 pair CR–39 Exec. Bifocal, clr
6650–00–NIB–0042—Lenses Only, 1 pair Glass Single Vision, clr
6650–00–NIB–0043—Lenses Only, 1 pair Glass Flat Top 28 Bifocal, clr
6650–00–NIB–0044—Lenses Only, 1 pair Glass Flat Top 35 Bifocal, clr
6650–00–NIB–0045—Lenses Only, 1 pair Glass Flat Top 7 x 28, trifoc, clr
6650–00–NIB–0046—Lenses Only, 1 pair Glass Flat Top 8 x 35, trifoc, clr
6650–00–NIB–0047—Lenses Only, 1 pair Glass Progressives,clr
6650–00–NIB–0048—Lenses Only, 1 pair Glass Executive Bifocal, clr
6650–00–NIB–0049—Lenses Only, 1 pair Polycarb SV = Single Vision, clr
6650–00–NIB–0050—Lenses Only, 1 pair Polycarb Flat Top 28, clr
6650–00–NIB–0051—Lenses Only, 1 pair Polycarb Flat Top 35 clr
6650–00–NIB–0052—Lenses Only, 1 pair Polycarb Flat Top 7 x 28, clr
6650–00–NIB–0053—Lenses Only, 1 pair Polycarb Flat Top 8 x 35, clr
6650–00–NIB–0054—Lenses Only, 1 pair Polycarb Progressives, clr
6650–00–NIB–0055—Photochr/Transition, CR–39 SV or MF (MF= Multi-focal)
6650–00–NIB–0056—Photochr-transition Polycarb SV or MF
6650–00–NIB–0057—Photogrey Glass SV or MF
6650–00–NIB–0058—Hi Index Transitions CR–39 SV or MF
6650–00–NIB–0059—Anti-refl. Coating CR–39—PC SV or MF
6650–00–NIB–0060—UV coating CR39
6650–00–NIB–0061—Polariz. Lens CR–39 SV or MF
6650–00–NIB–0062—Slab-off CR–39 SV or MF
6650–00–NIB–0063—Hi Index High Index SV or MF
6650–00–NIB–0064—Prism CR–39 or PC
6650–00–NIB–0065—Diopter CR–39 + or −9.0
6650–00–NIB–0066—Roll/polish edge CR–39, PC SV or MF
6650–00–NIB–0067—Hyper3 drop SV, MF CR–39 SV or MF
6650–00–NIB–0068—Add Powers over 4.0 CR–39 MF Only
6650–00–NIB–0069—Frame Only Plastic or Metal
Mandatory Source(s) of Supply: Winston-Salem Industries for the Blind, Inc., Winston-Salem, NC
Mandatory Purchase For: Department of Veterans Affairs, Veterans Integrated Service Network (VISN) 6 Medical Centers; Community Based Outpatient Clinics (CBOCs); and Health Care Centers that provide optical services.
Contracting Activity: Department of Veterans Affairs, Veterans Integrated Service Network (VISN) 6
Distribution: C-List

The U.S. AbilityOne Commission, whose mission is to provide employment opportunities for people who are blind or have significant disabilities in the manufacture and delivery of products and services to the Federal Government, received two public comments both more than 90 days after the expiration of the notice and comment period required by 5 U.S.C. 500, formerly known as the Administrative Procedure Act (APA). Notwithstanding that, the Commission is addressing the comments.

The Commenters recommended against the addition of these prescription eyewear products from the Commission's Procurement List. The Commenters did not assert a personal financial hardship or impact, one on behalf of its client and the other, itself, should the addition of these products to the Procurement List occur. Rather, the Commenters highlighted there may be an alternate method for the procurement of these products through veteran-owned sources and that addition of the products to the Procurement List may cause the Department of Veterans Affairs to be non-compliant no matter how it proceeds with such a procurement.

While the Commission appreciates there may be methods for purchasing the subject prescription eyewear products from veteran-owned sources, the Commission's mission and duty is to

provide employment opportunities for people who are blind or have significant disabilities, many of whom are veterans, through manufacture and delivery of products and services to the Federal Government. Adding the proposed products to the Commission's Procurement List will provide employment opportunities to a portion of the U.S. population that has a historically high rate of unemployment and underemployment, and is consistent with the Commission's authority [1] established by 41 U.S.C. Chapter 85.

Services

Service Type: Engineering and Environmental Service
Mandatory for: U.S. Air Force, 61st Civil Engineer & Logistics Squadron,Los Angeles Air Force Base, El Segundo, CA
Mandatory Source(s) of Supply: PRIDE Industries, Roseville, CA
Contracting Activity: Dept. of the Air Force, FA2816 SMC PKO

Service Type: Janitorial Service
Mandatory for: DHS, Federal Law Enforcement Training Center, Glynco, GA
Mandatory Source(s) of Supply: Goodwill Industries of the Coastal Empire, Inc., Savannah, GA
Contracting Activity: Federal Law Enforcement Training Center, FLETC Glynco Procurement Office

Deletions

On 7/1/2016 (81 FR 43191), the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed deletions from the Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the products and service listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing small entities to furnish the products and service to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the products and service deleted from the Procurement List.

End of Certification

Accordingly, the following products and service are deleted from the Procurement List:

Products

NSN(s)—Product Name(s): 7520–00–NIB–1314—Rotary Cutter
Mandatory Source(s) of Supply: The Lighthouse for the Blind, Inc. (Seattle Lighthouse), Seattle, WA
Contracting Activity: General Services Administration, New York, NY

NSN(s)—Product Name(s): 6530–00–784–4205—Strap, Patient Securing, Olive Drab, 72''
Mandatory Source(s) of Supply: Alphapointe, Kansas City, MO
Contracting Activity: Defense Logistics Agency Troop Support

NSN(s)—Product Name(s):
MR 3229—Goody Hair Care Product—So Gelous Purse Brush
MR 3217—Goody Hair Care Product—Fashion Contour Barrettes
Mandatory Source(s) of Supply: Association for Vision Rehabilitation and Employment, Inc., Binghamton, NY
Contracting Activity: Defense Commissary Agency

Service

Service Type: Linen Rental Service
Mandatory for: New Orleans Naval Air Station, New Orleans, LA
Mandatory Source(s) of Supply: St. Tammany Association for Retarded Citizens, Inc., Slidell, LA
Contracting Activity: Dept. of the Navy, Naval Hospital, Pensacola, FL

Barry S. Lineback,

Director, Business Operations.

[FR Doc. 2016–18648 Filed 8–4–16; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed Deletions from the Procurement List.

SUMMARY: The Committee is proposing to delete products and services from the Procurement List that were previously furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: Comments must be received on or before September 4, 2016.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia, 22202–4149.

FOR FURTHER INFORMATION CONTACT: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Deletions

The following products and services are proposed for deletion from the Procurement List:

Products

NSN(s)—Product Name(s)

8415–00–NSH–0376—Coat, Combat, BDU, Army, Urban Camouflage, XS–XS
8415–00–NSH–0377—Coat, Combat, BDU, Army, Urban Camouflage, XS–S
8415–00–NSH–0378—Coat, Combat, BDU, Army, Urban Camouflage, XS–R
8415–00–NSH–0379—Coat, Combat, BDU, Army, Urban Camouflage, SX–XS
8415–00–NSH–0380—Coat, Combat, BDU, Army, Urban Camouflage, S–XS
8415–00–NSH–0381—Coat, Combat, BDU, Army, Urban Camouflage, SS
8415–00–NSH–0382—Coat, Combat, BDU, Army, Urban Camouflage, SR
8415–00–NSH–0383—Coat, Combat, BDU, Army, Urban Camouflage, SL
8415–00–NSH–0384—Coat, Combat, BDU, Army, Urban Camouflage, SXL
8415–00–NSH–0385—Coat, Combat, BDU, Army, Urban Camouflage, M–XXS
8415–00–NSH–0386—Coat, Combat, BDU, Army, Urban Camouflage, M–XS
8415–00–NSH–0387—Coat, Combat, BDU, Army, Urban Camouflage, M–S
8415–00–NSH–0388—Coat, Combat, BDU, Army, Urban Camouflage, M–R
8415–00–NSH–0389—Coat, Combat, BDU, Army, Urban Camouflage, M–L
8415–00–NSH–0390—Coat, Combat, BDU, Army, Urban Camouflage, M–XL
8415–00–NSH–0391—Coat, Combat, BDU, Army, Urban Camouflage, L–XS
8415–00–NSH–0392—Coat, Combat, BDU, Army, Urban Camouflage, L–S
8415–00–NSH–0393—Coat, Combat, BDU, Army, Urban Camouflage, L–R
8415–00–NSH–0394—Coat, Combat, BDU, Army, Urban Camouflage, L–L
8415–00–NSH–0395—Coat, Combat, BDU, Army, Urban Camouflage, L–XL
8415–00–NSH–0396—Coat, Combat, BDU, Army, Urban Camouflage, XL–R
8415–00–NSH–0397—Coat, Combat, BDU, Army, Urban Camouflage, XL–LL
Contracting Activity: Army Contracting Command—Aberdeen Proving Ground, Natick Contracting Division

Services

Service Type: Mess Attendant Service
Mandatory for: 185th Air Refueling Wing

[1] OGC Legal Opinion 16–1, Legal Files, PLIMS record.

Dining Hall, Building 263, 2920 Headquarters Avenue, Sioux City, IA
Service Type: Custodial Service
Mandatory for: 185th Air Refueling Wing, Buildings 234 and 241, 2920 Headquarters Avenue, Sioux City, IA
Mandatory Source(s) of Supply: Goodwill Community Rehabilitation Services, Inc., Sioux City, IA
Contracting Activity: Dept of the Army, W7M8 USPFO ACTIVITY IA ARNG

Barry S. Lineback,

Director, Business Operations.

[FR Doc. 2016–18647 Filed 8–4–16; 8:45 am]

BILLING CODE 6353–01–P

COUNCIL ON ENVIRONMENTAL QUALITY

Final Guidance for Federal Departments and Agencies on Consideration of Greenhouse Gas Emissions and the Effects of Climate Change in National Environmental Policy Act Reviews

AGENCY: Council on Environmental Quality.

ACTION: Notice of Availability.

SUMMARY: The Council on Environmental Quality (CEQ) is issuing its final guidance on considering greenhouse gas (GHG) emissions and climate change in National Environmental Policy Act (NEPA) reviews. Many projects and programs proposed by, or requiring the approval of, Federal agencies have the potential to emit or sequester GHGs and may be affected by climate change. It follows that, under NEPA, Federal decision-makers and the public should be informed about a proposal's GHG emissions and climate change implications. Such information can help a decision-maker make an informed choice between alternative actions that will result in different levels of GHG emissions or consider mitigation measures that reduce climate change impacts. This final guidance applies to all types of proposed Federal agency actions, including land and resource management actions, and provides agencies with a framework for agency consideration of the effects of GHGs and climate change to ensure efficient and transparent agency decision-making.

DATES: The guidance is effective August 5, 2016.

ADDRESSES: The Final Guidance is available at *https://www.whitehouse.gov/administration/eop/ceq/initiatives/nepa/ghg-guidance* and *https://ceq.doe.gov/*. Paper copies are also available upon request.

FOR FURTHER INFORMATION CONTACT: Council on Environmental Quality (ATTN: Ted Boling, Associate Director for the National Environmental Policy Act), 722 Jackson Place NW., Washington, DC 20503. Telephone: (202) 395–5750.

SUPPLEMENTARY INFORMATION: Enacted by Congress in 1969, the National Environmental Policy Act (NEPA), 42 U.S.C. 4321 *et seq.,* is this Nation's basic charter for harmonizing our environmental, economic, and social goals and is a cornerstone of the Nation's efforts to protect the environment. NEPA is based on a recognition that many Federal activities affect the environment and mandates that Federal agencies consider the environmental impacts of their proposed actions before deciding to adopt proposals and take actions.[1]

On December 24, 2014, CEQ issued revised draft guidance [2] developed after considering comments received on the February 2010 draft guidance from the public, Federal agencies, and other affected stakeholders.[3] A **Federal Register** notice announced the availability of the revised draft guidance for public review and opened a 60-day public comment period through February 23, 2015. 79 FR 77801 (Dec. 24, 2014). In response to stakeholders who requested additional time to review and comment on the revised draft guidance, CEQ extended the public comment period 30 days until March 25, 2015. 80 FR 9443 (Feb. 23, 2015).

There were over 100 public comments from a broad range of stakeholders, including private citizens, members of Congress, corporations, environmental organizations, trade associations, academics, tribes, and Federal, state, and local agencies. CEQ considered the comments and the revised guidance reflects its consideration of the input.

This guidance is not a regulation. It presents CEQ's interpretation of what is appropriate under NEPA and the CEQ Regulations for Implementing the Procedural Provisions of NEPA, 40 CFR parts 1500–1508 (CEQ Regulations). This guidance does not change or substitute for any law, regulation, or other legally binding requirement. With this guidance, CEQ provides Federal agencies with an overarching framework for determining how to consider GHG emissions and climate change effects in NEPA reviews. Consequently, this guidance could reduce agency uncertainty and avoid impacts on project timelines and costs that stem from such uncertainty.

Agency discretion is an integral aspect of NEPA implementation and this guidance offers an approach to agencies on how to exercise that discretion. This guidance preserves agency discretion and recognizes agencies' abilities to evaluate the facts in the NEPA review at hand and determine how GHG emissions and climate change should be taken into account, the appropriate depth and scope for meaningfully comparing alternatives, and the appropriate GHG emission quantification tools.

The final guidance recommends that agencies use projected GHG emissions as a proxy for assessing potential climate change effects when preparing a NEPA analysis for a proposed agency action; recommends that agencies quantify projected direct and indirect GHG emissions, taking into account available data and GHG quantification tools that are suitable for the proposed agency action; and recommends that where agencies do not quantify the GHG emissions for a proposed agency action because tools, methodologies, or data inputs are not reasonably available, agencies include a qualitative analysis in the NEPA document and explain the basis for determining that quantification is not reasonably available. The guidance also:

- Counsels agencies to use information developed during the NEPA review to consider alternatives that would make the actions and affected communities more resilient to the effects of a changing climate.
- Outlines special considerations for analysis of biogenic carbon dioxide sources and carbon stocks associated with land and resource management actions.
- Encourages agencies to use and leverage existing NEPA tools and practices to assist in their analyses, such as scoping, broad-scale reviews and tiering, incorporation by reference, and available information.
- Advises agencies to rely on their expert judgment and experience to determine which tools and methodologies should be used when they conduct their analyses.

[1] For more information on the applicability of NEPA, *see* the Council on Environmental Quality (CEQ), ''*A Citizen's Guide to the NEPA,*'' *available at https://ceq.doe.gov/nepa/Citizens_Guide_Dec07.pdf.*

[2] *See* CEQ, ''Revised Draft Guidance for Federal Departments and Agencies on Consideration of Greenhouse Gas Emissions and the Effects of Climate Change in NEPA Reviews,'' (Dec. 24, 2014), *available at http://www.whitehouse.gov/sites/default/files/docs/nepa_revised_draft_ghg_guidance_searchable.pdf.*

[3] *See* CEQ, ''Draft NEPA Guidance on Consideration of the Effects of Climate Change and Greenhouse Gas Emissions,'' (Feb. 18, 2010), *available at http://www.whitehouse.gov/sites/default/files/microsites/ceq/20100218-nepa-consideration-effects-ghg-draft-guidance.pdf.*

This guidance is effective for use on all new proposals when a NEPA review is initiated. CEQ recommends that agencies consider applying this guidance to projects in ongoing EIS or EA processes where GHG emissions may be a significant aspect of the proposal.

The final guidance is available on the National Environmental Policy Act Web site (*www.nepa.gov*) specifically at, *https://ceq.doe.gov/ceq_regulations/guidance.html,* and on the CEQ Web site at *https://www.whitehouse.gov/administration/eop/ceq/initiatives/nepa/ghg-guidance*. For the reasons stated in the preamble, above, CEQ issues the following guidance on the consideration of GHG emissions and the effects of climate change in NEPA reviews.

Authority: 42 U.S.C. 4332, 4342, 4344 and 40 CFR parts 1500, 1501, 1502, 1503, 1505, 1506, 1507, and 1508.

Dated: August 1, 2016.

Christy Goldfuss,

Managing Director, Council on Environmental Quality.

[FR Doc. 2016–18620 Filed 8–4–16; 8:45 am]

BILLING CODE 3225–F6–P

DEPARTMENT OF DEFENSE

Department of the Air Force

Global Positioning System Directorate (GPSD) Meeting Notice

AGENCY: Global Positioning System Directorate (GPSD), Department of the Air Force, Department of Defense.

ACTION: Notice of meeting—2016 Public Interface Control Working Group and Open Forum for the NAVSTAR GPS public documents.

SUMMARY: This notice informs the public that the Global Positioning Systems (GPS) Directorate will host the 2016 Public Interface Control Working Group and Open Forum on 21 and 22 September 2016 for the following NAVSTAR GPS public documents: IS–GPS–200 (Navigation User Interfaces), IS–GPS–705 (User Segment L5 Interfaces), IS–GPS–800 (User Segment L1C Interface), ICD–GPS–240 (NAVSTAR GPS Control Segment to User Support Community Interfaces), and ICD–GPS–870 (NAVSTAR GPS Control Segment to User Support Community Interfaces). Additional logistical details can be found below.

The purpose of this meeting is to update the public on GPS public document revisions and collect issues/comments for analysis and possible integration into future GPS public document revisions. All outstanding comments on the GPS public documents will be considered along with the comments received at this year's open forum in the next revision cycle. The 2016 Interface Control Working Group and Open Forum are open to the general public. For those who would like to attend and participate, we request that you register no later than September 7, 2016. Please send the registration information to *SMCGPER@us.af.mil,* providing your name, organization, telephone number, email address, and country of citizenship.

Comments will be collected, catalogued, and discussed as potential inclusions to the version following the current release. If accepted, these changes will be processed through the formal directorate change process for IS–GPS–200, IS–GPS–705, IS–GPS–800, ICD–GPS–240, and ICD–GPS–870. All comments must be submitted in a Comments Resolution Matrix (CRM). These forms along with current versions of the documents and the official meeting notice are posted at: *http://www.gps.gov/technical/icwg/.*

Please submit comments to the SMC/GPS Requirements (SMC/GPER) mailbox at *SMCGPER@us.af.mil* by August 19, 2016. Special topics may also be considered for the Public Open Forum. If you wish to present a special topic, please coordinate with SMC/GPER no later than September 7, 2016. For more information, please contact Capt Robyn Anderson at 310–653–3064 or Daniel Godwin at 310–653–3640.

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DATES: *Date/Time:* 21–22 Sept 2016, 0830–1600 * (Pacific Standard Time P.S.T.).

Registration/check-in on 21 Sept 2016 will begin at 0800 hrs

ADDRESSES: *PCT:* 100 North Sepulveda Blvd., El Segundo, CA 90245, The Great Room.

Dial-In Information and Location: Phone Number: 1–310–653–2663, Meeting ID: 6272252, Passcode: 000001.

* Identification will be required at the entrance of the PCT facility (*e.g.,* Passport, state ID or Federal ID).

PCT Facility Phone Number: 310–615–0122.

FOR FURTHER INFORMATION CONTACT: Captain Robyn Anderson, *robyn.anderson.1@us.af.mil*, (310) 653–3064. Daniel Godwin, *daniel.godwin.5@us.af.mil*, (310) 653–3640.

Bao-Anh Trinh,

Air Force Federal Register Liaison Officer.

[FR Doc. 2016–18595 Filed 8–4–16; 8:45 am]

BILLING CODE 5001–10–P

DEPARTMENT OF ENERGY

Record of Decision and Floodplain Statement of Findings for the Lake Charles LNG Export Company, LLC Application To Export Liquefied Natural Gas to Non-Free Trade Agreement Countries

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Record of decision.

SUMMARY: The U.S. Department of Energy (DOE) announces its decision in Lake Charles LNG Export Company, LLC (Lake Charles LNG Export), DOE/FE Docket No. 13–04–LNG,[1] to issue DOE/FE Order No. 3868 granting final long-term, multi contract authorization for Lake Charles LNG Export to engage in export of domestically produced liquefied natural gas (LNG) from the Lake Charles Terminal located in Lake Charles, Calcasieu Parish, Louisiana (Terminal), in a volume equivalent to 730 Bcf/yr of natural gas for a term of 20 years. Lake Charles LNG Export is seeking to export LNG from the Terminal to countries with which the United States has not entered into a free trade agreement (FTA) that requires national treatment for trade in natural gas, and with which trade is not prohibited by U.S. law or policy (non-FTA countries). Order No. 3868 is issued under section 3 of the Natural Gas Act (NGA) [2] and 10 CFR part 590 of the DOE regulations.[3] DOE participated as a cooperating agency with the Federal Energy Regulatory Commission (FERC) in preparing an environmental impact statement (EIS) [4] analyzing the potential

[1] On Oct. 10, 2014, Trunkline LNG Export, LLC filed a request in DOE/FE Dkt. No. 13–04–LNG to change its corporate name to Lake Charles LNG Export Company, LLC. Subsequently, DOE/FE issued Order 3252–A granting the name change. See *Lake Charles LNG Export Company, LLC,* DOE/FE Order No. 3252–A, FE Dkt. No. 13–04–LNG (March 18, 2015).

[2] The authority to regulate the imports and exports of natural gas, including liquefied natural gas, under section 3 of the NGA (15 U.S.C. 717b) has been delegated to the Assistant Secretary for FE in Redelegation Order No. 00–006.02 issued on November 17, 2014.

[3] 10 CFR part 590 (2012).

[4] Federal Energy Regulatory Commission, Final Environmental Impact Statement for the Lake Charles Liquefaction Project, Docket Nos. CP14–

Continued

environmental impacts resulting from modification of the existing facilities at the Terminal.

ADDRESSES: The EIS and this Record of Decision (ROD) are available on DOE's National Environmental Policy Act (NEPA) Web site at: *http://energy.gov/nepa/nepa-documents.* Order No. 3868 is available on DOE/FE's Web site at: *http://www.fossil.energy.gov/programs/gasregulation/authorizations/2013_applications/Lake_Charles_LNG_Export_13-04-LNG.html.* For additional information about the docket in these proceedings, contact Larine Moore, U.S. Department of Energy (FE–34), Office of Regulation and International Engagement, Office of Oil and Natural Gas, Office of Fossil Energy, Room 3E–042, 1000 Independence Avenue SW., Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT: To obtain additional information about the EIS or the ROD, contact Mr. Kyle W. Moorman, U.S. Department of Energy (FE–34), Office of Regulation and International Engagement, Office of Oil and Natural Gas, Office of Fossil Energy, Room 3E–042, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586–5600, or Mr. Edward Le Duc, U.S. Department of Energy (GC–51), Office of the Assistant General Counsel for Environment, 1000 Independence Avenue SW., Washington, DC 20585.

SUPPLEMENTARY INFORMATION: DOE prepared this ROD and Floodplain Statement of Findings pursuant to the National Environmental Policy Act of 1969 (42 United States Code [U.S.C.] 4321, *et seq.*), and in compliance with the Council on Environmental Quality (CEQ) implementing regulations for NEPA (40 Code of Federal Regulations [CFR] parts 1500 through 1508), DOE's implementing procedures for NEPA (10 CFR part 1021), and DOE's ''Compliance with Floodplain and Wetland Environmental Review Requirements'' (10 CFR part 1022).

Background

Lake Charles LNG Export is a Delaware limited liability company, with its principal place of business in Houston, Texas.[5] On January 10, 2013, Lake Charles LNG Export filed the application (Application) with DOE/FE seeking authorization to export domestically produced LNG from proposed liquefaction facilities (Liquefaction Project) to be located at the existing Terminal in Lake Charles, Louisiana. Lake Charles LNG Export proposes to export this LNG to non-FTA countries in a total volume equivalent to 730 billion cubic feet per year (Bcf/yr) of natural gas.

The Terminal is owned and operated by a corporate affiliate currently known as Lake Charles LNG Company, LLC (Lake Charles LNG).[6] The Liquefaction Project will be owned by Lake Charles LNG Export. Both of these entities are owned by Energy Transfer Equity, L.P. and Energy Transfer Partners, L.P.

Lake Charles LNG Export states that FERC certificated the Terminal in 1977 and the original construction was completed in 1981.[7] According to Lake Charles LNG Export, the Terminal currently has a firm sustained sendout capacity of 1.8 Bcf/d and a peak sendout capacity of 2.1 Bcf/day. The Terminal has four LNG storage tanks with a combined capacity of approximately 425,000 cubic meters of LNG, or approximately 9.0 Bcf of natural gas. The Terminal's natural gas liquids processing facilities allow the extraction of ethane and other heavier hydrocarbons from the LNG stream.

Project Description

Among other features, the Liquefaction Project will include a new liquefaction facility consisting of three liquefaction trains, modifications and upgrades at the existing Terminal, and approximately 0.5 miles of 48-inch diameter feed gas line in Calcasieu Parish, Louisiana, to supply natural gas to the liquefaction facility from existing gas transmission pipelines.[8]

Lake Charles LNG Export states that, following completion of the Liquefaction Project, the Terminal will be bi-directional, meaning it will be capable of importing or exporting LNG, and its peak and sustained sendout capabilities will not be affected.

EIS Process

FERC was the lead federal agency and initiated the NEPA process by publishing a Notice of Intent (NOI) to prepare an EIS in the **Federal Register** (FR) on September 20, 2012 (77 FR 58373); DOE was a cooperating agency. FERC issued the draft EIS for the Liquefaction Project on April 10, 2015 (80 FR 20489), and the final EIS on August 20, 2015 (80 FR 50622). The final EIS addresses comments received on the draft EIS. Among other resource areas, the final EIS addresses geology, soils, water, wetlands, wildlife, air quality and noise, cumulative impacts and alternatives.[9]

The final EIS recommended that FERC subject any approval of Lake Charles LNG Export's proposed Liquefaction Project to 96 conditions to reduce the environmental impacts that would otherwise result from the construction and operation of the project. On December 17, 2015, FERC issued an Order Granting Section 3 and Section 7 Authorizations and Approving Abandonment (FERC Order),[10] which authorized Lake Charles LNG to site, construct, and operate the Lake Charles Liquefaction Project, subject to 95 of the 96 environmental conditions in Appendix B of that Order.

In accordance with 40 CFR 1506.3, after an independent review of FERC's final EIS, DOE/FE adopted FERC's final EIS for the Lake Charles Liquefaction Project (DOE/EIS–0491), and the U.S. Environmental Protection Agency published a notice of the adoption on July 15, 2016 (81 FR 46077).

Addendum to Environmental Review Documents Concerning Exports of Natural Gas From the United States (Addendum)

On June 4, 2014, DOE/FE published the Draft Addendum to Environmental Review Documents Concerning Exports of Natural Gas From the United States (Draft Addendum) for public comment (79 FR 32258). The purpose of this review was to provide additional information to the public concerning the potential environmental impacts of unconventional natural gas exploration and production activities, including hydraulic fracturing. Although not required by NEPA, DOE/FE prepared the Addendum in an effort to be responsive to the public and to provide

119–000, CP14–120–000, and CP14–122–000 (Aug. 2015).

[5] For more information on the corporate background, see DOE Order 3868, *Final Opinion and Order Granting Long-Term, Multi-Contract Authorization to Export Liquefied Natural Gas by Vessels from the Lake Charles Terminal in Calcasieu Parish, Louisiana to Non-Free Trade Agreement Nations,* issued July 29, 2016.

[6] In September 2014, Trunkline LNG Company, LLC changed its name to Lake Charles LNG Company, LLC. *See, Lake Charles LNG Export Co. LLC,* DOE/FE Order No. 3252–A, FE Docket No. 13–04–LNG, Order Granting Request to Amend DOE/FE Order No. 3252 and Pending Application to Reflect Corporate Name Change (Mar. 18, 2015).

[7] *Trunkline LNG Co., et al.,* 58 FPC 726 (Opinion No. 796), *order on reh'g* 58 FPC 2935 (1977) (Opinion No. 796–A).

[8] *See* Trunkline LNG Company, LLC *et al.,* Supplemental Notice of Intent to Prepare an Environmental Impact Statement for the Planned Lake Charles Liquefaction Project and Request for Comments on Environmental Issues, FERC Docket No. PF12–8–000, at 2 (Mar. 21, 2013), *available at http://energy.gov/sites/prod/files/EIS-0491-FERC-SNOI-2013.pdf.*

[9] *See* Final EIS at 1–10, Table 1.3–1 *Key Environmental Concerns Identified During the Scoping Process for the Lake Charles Liquefaction Project.*

[10] *Trunkline Gas Co., LLC, et al.,* Order Granting Section 3 and Section 7 Authorizations and Approving Abandonment, 153 FERC ¶ 61,300 (Dec. 17, 2015).

the best information available on a subject that had been raised by commenters in this and other LNG export proceedings.

The 45-day comment period on the Draft Addendum closed on July 21, 2014. DOE/FE received 40,745 comments in 18 separate submissions, and considered those comments in issuing the Final Addendum on August 15, 2014. DOE provided a summary of the comments received and responses to substantive comments in Appendix B of the Addendum. DOE/FE has incorporated the Draft Addendum, comments, and Final Addendum into the record in this proceeding.

Alternatives

The EIS assessed alternatives that could achieve the Liquefaction Project objectives. The range of alternatives analyzed included the No-Action Alternative, system alternatives, pipeline system alternatives, alternative liquefaction facility sites, alternative terminal configurations, alternative aboveground facility sites for pipeline expansion, and alternative power sources. Alternatives were evaluated and compared to the Liquefaction Project to determine if the alternatives were environmentally preferable.

Under the No-Action Alternative, the Liquefaction Project would not be developed. Additionally, the potential adverse and beneficial environmental impacts discussed within the EIS would not occur. Furthermore, this alternative could also require that potential end-users make different arrangements to obtain natural gas services, use other fossil fuel energy sources (*e.g.* coal or fuel oil), or possibly use traditional long-term energy sources (*e.g.* nuclear power) and/or renewable energy sources to compensate for lack of natural gas that would otherwise come from the supplies produced by the Liquefaction Project.

The EIS evaluated system alternatives for the Liquefaction Project, including six operating LNG import terminals in the Gulf of Mexico area, and several proposed or planned export projects along the Gulf Coast. All of the system alternatives were eliminated from further consideration for reasons that include the need for substantial construction beyond that currently proposed, production volume limitations, in-service dates scheduled significantly beyond Lake Charles LNG Export's commitments to its customers, and potential environmental impacts that were considered comparable to or greater than those of the Liquefaction Project.

The EIS evaluated three pipeline system alternatives for the Liquefaction Project. In order to be a viable pipeline system alternative, the alternative system would have to transport all or a part of the volume of natural gas required for liquefaction at the proposed new facility and cause significantly less impact on the environment. Additionally, a legitimate pipeline alternative must either connect directly to the proposed facility or to the existing pipeline system. Each of the three alternatives pipeline systems considered would require significant expansions in their looping and compression capabilities to achieve the necessary delivery capacity and require the construction of new segments to connect directly with the liquefaction facility. The construction associated with the alternatives, including significantly increasing pipeline looping capability or expansion would result in environmental impacts equal to or greater than the proposed pipeline system. As a result, none of the three proposed pipeline alternatives would provide a significant environmental advantage over the existing and proposed pipeline system.

The EIS evaluated five Liquefaction Project sites (including the current proposed site), all within relative close proximity to the existing Terminal. Construction of the Terminal at each of the alternative sites would have greater environmental impacts when compared to the proposed Terminal site; therefore, none of the four other sites evaluated were determined to be environmentally preferred.

For the Liquefaction Project configuration (*e.g.* siting for components such as liquefaction trains, pretreatment units and pipeline connections), the EIS considered the use design and configuration subject to the requirements of 49 CFR 193 and other industry or engineering standards. The EIS evaluated factors such as locations of interconnecting LNG transfer piping, operational noise, vapor dispersion requirements, and site evaluation associated with impacts on surrounding wetlands. Regulatory requirements associated with thermal exclusion and vapor dispersion zones would require additional fill material to increase elevation at the site that will likely cause further wetland losses on the site. As a result, the proposed configuration was determined to be environmentally preferred.

The EIS evaluated several alternative sites for the proposed above-ground facilities (*e.g.* one new compressor (Compressor Station 203–A) station and five new metering stations) for pipeline expansion. In each of the alternative sites analyzed for the facilities, the environmental impacts from construction and operational activities (*e.g.,* increased noise and air emissions) would not be environmentally preferred to the proposed sites.

Environmentally Preferred Alternative

When compared against the other action alternatives assessed in the EIS, as discussed above, the Lake Charles Liquefaction Project is the environmentally preferred alternative. While the No-Action Alternative would avoid the environmental impacts identified in the EIS, adoption of this alternative would not meet the Liquefaction Project objectives.

Decision

DOE has decided to issue Order No. 3868 authorizing Lake Charles LNG Export to export domestically produced LNG by vessel from the Terminal located in Lake Charles, Calcasieu Parish, Louisiana, in a volume up to the equivalent to 730 Bcf/yr of natural gas for a term of 20 years to commence on the earlier of the date of first export or seven years from the date that the Order is issued.

Concurrently with this Record of Decision, DOE is issuing Order No. 3868 in which it finds that the requested authorization has not been shown to be inconsistent with the public interest and the Application should be granted subject to compliance with the terms and conditions set forth in the Order, including the environmental conditions recommended in the EIS and adopted in the FERC Order at Appendix B. Additionally, this authorization is conditioned on Lake Charles LNG Export's compliance with any other preventative and mitigative measures imposed by other Federal or state agencies.

Basis of Decision

DOE's decision is based upon the analysis of potential environmental impacts presented in the EIS, and DOE's determination in Order No. 3868 that the opponents of Lake Charles LNG Export's Application have failed to overcome the statutory presumption that the proposed export authorization is not inconsistent with the public interest. Although not required by NEPA, DOE/FE also considered the Addendum, which summarizes available information on potential upstream impacts associated with unconventional natural gas activities, such as hydraulic fracturing.

Mitigation

As a condition of its decision to issue Order No. 3868 authorizing Lake Charles LNG Export to export LNG to non-FTA countries, DOE is imposing requirements that will avoid or minimize the environmental impacts of the project. These conditions include the environmental conditions recommended in the EIS and adopted in the FERC Order at Appendix B. Mitigation measures beyond those included in Order No. 3868 that are enforceable by other Federal and state agencies are additional conditions of Order No. 3868. With these conditions, DOE/FE has determined that all practicable means to avoid or minimize environmental harm from the Liquefaction Project have been adopted.

Floodplain Statement of Findings

DOE prepared this Floodplain Statement of Findings in accordance with DOE's regulations entitled ''Compliance with Floodplain and Wetland Environmental Review Requirements'' (10 CFR part 1022). The required floodplain assessment was conducted during development and preparation of the EIS (see Sections 3.3.1, 3.3.2, 4.1.3.4, and 4.13.2.1 of the EIS). DOE determined that the placement of some project components within floodplains would be unavoidable. However, the current design for the Lake Charles Liquefaction Project minimizes floodplain impacts to the extent practicable.

Issued in Washington, DC, on July 29, 2016.

Christopher A. Smith,

Assistant Secretary, Office of Fossil Energy.

[FR Doc. 2016–18651 Filed 8–4–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Record of Decision and Floodplain Statement of Findings for the Lake Charles Exports, LLC Application To Export Liquefied Natural Gas to Non-Free Trade Agreement Countries

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Record of decision.

SUMMARY: The U.S. Department of Energy (DOE) announces its decision in Lake Charles Exports, LLC (LCE), DOE/FE Docket No. 11–59–LNG, to issue DOE/FE Order No. 3324–A, granting final long-term, multi contract authorization for LCE to engage in the export of domestically produced liquefied natural gas (LNG) from the Lake Charles Terminal located in Lake Charles, Calcasieu Parish, Louisiana (Terminal), in a volume equivalent to 730 Bcf/yr of natural gas for a term of 20 years. LCE is seeking to export LNG from the Terminal to countries with which the United States has not entered into a free trade agreement (FTA) that requires national treatment for trade in natural gas, and with which trade is not prohibited by U.S. law or policy (non-FTA countries). Order No. 3324–A is issued under section 3 of the Natural Gas Act (NGA) [1] and 10 CFR part 590 of DOE's regulations.[2] DOE participated as a cooperating agency with the Federal Energy Regulatory Commission (FERC) in preparing an environmental impact statement (EIS) [3] analyzing the potential environmental impacts resulting from modification of the existing facilities at the Terminal.

ADDRESSES: The EIS and this Record of Decision (ROD) are available on DOE's National Environmental Policy Act (NEPA) Web site at: *http://energy.gov/nepa/nepa-documents.* Order No. 3324–A is available on DOE/FE's Web site at: *http://www.fossil.energy.gov/programs/gasregulation/authorizations/2011_applications/lake_charles_exports.html.* For additional information about the docket in these proceedings, contact Larine Moore, U.S. Department of Energy, Office of Regulation and International Engagement, Office of Oil and Natural Gas, Office of Fossil Energy, Room 3E–042, 1000 Independence Avenue SW., Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT: To obtain additional information about the EIS or the ROD, contact Mr. Kyle W. Moorman, U.S. Department of Energy (FE–34), Office of Regulation and International Engagement, Office of Oil and Natural Gas, Office of Fossil Energy, Room 3E–042, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586–5600, or Mr. Edward Le Duc, U.S. Department of Energy (GC–51), Office of the Assistant General Counsel for Environment, 1000 Independence Avenue SW., Washington, DC 20585.

SUPPLEMENTARY INFORMATION: DOE prepared this ROD and Floodplain Statement of Findings pursuant to the National Environmental Policy Act of 1969 (42 United States Code [U.S.C.] 4321, *et seq.*), and in compliance with the Council on Environmental Quality (CEQ) implementing regulations for NEPA (40 Code of Federal Regulations [CFR] parts 1500 through 1508), DOE's implementing procedures for NEPA (10 CFR part 1021), and DOE's ''Compliance with Floodplain and Wetland Environmental Review Requirements'' (10 CFR part 1022).

Background

LCE is a Delaware limited liability company with its principal place of business in Houston, Texas. In a Notice of Change in Control recently submitted to DOE/FE,[4] LCE states that, on February 15, 2016, Royal Dutch Shell, plc (Shell) acquired all of the share capital of BG Group plc (BG). Prior to the transaction, LCE was owned by subsidiaries of BG and Energy Transfer Equity, L.P. (ETE), and LCE's affiliate, BG LNG Services, LLC (BGLS), was an indirect subsidiary of BG. As a result of the transaction, LCE is now owned by subsidiaries of Shell and ETE [5] and BGLS is now an indirect wholly-owned subsidiary of Shell. According to LCE, LCE will remain the authorization holder for its existing DOE/FE authorizations and/or the applicant in its pending DOE/FE proceedings.

On May 6, 2011, LCE filed the application (Application) with DOE/FE seeking authorization to export domestically produced LNG from proposed liquefaction facilities (Liquefaction Project) to be located at the existing Terminal in Lake Charles, Louisiana. LCE proposes to export this LNG to non-FTA countries in a total volume equivalent to 730 billion cubic feet per year (Bcf/yr) of natural gas.

The Terminal is owned and operated by Lake Charles LNG Company, LLC (Lake Charles LNG, formerly Trunkline LNG Company, LLC), a corporate affiliate of LCE.[6] The Liquefaction Project will be owned by Lake Charles LNG Export Company, LLC (formerly Trunkline LNG Export, LLC), another corporate affiliate of LCE which is separately pursuing an authorization to

[1] The authority to regulate the imports and exports of natural gas, including liquefied natural gas, under section 3 of the NGA (15 U.S.C. 717b) has been delegated to the Assistant Secretary for FE in Redelegation Order No. 00–006.02 issued on November 17, 2014.

[2] 10 CFR part 590 (2012).

[3] Federal Energy Regulatory Commission, Final Environmental Impact Statement for the Lake Charles Liquefaction Project, Docket Nos. CP14–119–000, CP14–120–000, and CP14–122–000 (Aug. 2015).

[4] See Lake Charles Exports, LLC, Notice of Change in Control (Feb. 17, 2016) and DOE/FE letter responding to Notice (July 26, 2016) in DOE/FE Docket No. 11–59–LNG.

[5] DOE/FE takes administrative notice that Shell is a public limited company incorporated in the United Kingdom and headquartered in the Netherlands. ETE is a Delaware master limited partnership with its principal place of business in Dallas, Texas.

[6] In September 2014, Trunkline LNG Company, LLC changed its name to Lake Charles LNG Company, LLC. *See, Lake Charles LNG Export Co. LLC,* DOE/FE Order No. 3252–A, FE Docket No. 13–04–LNG, Order Granting Request to Amend DOE/FE Order No. 3252 and Pending Application to Reflect Corporate Name Change (Mar. 18, 2015).

export the same volume of LNG to non-FTA countries in DOE/FE Docket No. 13–04–LNG.[7] Lake Charles LNG and Lake Charles LNG Export Company are both owned by Energy Transfer Equity, L.P. and Energy Transfer Partners, L.P.

On August 7, 2013, DOE/FE issued Order No. 3324 (Conditional Order) to LCE, conditionally granting the portion of LCE's Application that requested long-term, multi-contract authority to export domestically produced LNG to non-FTA countries. Under the terms of that Conditional Order, LCE is conditionally authorized to export up to 15 mtpa, which LCE states is equivalent to approximately 730 billion Bcf/yr of natural gas (2.0 Bcf/d), by vessel from the Terminal for a term of 20 years. The Conditional Order reviewed the record evidence and entered findings on all non-environmental issues considered under NGA section 3(a), including the economic impacts, international impacts, and security of natural gas supply associated with LCE's proposed exports. Because DOE must also consider environmental issues, DOE/FE conditioned the order on: (i) FERC's satisfactory completion of the NEPA environmental review process, and (ii) DOE/FE's own issuance of a finding of No Significant Impact (FONSI) or a Record of Decision (ROD) under NEPA.[8]

LCE states that FERC certificated the Terminal in 1977 and the original construction was completed in 1981.[9] LCE states that Lake Charles LNG has expanded and enhanced the Terminal through the construction of additional storage capacity, additional gas-fired vaporization capacity, an additional marine berth, ambient air vaporization equipment, and natural gas liquids extraction capability.

According to LCE, the Terminal currently has a firm sustained sendout capacity of 1.8 Bcf/d and a peak sendout capacity of 2.1 Bcf/day. The Terminal has four LNG storage tanks with a combined capacity of approximately 425,000 cubic meters of LNG, or approximately 9.0 Bcf of natural gas. The Terminal's natural gas liquids processing facilities allow the extraction of ethane and other heavier hydrocarbons from the LNG stream.

Project Description

Among other features, the Liquefaction Project will include a new liquefaction facility consisting of three liquefaction trains, modifications and upgrades at the existing Terminal, and approximately 0.5 miles of 48-inch diameter feed gas line in Calcasieu Parish, Louisiana, to supply natural gas to the liquefaction facility from existing gas transmission pipelines.[10]

LCE states that, following completion of the Liquefaction Project, the Terminal will be bi-directional, meaning it will be capable of importing or exporting LNG, and its peak and sustained sendout capabilities will not be affected.

EIS Process

FERC was the lead federal agency and initiated the NEPA process by publishing a Notice of Intent (NOI) to prepare an EIS in the **Federal Register** (FR) on September 20, 2012 (77 FR 58373); DOE was a cooperating agency. FERC issued the draft EIS for the Liquefaction Project on April 10, 2015 (80 FR 20489), and the final EIS on August 20, 2015 (80 FR 50622). The final EIS addresses comments received on the draft EIS. Among other resource areas, the final EIS addresses geology, soils, water, wetlands, wildlife, air quality and noise, cumulative impacts and alternatives.[11]

The final EIS recommended that FERC subject any approval of LCE's proposed Liquefaction Project to 96 conditions to reduce the environmental impacts that would otherwise result from the construction and operation of the project. On December 17, 2015, FERC issued an Order Granting Section 3 and Section 7 Authorizations and Approving Abandonment (FERC Order),[12] which authorized Lake Charles LNG to site, construct, and operate the Lake Charles Liquefaction Project, subject to 95 of the 96 environmental conditions in Appendix B of that Order.

In accordance with 40 CFR 1506.3, after an independent review of FERC's final EIS, DOE/FE adopted FERC's final EIS for the Lake Charles Liquefaction Project (DOE/EIS–0491), and the U.S. Environmental Protection Agency published a notice of the adoption on July 15, 2016 (81 FR 46077).

Addendum to Environmental Review Documents Concerning Exports of Natural Gas From the United States (Addendum)

On June 4, 2014, DOE/FE published the Draft Addendum to Environmental Review Documents Concerning Exports of Natural Gas From the United States (Draft Addendum) for public comment (79 FR 32258). The purpose of this review was to provide additional information to the public concerning the potential environmental impacts of unconventional natural gas exploration and production activities, including hydraulic fracturing. Although not required by NEPA, DOE/FE prepared the Addendum in an effort to be responsive to the public and to provide the best information available on a subject that had been raised by commenters in this and other LNG export proceedings.

The 45-day comment period on the Draft Addendum closed on July 21, 2014. DOE/FE received 40,745 comments in 18 separate submissions, and considered those comments in issuing the Final Addendum on August 15, 2014. DOE provided a summary of the comments received and responses to substantive comments in Appendix B of the Addendum. DOE/FE has incorporated the Draft Addendum, comments, and Final Addendum into the record in this proceeding.

Alternatives

The EIS assessed alternatives that could achieve the Liquefaction Project objectives. The range of alternatives analyzed included the No-Action Alternative, system alternatives, pipeline system alternatives, alternative liquefaction facility sites, alternative terminal configurations, alternative aboveground facility sites for pipeline expansion, and alternative power sources. Alternatives were evaluated and compared to the Lake Charles Liquefaction Project to determine if the alternatives were environmentally preferable.

Under the No-Action Alternative, the Liquefaction Project would not be developed. Additionally, the potential adverse and beneficial environmental impacts discussed within the EIS would not occur. Furthermore, this alternative could also require that potential end-users make different arrangements to obtain natural gas services, use other fossil fuel energy sources (*e.g.* coal or

[7] On Oct. 10, 2014, Trunkline LNG Export, LLC filed a request in DOE/FE Dkt. No. 13–04–LNG to change its corporate name to Lake Charles Export Company, LLC. Order 3252–A granted the name change.

[8] LCE Conditional Order, DOE/FE No. 3324, at 133–34 (Term and Condition Para. H).

[9] *Trunkline LNG Co., et al.,* 58 FPC 726 (Opinion No. 796), *order on reh'g* 58 FPC 2935 (1977) (Opinion No. 796–A).

[10] *See* Trunkline LNG Company, LLC *et al.,* Supplemental Notice of Intent to Prepare an Environmental Impact Statement for the Planned Lake Charles Liquefaction Project and Request for Comments on Environmental Issues, FERC Docket No. PF12–8–000, at 2 (Mar. 21, 2013), *available at http://energy.gov/sites/prod/files/EIS-0491-FERC-SNOI-2013.pdf.*

[11] *See* Final EIS at 1–10, Table 1.3–1 *Key Environmental Concerns Identified During the Scoping Process for the Lake Charles Liquefaction Project.*

[12] *Trunkline Gas Co., LLC, et al.,* Order Granting Section 3 and Section 7 Authorizations and Approving Abandonment, 153 FERC ¶ 61,300 (Dec. 17, 2015).

fuel oil), or possibly use traditional long-term energy sources (*e.g.* nuclear power) and/or renewable energy sources to compensate for lack of natural gas that would otherwise come from the supplies produced by the Liquefaction Project.

The EIS evaluated system alternatives for the Liquefaction Project, including six operating LNG import terminals in the Gulf of Mexico area, and several proposed or planned export projects along the Gulf Coast. All of the system alternatives were eliminated from further consideration for reasons that include the need for substantial construction beyond that currently proposed, production volume limitations, in-service dates scheduled significantly beyond LCE's commitments to its customers, and potential environmental impacts that were considered comparable to or greater than those of the Liquefaction Project.

The EIS evaluated three pipeline system alternatives for the Liquefaction Project. In order to be a viable pipeline system alternative, the alternative system would have to transport all or a part of the volume of natural gas required for liquefaction at the proposed new facility and cause significantly less impact on the environment. Additionally, a legitimate pipeline alternative must either connect directly to the proposed facility or to the existing pipeline system. Each of the three alternatives pipeline systems considered would require significant expansions in their looping and compression capabilities to achieve the necessary delivery capacity and require the construction of new segments to connect directly with the liquefaction facility. The construction associated with the alternatives, including significantly increasing pipeline looping capability or expansion, would result in environmental impacts equal to or greater than the proposed pipeline system. As a result, none of the three proposed pipeline alternatives would provide a significant environmental advantage over the existing and proposed pipeline system.

The EIS evaluated five Liquefaction Project sites (including the current proposed site), all within relative close proximity to the existing Terminal. Construction of the Terminal at each of the alternative sites would have greater environmental impacts when compared to the proposed Terminal site; therefore, none of the four other sites evaluated were determined to be environmentally preferred.

For the Liquefaction Project configuration (*e.g.* siting for components such as liquefaction trains, pretreatment units and pipeline connections), the EIS considered the use, design, and configuration subject to the requirements of 49 CFR 193 and other industry or engineering standards. The EIS evaluated factors such as locations of interconnecting LNG transfer piping, operational noise, vapor dispersion requirements, and site evaluation associated with impacts on surrounding wetlands. Regulatory requirements associated with thermal exclusion and vapor dispersion zones would require additional fill material to increase elevation at the site that will likely cause further wetland losses on the site. As a result, the proposed configuration was determined to be environmentally preferred.

The EIS evaluated several alternative sites for the proposed above-ground facilities (*e.g.* one new compressor (Compressor Station 203–A) station and five new metering stations) for pipeline expansion. In each of the alternative sites analyzed for the facilities, the environmental impacts from construction and operational activities (*e.g.,* increased noise and air emissions) would not be environmentally preferred to the proposed sites.

Environmentally Preferred Alternative

When compared against the other action alternatives assessed in the EIS, as discussed above, the Lake Charles Liquefaction Project is the environmentally preferred alternative. While the No-Action Alternative would avoid the environmental impacts identified in the EIS, adoption of this alternative would not meet the Liquefaction Project objectives.

Decision

DOE has decided to issue Order No. 3324–A authorizing LCE to export domestically produced LNG by vessel from the Terminal located in Lake Charles, Calcasieu Parish, Louisiana, in a volume up to the equivalent to 730 Bcf/yr of natural gas for a term of 20 years to commence on the earlier of the date of first export or seven years from the date that the Order is issued.

Concurrently with this Record of Decision, DOE is issuing Order No. 3324–A in which it finds that the requested authorization has not been shown to be inconsistent with the public interest, and the Application should be granted subject to compliance with the terms and conditions set forth in the Order, including the environmental conditions recommended in the EIS and adopted in the FERC Order at Appendix B. Additionally, this authorization is conditioned on LCE's compliance with any other preventative and mitigative measures imposed by other Federal or state agencies.

Basis of Decision

DOE's decision is based upon the analysis of potential environmental impacts presented in the EIS, and DOE's determination in Order No. 3324–A that the opponents of LCE's Application have failed to overcome the statutory presumption that the proposed export authorization is not inconsistent with the public interest. Although not required by NEPA, DOE/FE also considered the Addendum, which summarizes available information on potential upstream impacts associated with unconventional natural gas activities, such as hydraulic fracturing.

Mitigation

As a condition of its decision to issue Order No. 3324–A authorizing LCE to export LNG to non-FTA countries, DOE is imposing requirements that will avoid or minimize the environmental impacts of the project. These conditions include the environmental conditions recommended in the EIS and adopted in the FERC Order at Appendix B. Mitigation measures beyond those included in Order No. 3324–A that are enforceable by other Federal and state agencies are additional conditions of Order No. 3324–A. With these conditions, DOE/FE has determined that all practicable means to avoid or minimize environmental harm from the Liquefaction Project have been adopted.

Floodplain Statement of Findings

DOE prepared this Floodplain Statement of Findings in accordance with DOE's regulations, entitled ''Compliance with Floodplain and Wetland Environmental Review Requirements'' (10 CFR part 1022). The required floodplain assessment was conducted during development and preparation of the EIS (see Sections 3.3.1, 3.3.2, 4.1.3.4, and 4.13.2.1 of the EIS). DOE determined that the placement of some project components within floodplains would be unavoidable. However, the current design for the Lake Charles Liquefaction Project minimizes floodplain impacts to the extent practicable.

Issued in Washington, DC, on July 29, 2016.

Christopher A. Smith,

Assistant Secretary, Office of Fossil Energy.

[FR Doc. 2016–18652 Filed 8–4–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. CP15–115–000 and CP15–115–001]

National Fuel Gas Supply Corporation, Empire Pipeline, Inc.; Notice of Availability of the Environmental Assessment for the Proposed Northern Access 2016 Project

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared an environmental assessment (EA) for the Northern Access 2016 Project, proposed by National Fuel Gas Supply Corporation and Empire Pipeline, Inc. (National Fuel) in the above-referenced dockets. National Fuel requests authorization to construct, operate, and maintain about 99 miles of natural gas transmission pipeline and related facilities in McKean County, Pennsylvania and Allegany, Cattaraugus, Erie, and Niagara Counties, New York. The Project would provide 350,000 dekatherms per day of capacity to markets in the northeastern United States and Canada.

The EA assesses the potential environmental effects of the construction and operation of the Northern Access 2016 Project in accordance with the requirements of the National Environmental Policy Act (NEPA). The FERC staff concludes that approval of the proposed project, with appropriate mitigating measures, would not constitute a major federal action significantly affecting the quality of the human environment.

The U.S. Army Corps of Engineers and New York State Department of Agriculture and Markets participated as cooperating agencies in the preparation of the EA. Cooperating agencies have jurisdiction by law or special expertise with respect to resources potentially affected by the proposal and participate in the NEPA analysis.

The proposed Northern Access 2016 Project includes the following facilities:

- 96.9 miles of 24-inch-diameter pipeline in McKean County, Pennsylvania and Allegany, Cattaraugus, and Erie Counties, New York;
- 0.9 mile of 16-inch-diameter pipeline and 1.2 miles of 24-inch-diameter pipeline in Niagara County, New York;
- a new 22,000 horsepower (hp) compressor station in Niagara County;
- an additional 5,000 hp of compression at an existing compressor station in Erie County;
- a metering, regulation, and delivery station in Erie County;
- a dehydration facility in Niagara County;
- tie-ins in McKean, Cattaraugus, and Erie Counties;
- modification of tie-in facilities in Niagara County;
- mainline block valves in McKean, Allegany, Cattaraugus, and Erie Counties; and
- access roads and contractor/staging yards in McKean, Allegany, Cattaraugus, and Erie Counties.

The FERC staff mailed copies of the EA to federal, state, and local officials; agency representatives; conservation organizations; local libraries and newspapers; Native American groups; property owners affected by the Project facilities; and parties to this proceeding. In addition, the EA is available for public viewing on the FERC's Web site (*www.ferc.gov*) using the eLibrary link. A limited number of copies of the EA are available for distribution and public inspection at: Federal Energy Regulatory Commission, Public Reference Room 888 First Street NE., Room 2A, Washington, DC 20426 (202) 502–8371.

Any person wishing to comment on the EA may do so. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. The more specific your comments, the more useful they will be. To ensure that the Commission has the opportunity to consider your comments prior to making its decision on this project, it is important that we receive your comments in Washington, DC on or before August 26, 2016.

For your convenience, there are three methods you can use to file your comments with the Commission. In all instances please reference the project docket number (CP15–115–000 or CP15–115–001) with your submission. The Commission encourages electronic filing of comments and has expert staff available to assist you at 202–502–8258 or *efiling@ferc.gov*.

(1) You can file your comments electronically using the eComment feature located on the Commission's Web site (*www.ferc.gov*) under the link to Documents and Filings. This is an easy method for submitting brief, text-only comments on a project;

(2) You can also file your comments electronically using the eFiling feature on the Commission's Web site (*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 must select the type of filing you are making. If you are filing a comment on a particular project, please select ''Comment on a Filing''; or

(3) You can file a paper copy of your comments by mailing them to the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Room 1A, Washington, DC 20426.

Any person seeking to become a party to the proceeding must file a motion to intervene pursuant to Rule 214 of the Commission's Rules of Practice and Procedures (18 CFR 385.214).[1] Only intervenors have the right to seek rehearing of the Commission's decision. The Commission grants affected landowners and others with environmental concerns intervenor status upon showing good cause by stating that they have a clear and direct interest in this proceeding which no other party can adequately represent. Simply filing environmental comments will not give you intervenor status, but you do not need intervenor status to have your comments considered.

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC Web site (*www.ferc.gov*) using the eLibrary link. Click on the eLibrary link, click on ''General Search,'' and enter the docket number excluding the last three digits in the Docket Number field (*i.e.*, CP15–115). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of 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. Go to *www.ferc.gov/docs-filing/esubscription.asp*.

Dated: July 27, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–18572 Filed 8–4–16; 8:45 am]

BILLING CODE 6717–01–P

[1] See the previous discussion on the methods for filing comments.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14793–000]

The Domestic and Foreign Missionary Society of the Protestant Episcopal Diocese of Alabama; Notice of Application Tendered for Filing With the Commission and Establishing Procedural Schedule for Licensing and Deadline for Submission of Final Amendments

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* 10 Megawatt Exemption.

b. *Project No.:* 14793–000.

c. *Date filed:* July 12, 2016.

d. *Applicant:* The Domestic and Foreign Missionary Society of the Protestant Episcopal Diocese of Alabama.

e. *Name of Project:* Camp McDowell Project.

f. *Location:* On Clear Creek, near Nauvoo in Winston County, Alabama. The project does not affect federal lands.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Frazier Christy, 3621 Kingshill Road, Birmingham, Alabama 35223.

i. *FERC Contact:* Michael Spencer, (202) 502–6093, *michael.spencer@ferc.gov.*

j. This application is not ready for environmental analysis at this time.

k. The proposed project would consist of: (1) an Archimedean Screw installed in the spillway of the dam; (2) a 10 acre reservoir; (3) a powerhouse containing a generator with a total installed capacity of 140 kilowatts; and (4) a transmission line. The project is estimated to generate an average of 950 megawatt-hours annually.

l. Locations of the Application: A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). A copy is also available for inspection and reproduction at the address in item (h) above.

m. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. Procedural schedule: The application will be processed according to the following preliminary Hydro Licensing Schedule. Revisions to the schedule will be made as appropriate.

Milestone	Target date
Notice of Acceptance/Notice of Ready for Environmental Analysis	October 2016.
Filing of recommendations, preliminary terms and conditions, and fishway prescriptions	December 2016.
Commission issues EA	June 2017.
Comments on EA	July 2017.

o. Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of the notice of ready for environmental analysis.

Dated: July 27, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–18579 Filed 8–4–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PF14–21–000]

Alaska Gasline Development Corporation, BP Alaska LNG LLC, Conoco Phillips Alaska LNG Company, ExxonMobil Alaska LNG LLC; Supplemental Notice Requesting Comments on the Denali National Park and Preserve Alterative for the Planned Alaska LNG Project

As previously noticed on March 4, 2015, the staff of the Federal Energy Regulatory Commission (FERC or Commission) is preparing an environmental impact statement (EIS) that will discuss the environmental impacts of the Alaska LNG Project that could result from construction and operation of facilities by Alaska Gasline Development Corporation; BP Alaska LNG LLC; Conoco Phillips Alaska LNG Company; and ExxonMobil Alaska LNG LLC (Applicants) in Alaska. This notice explains the additional scoping process that will be used to gather input from the public and interested agencies on a route alternative to be evaluated for crossing the Denali National Park and Preserve (DNPP).

The route currently planned by Alaska LNG is closely aligned with the Parks Highway, but deviates from the highway where the Parks Highway passes through the DNPP entrance area (see figure in appendix 1.[1]) In response to scoping comments, and in working with federal and state regulating agencies, as well as the local communities, Alaska LNG has identified an alternative route (the DNPP Alternative) that passes directly through the DNPP entrance area and is closely aligned with the Parks Highway (see figure in appendix 1). In this general area, the planned route would be 8.05 miles long and not enter the DNPP, while the corresponding segment of the DNPP Alternative would be 8.50 miles long (6.16 miles of which would pass through the DNPP).

This Supplemental Notice announces the opening of a limited scoping period to gather input from the public and interested agencies on the DNPP Alternative route. You can make a difference by providing us with your specific comments or concerns about the DNPP Alternative route. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. Your input will help the Commission staff determine what issues they need to evaluate in the EIS. To ensure that your comments are timely and properly recorded, please send your comments so that the Commission receives them in Washington, DC on or before September 25, 2016.

This notice is being sent to the Commission's current environmental mailing list for this project. State and local government representatives should

[1] The appendices referenced in this notice will not appear in the **Federal Register**. Copies of the appendices were sent to all those receiving this notice in the mail and are available at *www.ferc.gov* using the link called ''eLibrary'' or from the Commission's Public Reference Room, 888 First Street NE., Washington, DC 20426, or call (202) 502–8371. For instructions on connecting to eLibrary, refer to the last page of this notice.

notify their constituents of this planned project and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, a pipeline company representative may contact you about the acquisition of an easement to construct, operate, and maintain the planned facilities. The company would seek to negotiate a mutually acceptable agreement. However, if the Commission approves the project, that approval conveys with it the right of eminent domain. Therefore, if easement negotiations fail to produce an agreement, the pipeline company could initiate condemnation proceedings where compensation would be determined in accordance with state law.

A fact sheet prepared by the FERC entitled ''An Interstate Natural Gas Facility On My Land? What Do I Need To Know?'' is available for viewing on the FERC Web site (*www.ferc.gov*). This fact sheet addresses a number of typically asked questions, including the use of eminent domain and how to participate in the Commission's proceedings.

Public Participation

For your convenience, there are three methods you can use to submit your comments to the Commission. In all instances, please reference the project docket number (PF14–21–000) with your submission. The Commission encourages electronic filing of comments and has expert staff available to assist you at (202) 502–8258 or *efiling@ferc.gov.* Please carefully follow these instructions so that your comments are properly recorded.

(1) You can file your comments electronically using the *eComment* feature on the Commission's Web site (*www.ferc.gov*) under the link to *Documents and Filings.* This is an easy method for submitting brief, text-only comments on a project;

(2) You can file your comments electronically by using the *eFiling* feature on the Commission's Web site (*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.*'' If you are filing a comment on a particular project, please select ''Comment on a Filing'' as the filing type; or

(3) You can file a paper copy of your comments by mailing them to the following address. Be sure to reference the project docket number (PF14–21–000) with your submission: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Room 1A, Washington, DC 20426.

In addition, if you have questions regarding the FERC process and our review of the alternative, FERC staff will be available to answer questions on Tuesday, August 23, 2016, between 4:00 and 6:00 p.m. at the Murie Dining Hall within Denali National Park (next to the Murie Science and Learning Center),

Please note this is not your only public input opportunity; please refer to the review process flow chart in appendix 2.

Summary of the Planned Project

The Applicants are planning to transport and liquefy supplies of natural gas from the production fields at the Point Thomson and Prudhoe Bay Units (PTU and PBU, respectively) on Alaska's North Slope for export and potential in-state deliveries. To do this, the Alaska LNG Project would consist of a new Gas Treatment Plant (GTP) on the North Slope and associated pipelines to deliver the gas from the PTU and PBU to the GTP, as well as a pipeline to deliver natural gas processing byproducts from the GTP back to the PBU. The GTP would treat/process the natural gas for delivery to an approximately 800-mile-long, 42-inch-diameter pipeline that would transport the natural gas to a new planned liquefaction facility on the eastern shore of Cook Inlet in the Nikiski area of the Kenai Peninsula. Alaska LNG anticipates starting construction in late 2019, with construction and startup taking approximately 8 years. On this basis, the full planned Project system would be placed into service about 2027.

As previously described, the alternative we are scoping involves an alternative route directly through the DNPP entrance area and closely aligned with the Parks Highway (see figure in appendix 1). We are requesting input from stakeholders on both the DNPP Alternative route and the current route that is located outside the park.

The EIS Process

The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from an action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. NEPA also requires us [2] to discover and address concerns the public may have about proposals. This process is referred to as scoping. The main goal of the scoping process is to focus the analysis in the EIS on the important environmental issues. By this notice, the Commission requests public comments on the scope of the issues to address in the EIS. We will consider all filed comments during the preparation of the EIS.

In the EIS we will discuss impacts that could occur as a result of the construction and operation of the planned project under these general headings:

- Alternatives
- Geology and soils;
- Land use;
- Water resources, fisheries, and wetlands;
- Cultural resources;
- Vegetation and wildlife;
- Air quality and noise;
- Endangered and threatened species;
- Transportation;
- Socioeconomics;
- Public safety; and
- Cumulative impacts.

We will also evaluate possible alternatives to the planned project or portions of the project, and make recommendations on how to lessen or avoid impacts on the various resource areas.

Although no formal application has been filed, we have already initiated our NEPA review under the Commission's pre-filing process. The purpose of the pre-filing process is to encourage early involvement of interested stakeholders and to identify and resolve issues before the FERC receives an application. As part of our pre-filing review, we have already met with the Applicants, jurisdictional agencies, Alaska Native tribes, local officials, and other interested stakeholders to discuss the project and identify issues/impacts and concerns before the FERC receives an application.

In October and November 2016, FERC conducted a total of 12 scoping meetings throughout Alaska. During the scoping meetings, we garnered feedback from the local communities, including residents, elected officials, tribal leaders, community leaders, and other interested stakeholders.

Our independent analysis of the issues will be presented in the EIS. The draft EIS will be published and distributed for public review and comment. We will consider all timely comments and revise the document, as necessary, before issuing a final EIS. To ensure your comments are considered, please carefully follow the instructions in the Public Participation section of this notice.

[2] ''We,'' ''us,'' and ''our'' refer to the environmental staff of the Commission's Office of Energy Projects.

Environmental Mailing List

The environmental mailing list includes federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American Tribes; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the project. We will update the environmental mailing list as the analysis proceeds to ensure that we send the information related to this environmental review to all individuals, organizations, and government entities interested in and/or potentially affected by the planned project.

Copies of the completed draft EIS will be sent to the environmental mailing list for public review and comment. If you would prefer to receive a paper copy of the document instead of the CD version or would like to remove your name from the mailing list, please return the attached Information Request (appendix 3).

Becoming an Intervenor

Once the Applicants file their application with the Commission, you may want to become an ''intervenor'' which is an official party to the Commission's proceeding. Intervenors play a more formal role in the process and are able to file briefs, appear at hearings, and be heard by the courts if they choose to appeal the Commission's final ruling. An intervenor formally participates in the proceeding by filing a request to intervene. Instructions for becoming an intervenor are in the User's Guide under the ''efiling'' link on the Commission's Web site. Please note that the Commission will not accept requests for intervenor status at this time. You must wait until the Commission receives a formal application for the project.

Additional Information

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC Web site (*www.ferc.gov*) using the eLibrary link. Click on the eLibrary link, click on ''General Search'' and enter the docket number, excluding the last three digits in the Docket Number field (*i.e.,* PF14–21). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of 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. Go to *www.ferc.gov/docs-filing/esubscription.asp.*

Further, public meetings or site visits will be posted on the Commission's calendar located at *www.ferc.gov/EventCalendar/EventsList.aspx* along with other related information. Finally, additional information about the project can be seen from the Applicant's Web site at *http://ak-lng.com.*

Dated: July 27, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–18580 Filed 8–4–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13318–003]

Swan Lake North Pumped Storage Project; Notice of Meeting

Commission staff will meet with representatives of the Klamath Tribes (Tribes), the Oregon State Historic Preservation Officer and other state and federal agencies (to the extent they wish to participate), and Swan Lake North Hydro LLC regarding the proposed Swan Lake North Pumped Storage Project (Project No. 13318–003). The meeting will be held at the location and time listed below: Klamath Tribes, Tribal Administration Building, 501 Chiloquin Blvd., Chiloquin, OR 97624, Phone: (541) 783–2219, Thursday, August 11, 2016, 9:00 a.m. PDT.

Members of the public and intervenors in the referenced proceeding may attend this meeting; however, participation will be limited to tribal representatives and agency personnel. If the Tribes decide to disclose information about a specific location which could create a risk or harm to an archeological site or Native American cultural resource, the public will be excused for that portion of the meeting.[1] If you plan to attend this meeting, please contact Dr. Frank Winchell at the Federal Energy Regulatory Commission. He can be reached at (202) 502–6104.

Dated: July 27, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–18577 Filed 8–4–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP15–558–000]

PennEast Pipeline Company, LLC; Notice of Motion

On June 15, 2016, the New Jersey Conservation Foundation and Stony Brook-Millstone Watershed Association (Movants), filed with the Federal Energy Regulatory Commission (Commission) a pleading styled as a Rule 206 Complaint and Rule 212 Motion against PennEast Pipeline Company, LLC (PennEast), alleging that PennEast's application for a Certificate of Public Convenience and Necessity does not contain substantial evidence of public benefit, as required by the Natural Gas Act.[1] The pleading further requests the Commission initiate an evidentiary hearing to ''garner substantial evidence'' and develop the record upon which the Commission would rely in making its ''ultimate determination regarding PennEast's certificate of public convenience and necessity.''

While styled as a complaint under Rule 206, the pleading, filed in the PennEast certificate proceeding, Docket No. CP15–558–000, seeks resolution of the issue pending before the Commission in that proceeding, *i.e.,* whether PennEast's request for a certificate of convenience and necessity is supported by substantial evidence. Accordingly, action on the Movants' request for an evidentiary hearing, as well as consideration of the merits of the Movants' allegations, will take place in that forum.

Dated: July 27, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–18578 Filed 8–4–16; 8:45 am]

BILLING CODE 6717–01–P

[1] Protection from public disclosure involving this kind of specific information is based upon 18 CFR 4.32(b)(3)(ii) of the Commission's regulations implementing the Federal Power Act.

[1] 15 U.S.C. 717f(e) (2012).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 12449–013]

Neshkoro Power Associates, LLC, Wisconsin8, LLC; Notice of Application for Transfer of License and Soliciting Comments, Motions To Intervene, and Protests

On July 13, 2016, Neshkoro Power Associates, LLC (transferor) and Wisconsin8, LLC (transferee) filed an application for the transfer of license of the Big Falls Milldam Hydroelectric Project No. 2550. The project is located on the Little Wolf River in Waupaca County, Wisconsin. The project does not occupy federal lands.

The applicants seek Commission approval to transfer the license for the Big Falls Milldam Hydroelectric Project from the transferor to the transferee.

Applicants Contact: For transferor: Mr. Bernard H. Cherry, Neshkoro Power Associates, LLC, c/o Eagle Creek Renewable Energy, LLC, 65 Madison Avenue, Morristown, NJ 07960, Phone: 973–998–8400, Email: *bud.cherry@eaglecreekre.com* and Mr. Donald H. Clarke and Mr. Joshua E. Adrian, Duncan, Weinberg, Genzer & Pembroke, P.C., 1615 M Street NW., Suite 800, Washington, DC 20036, Phone 202–467–6370, Emails: *dhc@dwgp.com* and *jea@dwgp.com.* For Transferee: Mr. Dwight Bowler, Wisconsin8, LLC, 813 Jefferson Hill Road, Nassau, New York 12123, Phone: 518–766–2753, Email: *dbowler838@aol.com* and Mr. Joshua A. Sabo, 287 North Greenbush Road, Troy, New York 12180, Phone: 518–286–9050, Email: *jsabo@sabolaw.net.*

FERC Contact: Patricia W. Gillis, (202) 502–8735, *patricia.gillis@ferc.gov.*

Deadline for filing comments, motions to intervene, and protests: 30 days from the date that the Commission issues this notice. 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, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–12449–013.

Dated: July 26, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–18574 Filed 8–4–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2550–028]

N.E.W. Hydro, LLC; Wisconsin8, LLC; Notice of Application for Transfer of License and Soliciting Comments, Motions To Intervene, and Protests

On July 13, 2016, N.E.W. Hydro, LLC (transferor) and Wisconsin8, LLC (transferee) filed an application for the transfer of license of the Weyauwega Hydroelectric Project No. 2550. The project is located on the Waupaca River in Waupaca County, Wisconsin. The project does not occupy federal lands.

The applicants seek Commission approval to transfer the license for the Weyauwega Hydroelectric Project from the transferor to the transferee.

Applicants Contact: For transferor: Mr. Bernard H. Cherry, N.E.W. Hydro, LLC, c/o Eagle Creek Renewable Energy, LLC, 65 Madison Avenue, Morristown, NJ 07960, Phone: 973–998–8400, Email: *bud.cherry@eaglecreekre.com* and Mr. Donald H. Clarke and Mr. Joshua E. Adrian, Duncan, Weinberg, Genzer & Pembroke, P.C., 1615 M Street NW., Suite 800, Washington, DC 20036, Phone 202–467–6370, Emails: *dhc@dwgp.com* and *jea@dwgp.com.* For Transferee: Mr. Dwight Bowler, Wisconsin8, LLC, 813 Jefferson Hill Road, Nassau, New York 12123, Phone: 518–766–2753, Email: *dbowler838@aol.com* and Mr. Joshua A. Sabo, 287 North Greenbush Road, Troy, New York 12180, Phone: 518–286–9050, Email: *jsabo@sabolaw.net.*

FERC Contact: Patricia W. Gillis, (202) 502–8735, *patricia.gillis@ferc.gov.*

Deadline for filing comments, motions to intervene, and protests: 30 Days from the date that the Commission issues this notice. 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, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–2550–028.

Dated: July 26, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–18573 Filed 8–4–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2558–046]

Green Mountain Power Corporation; Notice of Application Accepted for Filing 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: Recreation Plan.

b. Project No: 2558–046.

c. Date Filed: May 31, 2016, as supplemented July 21, 2016.

d. Applicant: Green Mountain Power Corporation.

e. Name of Project: Otter Creek Hydroelectric Project.

f. Location: The project is located on Otter Creek in Addison and Rutland counties, Vermont.

g. Filed Pursuant to: Federal Power Act, 16 U.S.C. 791a–825r.

h. Applicant Contact: Mr. John Greenan, Principal Environmental Engineer, Green Mountain Power Corporation, 1252 Post Road, Rutland, VT 05701, (802) 770–3213.

i. FERC Contact: Mr. Kevin Anderson, (202) 502–6465, *kevin.anderson@ferc.gov.*

j. Deadline for filing comments, motions to intervene, and protests: August 29, 2016.

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, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–2558–046.

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 licensee filed a recreation plan for Commission approval pursuant to articles 401 and 405 of the license order issued October 23, 2014. The proposed plan provides for the construction, enhancement, and continued operation of recreation facilities at each of the project's four developments, including picnic areas, parking areas, interpretive signage, portages, and an observation deck. The proposed plan includes preliminary design drawings, an implementation schedule, and a provision for revising the plan, as needed, over the license term. Contrary to Article 405, the licensee proposes to not relocate the boat barrier at the Huntington Falls Development and, instead, would maintain the boat barrier in its current location and provide a portage take-out on the northern shoreline of Otter Creek upstream of the bridge on Morgan Horse Farm Road.

l. Locations of the Application: A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street NE., Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's Web site 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. A copy is also available for inspection and reproduction at the address in item (h) above. 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, .214, respectively. 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: July 27, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–18576 Filed 8–4–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Commissioner and Staff Attendance at the National Association of Regulatory Utility Commissioners Summer Committee Meetings

The Federal Energy Regulatory Commission (Commission) hereby gives notice that members of the Commission and/or Commission staff may attend the 2016 National Association of Regulatory Utility Commissioners Summer Committee Meetings, including the following:

Joint meeting with FERC, Part I: Are we building what we need?

July 27, 2016, 9:00 a.m.–10:30 a.m. (CDT)

The above-referenced meeting will be held at: Omni Nashville Hotel, 250 Fifth Avenue South, Nashville, TN 37203.

Further information may be found at *http://naruc.org/summermeetings/.*

The discussions at the meeting described above may address matters at issue in the following proceedings:

ISO New England Inc.—Docket Nos. RT04–2 & ER09–1532
Midwest Independent Transmission System Operator, Inc.—Docket No. ER11–1844
Northern Indiana Public Service Company v. Midcontinent Independent System Operator, Inc. and PJM Interconnection, L.L.C.—Docket No. EL13–88
New York Independent System Operator, Inc.—Docket No. ER13–102
PJM Interconnection, L.L.C.—Docket No. ER13–1924
PJM Interconnection, L.L.C.—Docket No. ER13–1942
PJM Interconnection, L.L.C.—Docket No. ER13–1944
PJM Interconnection, L.L.C.—Docket No. ER13–1945
PJM Interconnection, L.L.C.—Docket No. ER14–972
PJM Interconnection, L.L.C.—Docket No. ER14–1485
Xcel Energy Southwest Transmission Co., LLC—Docket No. ER14–2751
Consolidate Edison Company of New York, Inc. v. PJM Interconnection, L.L.C.—Docket No. EL15–18
Linden VFT, LLC v. PJM Interconnection, L.L.C.—Docket No. EL15–67
TranSource, LLC v. PJM Interconnection, L.L.C.—Docket No. EL15–79
Delaware Public Service Commission and Maryland Public Service Commission v. PJM and Certain Transmission Owners Designated Under Attachment A to the Consolidated Transmission Owners Agreement—Docket No. EL15–95
San Diego Gas & Electric Company—Docket No. EL15–103
New York Transco, LLC—Docket No. ER15–572
PJM Interconnection, L.L.C.—Docket No. ER15–1344
PJM Interconnection, L.L.C.—Docket No. ER15–1387
New York Independent System Operator, Inc.—Docket No. ER15–2059

NextEra Energy Transmission West, LLC—Docket No. ER15–2239
PJM Interconnection, L.L.C.—Docket No. ER15–2562
PJM Interconnection, L.L.C.—Docket No. ER15–2563
Southwestern Public Service Co. and Xcel Energy Southwest Transmission Co., LLC—Docket No. EC16–64
Pacific Gas and Electric Company—Docket No. EL16–47
DesertLink, LLC—Docket No. EL16–68
Boundless Energy NE, LLC v. New York Independent System Operator, Inc.—Docket No. EL16–84
New York Independent System Operator, Inc.—Docket No. ER16–120
PJM Interconnection, L.L.C.—Docket No. ER16–453
PJM Interconnection, L.L.C.—Docket No. ER16–736
New York Independent System Operator, Inc.—Docket No. ER16–835
New York Independent System Operator, Inc.—Docket No. ER16–966
PJM Interconnection, L.L.C.—Docket No. ER16–1232
PJM Interconnection, L.L.C.—Docket No. ER16–1335
PJM Interconnection, L.L.C.—Docket No. ER16–1499
Midcontinent Independent System Operator, Inc.—Docket No. ER16–1534
Citizens Energy Corporation—Docket No. EL16–102
New York Independent System Operator, Inc.—Docket No. ER16–1968

For more information, contact Sandra Waldstein, Office of External Affairs, Federal Energy Regulatory Commission at (202) 502–8092 or *sandra.waldstein@ferc.gov*.

Dated: July 26, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–18581 Filed 8–4–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. CP16–480–000; PF15–15–000]

Annova LNG Common Infrastructure, LLC, Annova LNG Brownsville A, LLC, Annova LNG Brownsville B, LLC, Annova LNG Brownsville C, LLC; Notice of Application

Take notice that on July 13, 2016, Annova LNG Common Infrastructure, LLC, Annova LNG Brownsville A, LLC, Annova LNG Brownsville B, LLC, and Annova LNG Brownsville C, LLC (collectively Annova LNG), 100 Constellation Way, Suite 500C, Baltimore, MD 21202, filed an application, in Docket No. CP16–480–000, pursuant to section 3(a) of the Natural Gas Act (NGA) and Part 153 of the Commission's Regulations, requesting authorization to site, construct, modify, and operate a natural gas liquefaction and liquefied natural gas export facility, located on the Brownsville Ship Channel in Cameron County, Texas. This filing may be viewed on the web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free (886) 208–3676 or TYY (202) 502–8659.

Any questions regarding this application should be directed to Christopher D. Young, Exelon Corporation, 100 Constellation Way, Suite 500C, Baltimore, MD 21202, by phone at (410) 470–3500, or by email at *Christopher.Young@constellation.com,* or to William Harris, Communications Senior Manager, South/West Region, Exelon Generation, by phone at (512) 542–7812, or by email at *Williamp.Harris@exeloncorp.com.*

Specifically, Annova LNG proposes to construct a LNG liquefaction and export terminal on the Port of Brownsville ship channel. The terminal will consist of six liquefaction trains with a total capacity of 0.9 Bcf per day, two LNG tanks capable of storing 6.8 Bcf of LNG, gas pretreatment facilities, boil-off gas handling system, flare system, marine transfer facilities, and all necessary ancillary and support facilities. Natural gas will be supplied by a third party-owned and operated intrastate pipeline.

On March 27, 2015, Commission staff granted Annova LNG's request to use the National Environmental Policy Act (NEPA) Pre-Filing Process and assigned Docket No. PF15–15–000 to staff activities involving the proposed facilities. Now, as of the filing of this application on July 13, 2016, the NEPA Pre-Filing Process for this project has ended. From this time forward, this proceeding will be conducted in Docket No. CP16–480–000, as noted in the caption of this Notice.

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: Complete its environmental assessment (EA) 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 EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule 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.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below, file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, 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 NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 5 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings

associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenters will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

Motions to intervene, protests and comments may be filed electronically via the Internet in lieu of paper; see, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages electronic filings.

Comment Date: 5:00 p.m. Eastern Time on August 17, 2016.

Dated: July 27, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–18575 Filed 8–4–16; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2016–0242 and EPA–HQ–OPP–2016–0226; FRL–9949–39]

Guidance for Pesticide Registrants on Pesticide Resistance Management Labeling and Guidance for Herbicide Resistance Management Labeling, Education, Training, and Stewardship; Extension of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; extension of comment period.

SUMMARY: EPA issued two notices in the **Federal Register** on June 3, 2016, each announcing the availability of a draft Pesticide Registration Notice (PR Notice) for review and comment: One entitled ''Guidance for Pesticide Registrants on Pesticide Resistance Management Labeling'' and the other entitled ''Guidance for Herbicide Resistance Management Labeling, Education, Training, and Stewardship.'' In response to requests received, this document extends the comment period for 30 days, from August 2, 2016 to September 1, 2016. This is one of the busiest times of year for pest control experts and this will allow them extra time to complete their review and comment on the PRNs.

DATES: Comments must be received on or before September 1, 2016.

ADDRESSES: Follow the detailed instructions provided under **ADDRESSES** in the **Federal Register** documents of June 3, 2016 (81 FR 35766) (FRL–9946–52) and (81 FR 35767) (FRL–9946–53).

FOR FURTHER INFORMATION CONTACT: For the Guidance for Pesticide Registrants on Pesticide Resistance Management Labeling; Notice of Availability, contact Nikhil Mallampalli, Biological and Economic Analysis Division (7503P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–1924; email address: *mallampalli.nikhil@epa.gov*. For information on the Guidance for Herbicide Resistance Management Labeling, Education, Training, and Stewardship contact, Bill Chism, Biological and Economic Analysis Division (7503P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–8136; email address: *chism.bill@epa.gov.*

SUPPLEMENTARY INFORMATION: This document extends the public comment period established in two **Federal Register** documents of June 3, 2016 (81 FR 35766) (FRL–9946–52) and (81 FR 35767) (FRL–9946–53), that each announced the availability of a draft PR Notice: One entitled ''Guidance for Pesticide Registrants on Pesticide Resistance Management Labeling'' and the other entitled ''Guidance for Herbicide Resistance Management Labeling, Education, Training, and Stewardship.'' EPA is hereby extending the comment period, which was set to end on August 2, 2016, to now end September 1, 2016.

To submit comments, or access the docket, please follow the detailed instructions provided under **ADDRESSES** in the **Federal Register** documents of June 3, 2016. If you have questions, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

Authority: 7 U.S.C. 136 *et seq.*

Dated: July 21, 2016.

Wynne F. Miller,

Acting Director, Biological and Economic Analysis Division, Office of Pesticide Programs.

[FR Doc. 2016–17922 Filed 8–4–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9028–4]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7146 or *http://www.epa.gov/nepa.*

Weekly receipt of Environmental Impact Statements (EISs)

Filed 07/25/2016 Through 07/29/2016 Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *http://www.epa.gov/compliance/nepa/eisdata.html.*

EIS No. 20160177, Draft Supplement, FHWA, VA, Hampton Roads Crossing Study, Comment Period Ends: 09/19/2016, Contact: Edward Sundra 804–775–3357

EIS No. 20160178, Final, BLM, CO, Previously Issued Oil and Gas Leases in the White River National Forest, Review Period Ends: 09/06/2016, Contact: Gregory Larson 970–876–9000

EIS No. 20160179, Final, AFS, MT, Lower Yaak, OBrien, Sheep Project, Review Period Ends: 09/06/2016, Contact: Miles Friend 406–295–4693

EIS No. 20160180, Final, FERC, TX, Golden Pass LNG Export Project, Review Period Ends: 09/06/2016, Contact: Eric Howard 202–502–6263

EIS No. 20160181, Final, FERC, OH, Rover Pipeline, Panhandle Backhaul, and Trunkline Backhaul Projects, Review Period Ends: 09/06/2016, Contact: Kevin Bowman 202–502–6287

EIS No. 20160182, Final, BLM, CA, West of Devers Upgrade Project, Review Period Ends: 09/06/2016, Contact: Frank McMenimen 760–833–7150

Dated: August 2, 2016.

Karin Leff,

Acting Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2016–18661 Filed 8–4–16; 8:45 am]

BILLING CODE 6560–50–P

EXPORT-IMPORT BANK

[Public Notice: 2016–3024]

Agency Information Collection Activities: Comment Request

AGENCY: Export-Import Bank of the United States.

ACTION: Submission for OMB Review and Final Comments Request.

Form Title: EIB 92–51 Application for Special Buyer Credit Limit under the Multi-Buyer Export Credit Insurance Policy.

SUMMARY: The Export-Import Bank of the United States (EXIM Bank), as a part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal Agencies to comment on the proposed information collection, as required by the Paperwork Reduction Act of 1995.

The Application for Special Buyer Credit Limit under the Multi-Buyer Export Credit Insurance Policy is used by policyholders, the majority of whom are U.S. small businesses, who export U.S. goods and services. This application provides EXIM Bank with the credit information necessary to make a determination of eligibility of a transaction for EXIM Bank support with a foreign buyer credit request and to obtain legislatively required assurance of repayment and fulfills other statutory requirements.

The application can be reviewed at: *http://www.exim.gov/sites/default/files/pub/pending/eib-92-51.pdf* Application for Special Buyer Credit Limit Multi-buyer Credit Insurance Policy.

DATES: Comments should be received on or before September 6, 2016 to be assured of consideration.

ADDRESSES: Comments may be submitted electronically on *WWW.REGULATIONS.GOV* or by mail to Office of Information and Regulatory Affairs, 725 17th Street NW., Washington, DC 20038 Attn: OMB 3048–0015.

SUPPLEMENTARY INFORMATION:

Titles and Form Number: EIB 92–51 Application for Special buyer credit Limit Multi-buyer Credit Insurance Policy.

OMB Number: 3048–0015.

Type of Review: Regular.

Need and Use: The information requested enables the applicant to provide EXIM Bank with the information necessary to obtain legislatively required assurance of repayment and fulfills other statutory requirements.

The only change to this form is to move a question about the buyer to an earlier section of the form. No new information is being collected.

Affected Public

This form affects entities involved in the export of U.S. goods and services.

The number of respondents: 4,300.

Estimated time per respondents: 25 minutes.

The frequency of response: As needed.

Annual hour burden: 1,792 total hours.

Government Expenses

Reviewing time per hour: 1 hour.

Responses per year: 4,300.

Reviewing time per year: 4,300 hours.

Average Wages per hour: $42.50.

*Average cost per year (time * wages):* $182,750.

Benefits and overhead: 20%.

Total Government Cost: $219,300.

Bonita Jones-McNeil,

Program Analyst, Agency Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2016–18636 Filed 8–4–16; 8:45 am]

BILLING CODE 6690–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0707]

Information Collection Being Reviewed by the Federal Communications Commission Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: 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; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC 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.

DATES: Written PRA comments should be submitted on or before October 4, 2016. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0707.

Title: Over-the-Air Reception Devices (OTARD).

Type of Review: Extension of a currently approved collection.

Respondents: State or Local, or Tribal Government.

Number of Respondents and Responses: 77 respondents; 77 responses.

Estimated Time per Response: 2–6 hours.

Frequency of Response: On occasion reporting; third party disclosure.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection of information is contained in Section 207 of the Communications Act of 1934, as amended.

Total Annual Burden: 288 hours.

Total Annual Cost: 17,100.

Privacy Act Impact Assessment: No impact.

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: Section 207 of the Telecommunications Act of 1996 (''1996 Act'') directs the Commission to promulgate rules prohibiting restrictions on viewers' ability to receive over-the-air signals by television broadcast, multichannel multipoint distribution, or direct broadcast satellite services.

In a Report and Order, Memorandum Opinion and Order and Further Notice of Proposed Rulemaking, CS Docket No. 96–83, FCC 96–328, released August 6, 1996, the Commission fully implemented Section 207 of the 1996 Act by adopting final rules for a preemption of state, local and non-governmental regulations that impair viewers ability to receive over-the-air signals. In doing so, the FCC acknowledged the necessity of allowing

state, local and non-governmental entities to continue to enforce certain regulations and restrictions, such as those serving safety purposes, and therefore exempted them from its prohibition.

Also, state, local and non-governmental entities were permitted to file petitions for waivers.

On September 25, 1998, the Commission released an Order on Reconsideration, FCC 98–214, in this proceeding that further modified and clarified Section 207 rules. Among other things, the Order on Reconsideration clarified how declaratory rulings and waivers in this matter are to be served on all interested parties. If a local government seeks a declaratory ruling or a waiver, it must take steps to afford reasonable, constructive notice to residents in its jurisdiction (*e.g.*, by placing notices in a local newspaper of general circulation). Certificates of service and proof of constructive notice also must be provided to the Commission with the petition.

In this regard, the petitioner should provide the Commission with a copy of the notice and an explanation of where the notice was placed and how many people the notice might reasonably have reached.

Effective January 22, 1999, FCC 98–273, the Commission amended the rules so that it applies to rental property where the renter has an exclusive use area, such as a balcony or patio.

In FCC 00–366, the Commission then further amended the rule so that it applies to customer-end antennas that receive and transmit fixed wireless signals. This amendment became effective on May 25, 2001.

Federal Communications Commission.

Marlene H. Dortch,

Secretary. Office of the Secretary.

[FR Doc. 2016–18585 Filed 8–4–16; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Open Commission Meeting, Thursday, August 4, 2016

July 28, 2016.

The Federal Communications Commission will hold an Open Meeting on the subjects listed below on Thursday, August 4, 2016 which is scheduled to commence at 10:30 a.m. in Room TW–C305, at 445 12th Street SW., Washington, DC.

Item No.	Bureau	Subject
1	Consumer & Governmental Affairs	*Title:* Implementation of the Twenty-First Century Communications and Video Accessibility Act of 2010, Section 105, Relay Services for Deaf-Blind Individuals (CG Docket No. 10–210). *Summary:* The Commission will consider a Report and Order that would convert the National Deaf Blind Equipment Distribution Program from a pilot to a permanent program.
2	Wireless Telecommunications	*Title:* Improvements to Benchmarks and Related Requirements Governing Hearing Aid-Compatible Mobile Handsets (WT Docket No. 15–285). *Summary:* The Commission will consider a Report and Order that would implement changes to the scope of the wireless hearing aid compatibility rules.
3	Wireline Competiton	*Title:* Rates for Interstate Inmate Calling Services (WC Docket No. 12–375). *Summary:* The Commission will consider an Order on Reconsideration, responding to a petition filed by Michael S. Hamden, that would ensure that the rates for Inmate Calling Services (ICS) are just, reasonable, and fair and explicitly account for facilities' ICS-related costs.

* * * * *

Consent Agenda

The Commission will consider the following subjects listed below as a consent agenda and these items will not be presented individually:

1	Media	*Title:* Atlantic City Board of Education, Applications for Renewal of License and Minor Modifications to WAJM(FM), Atlantic City, NJ. *Summary:* The Commission will consider a Memorandum Opinion and Order concerning the renewal of WAJM(FM), a student-run station and an Application for Review filed by Press Communications, LLC.
2	Media	*Title:* Amendment of Section 73.622(i), Post-Transition Table of DTV Allotments, Television Broadcast Stations (Seaford, Delaware). *Summary:* The Commission will consider a Memorandum Opinion and Order concerning the Application for Review filed by PMCM, former licensee of KJWY(TV).
3	General Counsel	*Title:* In the Matter of Warren Havens on Request for Inspection of Records (FOIA Control Nos. 2014–650, 2014–651, 2014–663, and 2014–664). *Summary:* The Commission will consider a Memorandum Opinion and Order concerning an Application for Review filed by Warren Havens, which appealed two decisions by the Enforcement Bureau denying four Freedom of Information Act requests.

The meeting site is fully accessible to people using wheelchairs or other mobility aids. Sign language interpreters, open captioning, and assistive listening devices will be provided on site. Other reasonable accommodations for people with disabilities are available upon request. In your request, include a description of the accommodation you will need and a way we can contact you if we need more information. Last minute requests will be accepted, but may be impossible to fill. Send an email to: *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (TTY).

Additional information concerning this meeting may be obtained from the Office of Media Relations, (202) 418–0500; TTY 1–888–835–5322. Audio/Video coverage of the meeting will be broadcast live with open captioning over the Internet from the FCC Live Web page at *www.fcc.gov/live.*

For a fee this meeting can be viewed live over George Mason University's Capitol Connection. The Capitol Connection also will carry the meeting live via the Internet. To purchase these services, call (703) 993–3100 or go to *www.capitolconnection.gmu.edu.*

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2016–18586 Filed 8–4–16; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Termination; 10259 Metro Bank of Dade County, Miami, Florida

The Federal Deposit Insurance Corporation (FDIC), as Receiver for 10259 Metro Bank of Dade County, Miami, Florida (Receiver) has been authorized to take all actions necessary to terminate the receivership estate of Metro Bank of Dade County (Receivership Estate); the Receiver has made all dividend distributions required by law.

The Receiver has further irrevocably authorized and appointed FDIC-Corporate as its attorney-in-fact to execute and file any and all documents that may be required to be executed by the Receiver which FDIC-Corporate, in its sole discretion, deems necessary; including but not limited to releases, discharges, satisfactions, endorsements, assignments and deeds.

Effective August 1, 2016, the Receivership Estate has been terminated, the Receiver discharged, and the Receivership Estate has ceased to exist as a legal entity.

Dated: August 1, 2016.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2016–18554 Filed 8–4–16; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice to All Interested Parties of the Termination of the Receivership of 10045, Colorado National Bank, Colorado Springs, Colorado

Notice is hereby given that the Federal Deposit Insurance Corporation (''FDIC'') as Receiver for Colorado National Bank, Colorado Springs, Colorado (''the Receiver'') intends to terminate its receivership for said institution. The FDIC was appointed receiver of Colorado National Bank on March 20, 2009. The liquidation of the receivership assets has been completed. To the extent permitted by available funds and in accordance with law, the Receiver will be making a final dividend payment to proven creditors.

Based upon the foregoing, the Receiver has determined that the continued existence of the receivership will serve no useful purpose. Consequently, notice is given that the receivership shall be terminated, to be effective no sooner than thirty days after the date of this Notice. If any person wishes to comment concerning the termination of the receivership, such comment must be made in writing and sent within thirty days of the date of this Notice to: Federal Deposit Insurance Corporation, Division of Resolutions and Receiverships, Attention: Receivership Oversight Department 34.6, 1601 Bryan Street, Dallas, TX 75201.

No comments concerning the termination of this receivership will be considered which are not sent within this time frame.

Dated: August 2, 2016.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2016–18655 Filed 8–4–16; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Termination 10480, Pisgah Community Bank, Asheville, North Carolina

The Federal Deposit Insurance Corporation (FDIC), as Receiver for 10480, Pisgah Community Bank, Asheville, North Carolina (Receiver) has been authorized to take all actions necessary to terminate the receivership estate of Pisgah Community Bank (Receivership Estate); the Receiver has made all dividend distributions required by law.

The Receiver has further irrevocably authorized and appointed FDIC-Corporate as its attorney-in-fact to execute and file any and all documents that may be required to be executed by the Receiver which FDIC-Corporate, in its sole discretion, deems necessary; including but not limited to releases, discharges, satisfactions, endorsements, assignments and deeds.

Effective August 1, 2016, the Receivership Estate has been terminated, the Receiver discharged, and the Receivership Estate has ceased to exist as a legal entity.

Dated: August 2, 2016.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2016–18653 Filed 8–4–16; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Termination; 10475 Heritage Bank of North Florida, Orange Park, Florida

The Federal Deposit Insurance Corporation (FDIC), as Receiver for 10475 Heritage Bank of North Florida, Orange Park, Florida (Receiver) has been authorized to take all actions necessary to terminate the receivership estate of Heritage Bank of North Florida (Receivership Estate); the Receiver has made all dividend distributions required by law.

The Receiver has further irrevocably authorized and appointed FDIC-Corporate as its attorney-in-fact to execute and file any and all documents that may be required to be executed by the Receiver which FDIC-Corporate, in its sole discretion, deems necessary; including but not limited to releases, discharges, satisfactions, endorsements, assignments and deeds.

Effective August 1, 2016, the Receivership Estate has been terminated, the Receiver discharged, and the Receivership Estate has ceased to exist as a legal entity.

Dated: August 2, 2016.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2016–18654 Filed 8–4–16; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice to All Interested Parties of the Termination of the Receivership of 10508, Frontier Bank, FSB, Palm Desert, California

NOTICE IS HEREBY GIVEN that the Federal Deposit Insurance Corporation (''FDIC'') as Receiver for Frontier Bank, FSB, Palm Desert, California (''the Receiver'') intends to terminate its receivership for said institution. The FDIC was appointed receiver of Frontier Bank, FSB on November 7, 2014. The liquidation of the receivership assets has been completed. To the extent permitted by available funds and in accordance with law, the Receiver will be making a final dividend payment to proven creditors.

Based upon the foregoing, the Receiver has determined that the continued existence of the receivership will serve no useful purpose. Consequently, notice is given that the receivership shall be terminated, to be effective no sooner than thirty days after the date of this Notice. If any person wishes to comment concerning the termination of the receivership, such comment must be made in writing and sent within thirty days of the date of this Notice to: Federal Deposit Insurance Corporation, Division of Resolutions and Receiverships, Attention: Receivership Oversight Department 34.6, 1601 Bryan Street, Dallas, TX 75201.

No comments concerning the termination of this receivership will be considered which are not sent within this time frame.

Dated: August 1, 2016.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2016–18553 Filed 8–4–16; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice to All Interested Parties of the Termination of the Receivership of 10272, Coastal Community Bank, Panama City Beach, Florida

Notice is hereby given that the Federal Deposit Insurance Corporation (''FDIC'') as Receiver for Coastal Community Bank, Panama City Beach, Florida (''the Receiver'') intends to terminate its receivership for said institution. The FDIC was appointed receiver of Coastal Community Bank on July 30, 2010. The liquidation of the receivership assets has been completed. To the extent permitted by available funds and in accordance with law, the Receiver will be making a final dividend payment to proven creditors.

Based upon the foregoing, the Receiver has determined that the continued existence of the receivership will serve no useful purpose. Consequently, notice is given that the receivership shall be terminated, to be effective no sooner than thirty days after the date of this Notice. If any person wishes to comment concerning the termination of the receivership, such comment must be made in writing and sent within thirty days of the date of this Notice to: Federal Deposit Insurance Corporation, Division of Resolutions and Receiverships, Attention: Receivership Oversight Department 34.6, 1601 Bryan Street, Dallas, TX 75201.

No comments concerning the termination of this receivership will be considered which are not sent within this time frame.

Dated: August 2, 2016.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2016–18596 Filed 8–4–16; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice to All Interested Parties of the Termination of the Receivership of 10271, Bayside Savings Bank, Port Saint Joe, Florida

NOTICE IS HEREBY GIVEN that the Federal Deposit Insurance Corporation (''FDIC'') as Receiver for Bayside Savings Bank, Port Saint Joe, Florida (''the Receiver'') intends to terminate its receivership for said institution. The FDIC was appointed receiver of Bayside Savings Bank on July 30, 2010. The liquidation of the receivership assets has been completed. To the extent permitted by available funds and in accordance with law, the Receiver will be making a final dividend payment to proven creditors.

Based upon the foregoing, the Receiver has determined that the continued existence of the receivership will serve no useful purpose. Consequently, notice is given that the receivership shall be terminated, to be effective no sooner than thirty days after the date of this Notice. If any person wishes to comment concerning the termination of the receivership, such comment must be made in writing and sent within thirty days of the date of this Notice to: Federal Deposit Insurance Corporation, Division of Resolutions and Receiverships, Attention: Receivership Oversight Department 34.6, 1601 Bryan Street, Dallas, TX 75201.

No comments concerning the termination of this receivership will be considered which are not sent within this time frame.

Dated: August 1, 2016.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2016–18552 Filed 8–4–16; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL LABOR RELATIONS AUTHORITY

Senior Executive Service Performance Review Board

AGENCY: Federal Labor Relations Authority.

ACTION: Notice.

SUMMARY: The Federal Labor Relations Authority (FLRA) publishes the names of the persons selected to serve on its SES Performance Review Board (PRB). This notice supersedes all previous notices of the PRB membership.

DATES: Upon publication.

ADDRESSES: Written comments about this final rule can be emailed to *EngagetheFLRA@flra.gov* or sent to the Case Intake and Publication Office, Federal Labor Relations Authority, 1400 K Street NW., Washington, DC 20424. All written comments will be available for public inspection during normal business hours at the Case Intake and Publication Office.

FOR FURTHER INFORMATION CONTACT: Gina Grippando, Counsel for Regulatory and Public Affairs, Federal Labor Relations Authority, Washington, DC 20424, (202) 218–7776.

SUPPLEMENTARY INFORMATION: Section 4314(c) 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 PRBs. The PRB shall review and evaluate the initial appraisal of a senior executive's performance by the supervisor, along with any response by the senior executive, and make recommendations to the final rating authority relative to the performance of the senior executive.

The following individuals have been selected to serve on the FLRA's PRB:

Sarah Whittle Spooner, Executive Director; Peter A. Sutton, Deputy

General Counsel; Richard S. Jones, Atlanta Regional Director; William R. Tobey, Chief Counsel; Kimberly D. Moseley, Executive Director, Federal Service Impasses Panel; and Bruce Gripe, Chief Operating Officer, Office of Special Counsel.

Dated: August 3, 2016.

Sarah Whittle Spooner,

Executive Director.

[FR Doc. 2016–18614 Filed 8–4–16; 8:45 am]

BILLING CODE P

FEDERAL TRADE COMMISSION

[File No. 1410042; Docket No. C–4586]

Victrex, plc; Invibio, Limited; and Invibio, Inc.

AGENCY: Federal Trade Commission.

ACTION: Consent Order and Statement of the Commission.

SUMMARY: The Commission has approved a final consent order in this matter, settling alleged violations of federal law prohibiting unfair methods of competition, and has issued a Statement of the Commission. The attached Analysis to Aid Public Comment and Statement of the Commission describe both the allegations in the Complaint and the terms of the Decision and Order.

DATES: Issued on July 13, 2016.

SUPPLEMENTARY INFORMATION:

Analysis of Agreement Containing Consent Order To Aid Public Comment

I. Introduction

The Federal Trade Commission has approved a final consent order with Victrex plc and its wholly owned subsidiaries Invibio Limited and Invibio, Inc. (collectively, ''Invibio''). Invibio makes and sells implant-grade PEEK, a high-performance polymer contained in implantable devices used in spinal interbody fusion and other medical procedures. The order seeks to address allegations that Invibio used exclusive supply contracts to maintain its monopoly power in the market for implant-grade PEEK, in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. 45.

The order requires Invibio to cease and desist from enforcing most exclusivity terms in current supply contracts and generally prohibits Invibio from requiring exclusivity in future contracts. The order also prevents Invibio from adopting other mechanisms, such as market-share discounts or retroactive volume discounts, to maintain its monopoly power.

The order was placed on the public record for 30 days in order to receive comments from interested persons. Comments received during this period became part of the public record. After the public comment period, the Commission determined to make the proposed order final.

The purpose of this analysis, which was placed on the Commission Web site on April 27, 2016, was to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the complaint, the consent agreement, or the order, or to modify their terms in any way. The consent agreement is for settlement purposes only and does not constitute an admission by Invibio that the law has been violated as alleged in the complaint or that the facts alleged in the complaint, other than jurisdictional facts, are true.

II. The Complaint

The complaint makes the following allegations.

A. Industry Background

Implant-grade PEEK has properties, such as elasticity, machinability, and radiolucency, that are distinct from other materials used in implantable medical devices, such as titanium and bone. These properties make PEEK especially suitable for many types of implantable medical devices, particularly spinal interbody fusion devices. Invibio was the first company to develop and sell implant-grade PEEK. The United States Food and Drug Administration (''FDA'') first cleared a medical device containing Invibio PEEK in 1999. Upon introducing implant-grade PEEK, Invibio sold the product to its medical device maker customers under long-term supply contracts, many of which included exclusivity requirements.

For a number of years, Invibio was the only supplier of implant-grade PEEK. In the late 2000s, however, first Solvay Specialty Polymers LLC (''Solvay'') and then Evonik Corporation (''Evonik'') took steps to enter the market. The FDA cleared the first spinal implant device containing Solvay PEEK in 2010, and the first one containing Evonik PEEK in 2013.

B. Invibio's Use of Exclusivity Terms To Impede Competitors

Invibio responded to Solvay's and Evonik's entry by tightening and expanding the scope of exclusivity provisions in its supply contracts with medical device makers. Invibio did this to impede Solvay and Evonik from developing into effective rivals. Invibio knew that if Solvay and Evonik could gain reputation and experience, in particular, by developing supply relationships with leading medical device makers, this would validate their status as PEEK suppliers with other potential PEEK buyers and ultimately lead to significant price competition—painful for Invibio but beneficial to medical device makers.

Invibio extracted exclusivity terms from customers both by threatening to withhold critical supply or support services and by offering minor inducements. For example, Invibio threatened to withhold access to new brands of its PEEK and to Invibio's FDA master file if a customer declined to purchase exclusively from Invibio. Where necessary, Invibio offered small price discounts in exchange for exclusivity.

Due to Invibio's efforts, nearly all medical device makers that purchase PEEK from Invibio do so under contracts that impose some form of exclusivity. Although precise exclusivity terms vary, they generally take one of three forms: (1) Requiring the use of Invibio PEEK for all PEEK-containing devices; (2) requiring the use of Invibio PEEK for a broad category of PEEK-containing devices; or (3) requiring the use of Invibio PEEK for a list of identified PEEK-containing devices. Even where exclusivity terms apply at the device level, *i.e.*, to a list of specified devices, the foreclosure effect is substantial: The list often includes nearly every device in the customer's portfolio and the customer thus cannot source substantial volumes of PEEK from Invibio's competitors. Taken together, Invibio's exclusive contracts foreclose a substantial majority of PEEK sales from Invibio's rivals.

C. Invibio's Monopoly Power

Both direct and indirect evidence demonstrate that Invibio has monopoly power in the market for implant-grade PEEK. Invibio has priced its PEEK substantially higher than competing versions of PEEK, without ceding material market share, and has impeded competitors through its exclusive contracts. In addition, Invibio has consistently held an over-90% share of a relevant market with substantial entry barriers, which indirectly evidences its monopoly power. PEEK has distinctive properties from other materials used in spinal and other implants. Physician preferences typically drive the choice of materials used in an implant, and these preferences largely reflect material properties rather than price. Other materials are therefore not sufficiently

close substitutes to prevent a monopolist PEEK supplier from profitably raising prices. The relevant product market is therefore no broader than implant-grade PEEK, *i.e.*, PEEK that has been used in at least one device cleared by the FDA.

D. Competitive Impact of Invibio's Conduct

Through its exclusive contracting strategy, Invibio has maintained its monopoly power and harmed competition by marginalizing its competitors. In addition, Invibio's exclusive contracts have prevented its customers from exercising a meaningful choice between implant-grade PEEK suppliers and from enjoying the full benefits of competition, including price competition.

Invibio's exclusivity terms have prevented Solvay and Evonik from achieving a significant volume of implant-grade PEEK sales, notwithstanding their offering of significantly lower prices. Invibio has also excluded Solvay and Evonik from forming supply relationships with key medical device makers. As a result, Solvay and Evonik have been unable to achieve significant market share and have consistently missed sales targets. There is a significant risk that continued enforcement of Invibio's exclusive contracts would preclude Solvay and Evonik from achieving sufficient returns to justify future investments, including in innovative technologies. Without those investments, the firms would be even less effective competitors in the future.

Additionally, Invibio's exclusive contracts have deprived medical device makers of the opportunity to make a meaningful choice among competing suppliers and thereby enjoy the benefits of price, innovation, and quality competition. Even medical device makers that would not have switched to a competitor of Invibio would have benefited from a more competitive market. In addition, many medical device makers prefer to have more than one source of PEEK in order to mitigate risk and for other commercial benefits. Absent Invibio's exclusivity requirements, a significant number of device makers would contract with Solvay or Evonik to secure lower-priced PEEK and additional or alternate sources of supply. However, medical device makers locked into long-term exclusive contracts have been precluded from pursuing their preferred procurement strategy.

III. Legal Analysis

Monopolization is among the ''unfair methods of competition'' prohibited by Section 5 of the FTC Act.[1] A firm unlawfully maintains monopoly power when it ''engage[s] in anti-competitive conduct that reasonably appears to be a significant contribution to maintaining monopoly power.'' [2]

Exclusive dealing by a monopolist may be condemned when it ''allows [the] monopolist to maintain its monopoly power by raising its rivals' costs sufficiently to prevent them from growing into effective competitors.'' [3] Of particular relevance is whether an exclusive dealing policy has ''foreclose[d] competition in such a substantial share of the relevant market so as to adversely affect competition.'' [4] To be unlawful, exclusive dealing need not have foreclosed all competition from the market.[5]

The factual allegations in the complaint support a finding of monopolization. Invibio's exclusivity strategy has not prevented entry entirely. But its exclusivity terms—whether full exclusivity terms or terms that apply at the product or product category level across a wide range of products—have foreclosed its rivals from a substantial portion of available sales opportunities in the relevant market and prevented those rivals from competing effectively. Among the foreclosed sales opportunities are key customers that would validate the reputations of Solvay and Evonik as legitimate rivals of Invibio, notwithstanding their more recent entry into the market. Invibio's exclusionary conduct has also reduced incentives to innovate and prevented PEEK consumers from exercising a meaningful choice among suppliers.

A monopolist may rebut a showing of competitive harm by demonstrating that the challenged conduct is reasonably necessary to achieve a procompetitive benefit.[6] Any proffered justification, if proven, must be balanced against the harm caused by the challenged conduct.[7] Here, no procompetitive efficiencies justify the scope of Invibio's exclusionary and anticompetitive conduct. Any procompetitive benefit could have been achieved through less restrictive means.

IV. The Consent Order

The Decision and Order remedies Invibio's anticompetitive conduct and imposes certain fencing-in requirements in order to prevent *de facto* exclusivity between Invibio and its customers.

Paragraph I of the order defines the key terms used throughout the rest of the order.

Paragraph II addresses the core of Invibio's anticompetitive conduct. Paragraph II.A prohibits Invibio from adopting or implementing any agreement or policy that results in ''exclusivity'' with customers. ''Exclusivity'' is defined to include any limit or prohibition by Invibio on its customers dealing with a competing implant-grade PEEK supplier or any requirement by Invibio that a customer use only Invibio PEEK in (1) all of its devices, (2) in any group of devices, or (3) in any one device. The order thus applies to all forms of exclusivity that appear in Invibio's contracts.

Under Paragraph II.A, Invibio may not require exclusivity for any new contract, except in the limited circumstances set forth in Paragraph II.E (described below). Further, Invibio may not enforce exclusivity terms in an existing contract with any medical device maker that chooses to use an alternate implant-grade PEEK supplier instead of Invibio for any or all future devices. In addition, Paragraph II.A, in conjunction with Paragraph II.F (described below), prohibits Invibio from enforcing provisions in an existing contract that would prevent a medical device maker from using other suppliers of implant-grade PEEK for any device, or from switching suppliers for any current device, provided that the device maker agrees to the tracking requirements contained in Exhibit C of the order. The

[1] *See, e.g., McWane, Inc.* v. *FTC,* 783 F.3d 814, 827 n.10 (11th Cir. 2015), *cert. denied* 577 U.S.— (Mar. 21, 2016).

[2] *McWane,* 783 F.3d at 833 (internal quotation marks and citations omitted); *accord United States* v. *Dentsply Int'l, Inc.,* 399 F.3d 181, 187 (3d Cir. 2005); *United States* v. *Microsoft Corp.,* 253 F.3d 34, 79 (D.C. Cir. 2001) (*en banc*) (citing 3 Philip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 651c, at 78 (1996)).

[3] *McWane,* 783 F.3d at 832 (citing XI Philip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 1804 a, at 116–17 (2011)); *accord Dentsply,* 399 F.3d at 191; *Microsoft,* 253 F.3d at 69–71; *see also In re McWane, Inc.,* No. 9351, 2014 WL 556261 at *19, *28 (F.T.C. Jan. 30, 2014) (exclusive dealing by a monopolist may be unlawful where it ''impair[s] the ability of rivals to grow into effective competitors that might erode the firm's dominant position'' or ''denie[s] its customers the ability to make a meaningful choice'') (internal quotation marks and citations omitted), *aff'd, McWane, Inc.* v. *FTC,* 783 F.3d 814 (11th Cir. 2015).

[4] *ZF Meritor, LLC* v. *Eaton Corp.,* 696 F.3d 254, 271 (3d Cir. 2012); *see also Tampa Elec. Co.* v. *Nashville Coal Co.,* 365 U.S. 320, 327 (1961) (''In practical application, even though a contract is found to be an exclusive-dealing arrangement, it does not violate the section unless the court believes it probable that performance of the contract will foreclose competition in a substantial share of the line of commerce affected.'').

[5] *Dentsply,* 399 F.3d at 191.

[6] *See, e.g., Microsoft,* 253 F.3d at 59.

[7] *Id.*

tracking requirements are designed to accommodate Invibio's concerns, related to potential product liability actions, about maintaining the ability to identify devices that use Invibio PEEK and are generally consistent with industry practice.

Paragraph II.B prohibits Invibio from retaliating against customers for using or preparing to use an alternate PEEK supplier. Prohibited retaliation includes cutting off PEEK sales or withholding access to regulatory support.

Paragraph II.C contains provisions designed to prevent *de facto* exclusivity in the future. For all new contracts, Invibio may not require minimum purchases, either as a condition of sale or as a condition for receiving important contract terms or services, other than as described in Paragraph II.D. Invibio may not offer volume discounts that are applied retroactively once a customer reaches a specified threshold. For example, Invibio may provide a discount on sales beyond 100 units but it may not lower the price of the first 99 units if and when the customer buys the 100th unit. Invibio may, however, provide certain discounts and non-price incentives designed to meet competition.

Paragraph II.D allows Invibio to condition its provision of certain types of extraordinary support to a customer for new devices on minimum purchase requirements for three years after the date of FDA clearance for such devices, so long as the minimum purchase amounts to less than 30 percent of the customer's implant-grade PEEK requirements for the device(s) that received the support. Extraordinary support excludes routine services such as maintaining and granting access to Invibio's FDA master file.

Paragraph II.E contains provisions designed to allow for procompetitive collaboration with a customer and preserve Invibio's incentives to innovate, including through investments that may be susceptible to free-riding by competitors. The paragraph allows Invibio to enter into a mutually exclusive contract with a customer when Invibio and the customer have engaged in the joint development of a new product that has required the contribution of significant capital, intellectual property rights, or labor by both Invibio and the customer, or when a customer asks that Invibio manufacture a custom component to the customer's specifications. Current PEEK sales subject to such contracts represent a small portion of the relevant market. Nonetheless, several limitations apply under this paragraph. The contracts must be: In writing, time-limited, applicable only to the jointly developed or custom product, and notified to the Commission. Invibio may not tie the availability of other forms, grades, or types of PEEK to a customer's willingness or agreement to enter into this type of contract. Further, sales resulting from these exclusive contracts may not account for more than 30 percent of Invibio's total annual sales.

Paragraph II.F allows Invibio to maintain limited exclusivity in existing contracts if customers do not agree to certain tracking requirements. Specifically, Invibio may enforce specified product-level exclusivity terms in existing contracts if the customer does not accept the terms set forth in Exhibit C to the order, thereby agreeing: (1) Not to mix (commingle) PEEK from different suppliers in a single unit of a device; (2) to maintain records that identify which supplier's PEEK is used in any batch of devices that are dual-sourced; and (3) to notify Invibio in the event of an adverse event related to Invibio's PEEK. These tracking requirements are generally consistent with existing industry practice.

Paragraph III requires Invibio to implement an antitrust compliance program, which includes providing notice of the order to Invibio's customers. Paragraphs IV–VI impose reporting and other compliance requirements.

The Decision and Order will expire on July 13, 2036.

Statement of the Federal Trade Commission

The Commission has approved a final consent order settling charges that Victrex plc, together with its subsidiaries Invibio Limited and Invibio, Inc. (collectively ''Invibio''), violated Section 5 of the Federal Trade Commission Act by using exclusive supply contracts to maintain Invibio's monopoly power in the market for a high performance polymer used in medical implants known as polyetheretherketone or PEEK. Our order aims to facilitate price competition, spur innovation, and provide medical device makers with a meaningful choice among PEEK suppliers. This enforcement action reflects our commitment to intervene when a dominant firm employs exclusionary practices to maintain its monopoly power and harm competition.

It is well established that exclusive dealing can promote or harm competition, depending on the circumstances.[1] The Commission therefore examines exclusive dealing under the rule of reason to determine whether the probable net effect of an exclusive dealing policy is to benefit or harm competition. In particular, we focus on evidence that the suspect conduct has affected or is likely to affect prices, output, quality, innovation, and consumer choice. Because its legality turns on its impact on competition, an exclusive dealing policy may be lawful when used by a firm in a competitive market, but unlawful if a monopolist uses the policy to maintain its dominant position, for example, by diminishing its rivals' ability to compete.[2] We have reason to believe that the latter occurred here.

Invibio was the first, and for several years the only, PEEK supplier in the market. We charge that, when faced with the entry of two new rivals in the late 2000s, Solvay Specialty Polymers LLC and Evonik Corporation, Invibio sought to lock up its customers and lock out these rivals. Invibio recognized that denying Solvay and Evonik access to the largest and most influential customers was critical to preventing the two entrants from validating their reputations in the market and achieving the experience needed to pose a serious threat to Invibio's market dominance.

As described in our complaint, Invibio had entered into long-term exclusive contracts with nearly every medical device maker producing implants using PEEK. We allege that, to prevent Solvay and Evonik from gaining scope, experience, and supply relationships, Invibio tightened the exclusivity terms of its supply agreements. Some of these provisions explicitly require the use of Invibio's PEEK for all of a customer's PEEK-containing devices, while others impose exclusivity for a list of product categories or designated products that often comprise nearly every PEEK-containing device in a customer's portfolio.

Invibio threatened customers that resisted its demand for exclusivity with retaliation, including termination of the

[1] *See, e.g., McWane, Inc.* v. *FTC, 783 F.3d 814, 827–28* (11th Cir. 2015), *cert. denied,* 136 S. Ct. 1452 (2016); United States v. Dentsply Int'l, Inc., 399 F.3d 181, 187 (3d Cir. 2005); Ilya R. Segal & Michael D. Whinston, *Exclusive Contracts and Protection of Investments,* 31 RAND J. Econ. 603, 603 (2000); Eric B. Rasmusen, J. Mark Ramseyer & John S. Wiley, Jr., *Naked Exclusion,* 81 Am. Econ. Rev. 1137, 1137–38 (1991), *as corrected by* Ilya R. Segal & Michael D. Whinston, *Naked Exclusion: Comment,* 90 Am. Econ. Rev. 296, 307 (2000).

[2] *See, e.g., Dentsply,* 399 F.3d at 187 (''Although not illegal in themselves, exclusive dealing arrangements can be an improper means of maintaining a monopoly.'').

PEEK supply for all of a device maker's products, lack of access to new types of PEEK developed by Invibio, and the loss of necessary regulatory support. In certain cases, Invibio provided customers with a small price discount or other benefit in exchange for exclusivity. Notably, both Solvay and Evonik offered PEEK at prices significantly below those charged by Invibio, lower even than prices reflecting discounts Invibio offered to secure customer exclusivity.

As alleged in the complaint, this strategy worked. Even after Solvay and Evonik's entry, Invibio still accounted for approximately 90 percent of implant-grade PEEK sales. Invibio's exclusive dealing policy foreclosed a substantial majority of PEEK sales for which its rivals otherwise could have competed. The evidence shows that Invibio has been able to charge supracompetitive prices to many device makers notwithstanding Solvay and Evonik's entry. Largely limited to competing for small or start-up device makers that do not have exclusive contracts with Invibio, Solvay and Evonik missed their respective sales targets. Absent the Commission's enforcement action, Invibio's conduct would continue to deny Solvay and Evonik the opportunity to contest most sales opportunities. They would be unable to achieve sales volumes sufficient to incentivize continued investment in the business that would yield further innovations in PEEK technology. Importantly, Invibio has failed to identify any procompetitive justification that would offset the harm that its exclusive supply contracts inflicted on competition.

In order to safeguard competition, the Commission's order generally prohibits Invibio from entering into exclusive supply contracts and from preventing current customers from using an alternative source of PEEK in new products. The order also prohibits Invibio from imposing contract terms that would deter a customer from purchasing additional units of PEEK from a rival. In general, Invibio may neither condition price or other sales terms on a customer's purchase of a specified portion or percentage of its PEEK requirements from Invibio, nor offer volume discounts that are applied retroactively once a customer's total purchases of Invibio PEEK reach a specified threshold. Invibio may, however, offer volume discounts that are not retroactive.

At the same time, we recognize that collaborative research and development efforts involving a PEEK supplier and a device maker present a different set of issues, including potential concerns about free riding. Consequently, our order leaves room for limited exclusive arrangements where Invibio and a device maker jointly research and develop new or custom PEEK products or devices.

In sum, our order appropriately addresses Invibio's exclusionary conduct, provides its rivals a meaningful opportunity to compete, and opens the door for price competition, innovation, and more choice for PEEK customers.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2016–18565 Filed 8–4–16; 8:45 am]

BILLING CODE 6750–01–P

FEDERAL TRADE COMMISSION

[File No. 151 0175]

Koninklijke Ahold N.V. and Delhaize Group NV/SA; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before August 22, 2016.

ADDRESSES: Interested parties may file a comment at *https://ftcpublic.commentworks.com/ftc/aholddelhaizeconsent* online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write ''In the Matter of Koninklijke Ahold N.V. and Delhaize Group NV/SA File No. 151–0175—Consent Agreement'' on your comment and file your comment online at *https://ftcpublic.commentworks.com/ftc/aholddelhaizeconsent* by following the instructions on the web-based form. If you prefer to file your comment on paper, write ''In the Matter of Koninklijke Ahold N.V. and Delhaize Group NV/SA File No. 151–0175—Consent Agreement'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Alexis Gilman (202–326–2579) or Dan Ducore (202–326–2526), Bureau of Competition, 600 Pennsylvania Avenue NW., Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for July 22, 2016), on the World Wide Web, at *http://www.ftc.gov/os/actions.shtm.*

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before August 22, 2016. Write ''In the Matter of Koninklijke Ahold N.V. and Delhaize Group NV/SA File No. 151–0175—Consent Agreement'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at *http://www.ftc.gov/os/publiccomments.shtm.* As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any ''[t]rade secret or any commercial or financial information which . . . is privileged or confidential,'' as discussed

in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c).[1] Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/aholddelhaizeconsent* by following the instructions on the web-based form. If this Notice appears at *http://www.regulations.gov/#!home,* you also may file a comment through that Web site.

If you file your comment on paper, write ''In the Matter of Koninklijke Ahold N.V. and Delhaize Group NV/SA File No. 151–0175—Consent Agreement'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Web site at *http://www.ftc.gov* to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before August 22, 2016. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at *http://www.ftc.gov/ftc/privacy.htm.*

[1] In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

Analysis of Agreement Containing Consent Order To Aid Public Comment

I. Introduction and Background

The Federal Trade Commission (''Commission'') has accepted for public comment, subject to final approval, an Agreement Containing Consent Order (''Consent Order'') from Koninklijke Ahold N.V. (''Ahold'') and Delhaize Group NV/SA (''Delhaize'') (collectively, the ''Respondents''). Pursuant to an Agreement and Plan of Merger dated June 24, 2015, Ahold and Delhaize will combine their businesses through a merger of equals, resulting in a combined entity valued at approximately $28 billion (''the Merger''). The purpose of the proposed Consent Order is to remedy the anticompetitive effects that otherwise would result from the Merger. Under the terms of the proposed Consent Order, Respondents are required to divest 81 supermarkets and related assets in 46 local geographic markets (collectively, the ''relevant markets'') in seven states to seven Commission-approved buyers. The divestitures must be completed within a time-period ranging from 60 to 360 days following the date of the Merger. The Commission and Respondents have agreed to an Order to Maintain Assets that requires Respondents to operate and maintain each divestiture store in the normal course of business through the date the store is ultimately divested to a buyer.

The proposed Consent Order has been placed on the public record for 30 days to solicit comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission again will review the proposed Consent Order and any comments received, and decide whether it should withdraw the Consent Order, modify the Consent Order, or make the Consent Order final.

The Commission's Complaint alleges that the Merger, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, by removing an actual, direct, and substantial supermarket competitor in each of the 46 local geographic markets. The elimination of this competition would result in significant competitive harm; specifically, the Merger will allow the merged firm to increase prices above competitive levels, unilaterally or through coordinated interaction among the remaining market participants. Similarly, absent a remedy, there is significant risk that the merged firm may decrease quality and service aspects of its stores below competitive levels. The proposed Consent Order would remedy the alleged violations by requiring divestitures to replace competition that otherwise would be lost in the relevant markets because of the Merger.

II. The Respondents

Respondent Ahold is a Dutch company that operates in the United States through its principal U.S. subsidiary Ahold U.S.A., Inc. As of June 24, 2015, Ahold operated 760 supermarkets in the United States under the Stop & Shop, Giant, and Martin's banners. Ahold's stores are located in Connecticut, Delaware, the District of Columbia, Maryland, Massachusetts, New Jersey, New York, Pennsylvania, Rhode Island, Virginia, and West Virginia.

Delhaize is a Belgian company that operates in the United States through its principal U.S. subsidiary Delhaize America, LLC. As of June 24, 2015, Delhaize operated 1,291 supermarkets in the United States under the Food Lion and Hannaford banners, dispersed throughout Delaware, Georgia, Kentucky, Maine, Maryland, Massachusetts, New Hampshire, New York, North Carolina, Pennsylvania, South Carolina, Tennessee, Vermont, and West Virginia.

III. Retail Sale of Food and Other Grocery Products in Supermarkets

The Merger presents substantial antitrust concerns for the retail sale of food and other grocery products in supermarkets. Supermarkets are traditional full-line retail grocery stores that sell food and non-food products that customers regularly consume at home—including, but not limited to, fresh produce and meat, dairy products, frozen foods, beverages, bakery goods, dry groceries, household products, detergents, and health and beauty products. Supermarkets also provide service options that enhance the shopping experience, including deli, butcher, seafood, bakery, and floral counters. This broad set of products and services provides consumers with a ''one-stop shopping'' experience by enabling them to shop in a single store for all of their food and grocery needs. The ability to offer consumers one-stop shopping is the critical difference between supermarkets and other food retailers.

The relevant product market includes supermarkets within ''hypermarkets'' such as Walmart Supercenters.

Hypermarkets also sell an array of products not found in traditional supermarkets. Like conventional supermarkets, however, hypermarkets contain bakeries, delis, dairy, produce, fresh meat, and sufficient product offerings to enable customers to purchase all of their weekly grocery requirements in a single shopping visit.

Other types of retailers, such as hard discounters, limited assortment stores, natural and organic markets, ethnic specialty stores, and club stores, also sell food and grocery items. These types of retailers are not in the relevant product market because they offer a more limited range of products and services than supermarkets and because they appeal to a distinct customer type. Shoppers typically do not view these other food and grocery retailers as adequate substitutes for supermarkets.[2] Consistent with prior Commission precedent, the Commission has excluded these other types of retailers from the relevant product market.[3]

The relevant geographic markets in which to analyze the effects of the Merger are areas that range from one-tenth of a mile to a ten-mile radius around each of the Respondents' supermarkets, though the majority of Respondents' overlapping supermarkets raising concerns are within six miles or less of each other.[4] The length of the radius depends on factors such as population density, traffic patterns, and other specific characteristics of each market. Where the Respondents' supermarkets are located in rural areas, the relevant geographic areas are larger than areas where the Respondents' supermarkets are located in more densely populated cities. A hypothetical monopolist of the retail sale of food and grocery products in supermarkets in each relevant area could profitably impose a small but significant nontransitory increase in price.

The 46 geographic markets in which to analyze the effects of the Merger are local areas in and around:

(1) Lewes & Rehoboth Beach, Delaware; (2) Millsboro, Delaware; (3) Millville, Delaware; (4) Accokeek, Maryland; (5) Bowie, Maryland; (6) California, Maryland; (7) Columbia, Maryland; (8) Cumberland & Frostburg, Maryland; (9) Easton, Maryland; (10) Edgewater, Maryland; (11) Gaithersburg, Maryland; (12) Hagerstown (north), Maryland; (13) Hagerstown (south), Maryland; (14) La Plata, Maryland; (15) Lusby, Maryland; (16) Owings Mills, Maryland; (17) Prince Frederick, Maryland; (18) Reisterstown, Maryland; (19) Salisbury, Maryland; (20) Sykesville, Maryland; (21) Upper Marlboro, Maryland; (22) Gardner, Massachusetts; (23) Kingston, Massachusetts; (24) Mansfield & South Easton, Massachusetts; (25) Milford, Massachusetts; (26) Norwell, Massachusetts; (27) Norwood & Walpole, Massachusetts; (28) Quincy, Massachusetts; (29) Saugus, Massachusetts; (30) Mahopac & Carmel, New York; (31) New Paltz & Modena, New York; (32) Poughkeepsie & Lagrangeville, New York; (33) Rhinebeck & Red Hook, New York; (34) Wappingers Falls, New York; (35) Chambersburg, Pennsylvania; (36) Waynesboro, Pennsylvania; (37) York, Pennsylvania; (38) Culpeper, Virginia; (39) Fredericksburg, Virginia; (40) Front Royal, Virginia; (41) Purcellville, Virginia; (42) Richmond, Virginia; (43) Stafford, Virginia; (44) Stephens City, Virginia; (45) Winchester, Virginia; and (46) Martinsburg, West Virginia.

Under the 2010 Department of Justice and Federal Trade Commission Horizontal Merger Guidelines, an acquisition that results in an HHI in excess of 2,500 and increases the HHI by more than 200 significantly increases concentration in a highly concentrated market and therefore is presumed anticompetitive. With the exception of one market,[5] each of the relevant geographic markets identified above meets the Horizontal Merger Guidelines presumption. Based on the market shares of the parties and other market participants, the post-Merger HHI levels in the relevant markets vary from 2,268 to 10,000, and the HHI deltas vary from 243 to 5,000.

The relevant markets are also highly concentrated in terms of the number of remaining market participants post-Merger. Of the 46 geographic markets, the Merger will result in a merger-to-monopoly in three markets and a merger-to-duopoly in 14 markets. In the remaining markets, the Merger will reduce the number of market participants from four to three in 18 markets, from five to four in ten markets, and from seven to six in one market.[6]

The anticompetitive implications of such significant increases in market concentration are reinforced by substantial evidence demonstrating that Ahold and Delhaize are close and vigorous competitors in terms of price, format, service, product offerings, promotional activity, and location in each of the relevant geographic markets. Absent relief, the Merger would eliminate significant head-to-head competition between Ahold and Delhaize and would increase the ability and incentive of Ahold to raise prices unilaterally post-Merger. The Merger would also decrease incentives to compete on non-price factors, such as service levels, convenience, and quality. Lastly, the high levels of concentration also increase the likelihood of competitive harm through coordinated interaction.

New entry or expansion in the relevant markets is unlikely to deter or counteract the anticompetitive effects of the Merger. Even if a prospective entrant existed, the entrant must secure an economically-viable location, obtain the necessary permits and governmental approvals, build its retail establishment or renovate an existing building, and open to customers before it could begin operating and serve as a relevant competitive constraint. As a result, new entry sufficient to achieve a significant market impact and act as a competitive constraint is unlikely to occur in a timely manner.

[2] That is, supermarket shoppers would be unlikely to switch to one of these other types of retailers in response to a small but significant nontransitory increase in price or ''SSNIP'' by a hypothetical supermarket monopolist. *See* U.S. DOJ and FTC Horizontal Merger Guidelines § 4.1.1 (2010).

[3] *See, e.g.,* Cerberus Institutional Partners, L.P./Safeway, Inc., Docket C–4504 (Jul. 2, 2015); Bi-Lo Holdings, LLC/Delhaize America, LLC, Docket C–4440 (Feb. 25, 2014); AB Acquisition, LLC, Docket C–4424 (Dec. 23, 2013); Koninklijke Ahold N.V./Safeway Inc., Docket C–4367 (Aug. 17, 2012); Shaw's/Star Markets, Docket C–3934 (Jun. 28, 1999); Kroger/Fred Meyer, Docket C–3917 (Jan. 10, 2000); Albertson's/American Stores, Docket C–3986 (Jun. 22, 1999); Ahold/Giant, Docket C–3861 (Apr. 5, 1999); Albertson's/Buttrey, Docket C–3838 (Dec. 8, 1998); Jitney-Jungle Stores of America, Inc., Docket C–3784 (Jan. 30, 1998). *But see* Wal-Mart/Supermercados Amigo, Docket C–4066 (Nov. 21, 2002) (the Commission's complaint alleged that in Puerto Rico, club stores should be included in a product market that included supermarkets because club stores in Puerto Rico enabled consumers to purchase substantially all of their weekly food and grocery requirements in a single shopping visit).

[4] For purpose of the Complaint and remedial orders, Richmond, Virginia, is considered one geographic market because of the particular facts in this case, including the extensive overlaps between the Respondents' supermarkets in Richmond and because identifying narrower relevant geographic markets in Richmond would not have changed the analysis.

[5] Based on a calculation giving full weight to a third-party supermarket with a large draw area, the Merger results in a post-Merger HHI that does not meet the threshold for a highly concentrated market in the Norwood/Walpole, Massachusetts, market, even though the change in concentration is more than double the level that raises significant competitive concerns. Under calculations giving less than full weight to that supermarket, the Merger results in a highly concentrated market that meets the presumption for enhanced market power. Ultimately, an analysis of all the evidence indicates that the Merger is likely to substantially lessen competition in this market.

[6] *See* Exhibit A.

IV. The Proposed Consent Order

The proposed remedy, which requires the divestiture of either Ahold or Delhaize supermarkets in each relevant market to seven Commission-approved upfront buyers (the ''proposed buyers'') will restore fully the competition that otherwise would be eliminated in these markets as a result of the Merger. Specifically, Respondents have agreed to divest:

- 1 store in Maryland to New Albertson's Inc. (''Albertsons'');
- 7 stores in Massachusetts to Big Y Foods, Inc. (''Big Y'');
- 10 stores in Virginia to Publix North Carolina, LP (''Publix'');
- 1 store in Pennsylvania to Saubel's Market, Inc. (''Saubels'');
- 18 stores in Maryland, Pennsylvania, Virginia, and West Virginia to Shop 'N Save East, LLC (''Supervalu'');
- 6 stores in Massachusetts and New York to Tops Markets, LLC (''Tops''); and
- 38 stores in Delaware, Maryland, and Virginia to Weis Markets Inc. (''Weis'').

The proposed buyers appear to be highly suitable purchasers that are well positioned to enter the relevant geographic markets through the divested stores and prevent the increase in market concentration and likely competitive harm that otherwise would have resulted from the Merger. The supermarkets currently owned by the proposed buyers are all located outside the relevant geographic markets in which they are purchasing divested stores.

Albertsons is a large supermarket chain operating over 2,200 stores around the country. Albertsons will purchase the Salisbury, Maryland, store. Big Y is a regional supermarket operator with 61 stores in Connecticut and Massachusetts. Big Y will purchase seven divested stores in Massachusetts. Publix is a large supermarket chain with approximately 1,100 supermarkets in Alabama, Florida, Georgia, North Carolina, South Carolina, and Tennessee. Publix will purchase ten divested stores in Richmond, Virginia. Saubels is a small supermarket chain with three stores in Pennsylvania and Maryland. Saubels will purchase the York, Pennsylvania, store. Tops operates 165 supermarkets in New York, Pennsylvania, and Vermont. Tops will purchase five divested stores in New York and one divested store in Massachusetts. Supervalu is a wholesale food distributor that operates corporate-owned stores. Supervalu will purchase 18 divested stores in Maryland, Pennsylvania, Virginia, and West Virginia. Because Supervalu has in the past sold or assigned its rights in corporate-owned stores to independent operators, the Order requires Supervalu to seek prior approval for any such transfer of the divested stores for a period of three years. Weis is a regional supermarket operating 163 stores in Maryland, New Jersey, New York, Pennsylvania, and West Virginia. Weis will purchase 38 divested stores in Delaware, Maryland, and Virginia.

The proposed Consent Order requires Respondents to divest: (a) The Salisbury, Maryland, asset to Albertsons within 60 days of the date of Merger; (b) the Massachusetts (except Gardner) assets to Big Y within 90 days from the date of the Merger; (c) the Richmond, Virginia, assets to Publix in three groupings (the first within 180 days of the date of Merger, the second within 240 days, and the third within 360 days); (d) the York, Pennsylvania, asset to Saubels within 60 days of the date of Merger; (e) the Chambersburg and Waynesboro, Pennsylvania, assets, the Hagerstown, Maryland, assets, certain of the Virginia assets, and the West Virginia assets to Supervalu within 105 days of the date of the Merger; (f) the New York and Gardner, Massachusetts, assets to Tops within 60 days of the date of the Merger; and (g) the Delaware, Maryland (except Hagerstown and Salisbury), and certain of the Virginia assets to Weis in two phases (the first within 90 days of the date of the Merger, and the second within 230 days).

The variation in divestiture date deadlines is a function of the number of stores being acquired by each proposed buyer, as those acquiring a larger number of stores have requested and need a longer acquisition and transition period than those acquiring a smaller number of stores. In the case of Publix, the divestiture schedule is extended in order to give Publix sufficient time prior to the divestitures to secure permits and approvals needed for remodeling and construction work for the store locations it is acquiring. Publix is planning to make significant improvements to the acquired stores, including rebuilding several of them, in order to conform them to a typical Publix store. In addition, the extended divestiture schedule will reduce the time periods these stores will need to be closed before being reopened as Publix stores.

The proposed Consent Order and the Order to Maintain Assets require Respondents to continue operating and maintaining the divestiture stores in the normal course of business until the date that each store is sold to the proposed buyer. If, at the time before the proposed Consent Order is made final, the Commission determines that any of the proposed buyers are not acceptable buyers, Respondents must rescind the divestiture(s) and divest the assets to a different buyer that receives the Commission's prior approval.[7]

The proposed Consent Order contains additional provisions designed to ensure the adequacy of the proposed relief. For example, Respondents have agreed to an Order to Maintain Assets that will be issued at the time the proposed Consent Order is accepted for public comment. The Order to Maintain Assets requires Ahold and Delhaize to operate and maintain each divestiture store in the normal course of business through the date the store is ultimately divested to a buyer. Since the divestiture schedule with certain stores runs for an extended period of time (potentially up to 360 days following the Merger date), the proposed Consent Order appoints Brad Wise[8] as a Monitor to oversee the Respondents' compliance with the requirements of the proposed Consent Order and Order to Maintain Assets. Brad Wise has the experience and skills to be an effective Monitor, no identifiable conflicts, and sufficient time to dedicate to this matter through its conclusion. Lastly, for a period of ten years, Ahold is required to give the Commission prior notice of plans to acquire any interest in a supermarket that has operated or is operating in the counties included in the relevant markets.

The sole purpose of this Analysis is to facilitate public comment on the proposed Consent Order. This Analysis does not constitute an official interpretation of the proposed Consent Order, nor does it modify its terms in any way.

[7] In the case of the Richmond, Virginia, the Consent Order also provides the Commission the option to add six additional Richmond-area Ahold stores to the Richmond divestiture package, as may be needed, to secure an approvable alternative buyer for the Richmond assets.

[8] Mr. Wise is a retired, long-time industry executive, having most recently served as President of Hannaford until his retirement in 2015. Mr. Wise currently works at pro-voke, a business consulting firm.

EXHIBIT A

Area number	City	State	Merger result	HHI (pre)	HHI (post)	Delta	Divested store(s)
1	Lewes & Rehoboth Beach	DE	4 to 3	2,947	5,369	2,421	D2565 & D488
2	Millsboro	DE	3 to 2	3,794	6,440	2,646	D960
3	Millville	DE	4 to 3	4,065	5,762	1,697	D1321
4	Gardner	MA	4 to 3	2,517	3,723	1,207	A434
5	Kingston	MA	5 to 4	3,140	4,459	1,318	D8008
6	Mansfield & South Easton	MA	4 to 3	2,834	4,307	1,472	D8382
7	Milford	MA	5 to 4	2,298	2,780	482	D8021
8	Norwell	MA	4 to 3	4,052	5,840	1,789	D8020
9	Norwood & Walpole	MA	7 to 6	2,025	2,268	243	D8022
10	Quincy	MA	4 to 3	3,854	5,092	1,239	D8018
11	Saugus	MA	5 to 4	2,140	2,819	679	D8286
12	Accokeek	MD	2 to 1	5,430	10,000	4,570	D1356
13	Bowie	MD	4 to 3	3,288	3,750	462	D1387
14	California	MD	4 to 3	3,043	4,121	1078	D784, D1210 & D2515
15	Columbia	MD	5 to 4	3,093	3,679	586	D2598 & D1529
16	Cumberland & Frostburg	MD	3 to 2	4,032	5,157	1,125	D1549 & D1187
17	Easton	MD	4 to 3	2,803	3,578	775	D1289
18	Edgewater	MD	3 to 2	3,920	5,261	1,341	D1315
19	Gaithersburg	MD	5 to 4	4,203	5,193	989	D1345 & D1477
20	Hagerstown (South)	MD	4 to 3	3,910	4,525	615	D626, D1683 & D1180
21	Hagerstown (North)	MD	4 to 3	4,043	4,323	281	D1147
22	La Plata	MD	3 to 2	3,935	5,007	1,072	D1168
23	Lusby	MD	2 to 1	5,108	10,000	4,892	D1443 & D2606
24	Owings Mills	MD	4 to 3	3,325	4,017	692	D2535
25	Prince Frederick	MD	3 to 2	3,734	5,242	1,508	D1526
26	Reisterstown	MD	4 to 3	3,423	4,169	746	D786
27	Salisbury	MD	3 to 2	3,976	5,029	1,053	A351
28	Sykesville	MD	5 to 4	3,012	3,732	720	D1324
29	Upper Marlboro	MD	3 to 2	3,645	5,328	1,683	D1535
30	Mahopac & Carmel	NY	5 to 4	2,940	4,352	1,412	D8325
31	New Paltz, Modena & Highland.	NY	3 to 2	3,690	6,601	2,911	A515
32	Poughkeepsie & Lagrangeville.	NY	4 to 3	3,269	5,786	2,517	D8368
33	Rhinebeck & Red Hook	NY	2 to 1	5,023	10,000	4,977	A536
34	Wappingers Falls	NY	3 to 2	2,646	4,256	1,610	A598
35	Chambersburg	PA	5 to 4	3,277	4,232	955	D1527 & D994
36	Waynesboro	PA	3 to 2	5,030	5,537	506	D1663
37	York	PA	4 to 3	3,710	4,135	424	D1241
38	Culpepper	VA	4 to 3	3,329	4,371	1,042	D250 & D1567
39	Fredericksburg	VA	5 to 4	2,696	3,560	864	D358, D419, D450, D1043, D1177, D1235, D1243, D1579 & D2583
40	Front Royal	VA	3 to 2	3,638	5,095	1,456	D1059
41	Purcellville	VA	3 to 2	3,679	5,321	1,642	D745
42	Richmond	VA	5 to 4	2,198	2,857	659	A6421, A6434, A6433, A6498, A6429, A6439, A6435, A6499, A6438 & A6494
43	Stafford	VA	4 to 3	3,333	4,038	705	D578 & D1166
44	Stephens City	VA	3 to 2	4,045	5,018	973	D1489
45	Winchester	VA	3 to 2	3,662	5,094	1,433	D366, D362, D733, D1281, D2668 & D1164
46	Martinsburg	WV	4 to 3	2,759	3,568	809	D1189 & D2568

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2016–18564 Filed 8–4–16; 8:45 am]

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FEDERAL TRADE COMMISSION

[File No. 151 0196]

Teva Pharmaceutical Industries Ltd. and Allergan plc; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the complaint and the terms of the consent orders—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before August 29, 2016.

ADDRESSES: Interested parties may file a comment at *https://ftcpublic.commentworks.com/ftc/tevaallerganconsent* online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section

below. Write ''In the Matter of Teva Pharmaceutical Industries Ltd. and Allergan plc, File No. 151–0196, C–4589—Consent Agreement'' on your comment and file your comment online at *https://ftcpublic.commentworks.com/ftc/tevaallerganconsent* by following the instructions on the web-based form. If you prefer to file your comment on paper, write ''In the Matter of Teva Pharmaceutical Industries Ltd. and Allergan plc, File No. 151–0196, C–4589—Consent Agreement'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Michael Moiseyev (202–326–3106), Bureau of Competition, 600 Pennsylvania Avenue NW., Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing consent orders to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for July 27, 2016), on the World Wide Web, at *http://www.ftc.gov/os/actions.shtm*.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before August 29, 2016. Write ''In the Matter of Teva Pharmaceutical Industries Ltd. and Allergan plc, File No. 151–0196, C–4589—Consent Agreement'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at *http://www.ftc.gov/os/publiccomments.shtm*. As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any ''[t]rade secret or any commercial or financial information which . . . is privileged or confidential,'' as discussed in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c).[1] Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/tevaallerganconsent* by following the instructions on the web-based form. If this Notice appears at *http://www.regulations.gov/#!home,* you also may file a comment through that Web site.

If you file your comment on paper, write ''In the Matter of Teva Pharmaceutical Industries Ltd. and Allergan plc, File No. 151–0196, C–4589—Consent Agreement'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Web site at *http://www.ftc.gov* to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before August 29, 2016. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at *http://www.ftc.gov/ftc/privacy.htm*.

Analysis of Agreement Containing Consent Orders To Aid Public Comment

The Federal Trade Commission (''Commission'') has accepted, subject to final approval, an Agreement Containing Consent Orders (''Consent Agreement'') from Teva Pharmaceutical Industries Ltd. (''Teva'') and Allergan plc (''Allergan''), which is designed to remedy the anticompetitive effects resulting from Teva's proposed acquisition of Allergan's generic pharmaceutical business. The proposed Consent Agreement requires the parties (1) to divest rights and assets related to pharmaceutical markets for one or more strengths of seventy-nine pharmaceutical products and (2) provide certain Teva active pharmaceutical ingredient (''API'') customers that market one or more of fifteen pharmaceutical products with the option to enter into long-term API supply contracts.

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again evaluate the proposed Consent Agreement, along with the comments received, to make a final decision as to whether it should withdraw from the proposed Consent Agreement or make final the Decision and Order (''Order'').

On July 26, 2015, Teva proposed to acquire Allergan's generic pharmaceutical business for approximately $40.5 billion. The Commission alleges in its Complaint that the proposed acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15

[1] In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, by lessening current or future competition in pharmaceutical markets for one or more strengths of ninety-four pharmaceutical products in the United States. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be eliminated by the proposed acquisition.

I. The Products and Structure of the Markets

a. Horizontal Competition in Pharmaceutical Markets

Generic drugs are chemically and therapeutically equivalent to branded drugs. When a physician prescribes a particular branded drug, a pharmacy may only dispense that branded drug or its generic equivalent, which is ''AB-rated'' to the branded product. State laws permit or require pharmacies to automatically substitute the generic equivalent for the prescribed branded drug unless a physician expressly states not to do so.

The 1984 Hatch-Waxman Act provides the statutory framework for the Food and Drug Administration (''FDA'') to approve generic drugs. Under Hatch-Waxman, a generic drug manufacturer can rely on an already-approved branded drug's safety and efficacy data in its own application—called an Abbreviated New Drug Application (''ANDA'')—to the FDA, substantially lowering the research and development cost of the generic drug. Upon FDA approval, a generic drug typically launches at a discount to the branded drug's price. When there is only one generic drug on the market, the branded drug usually competes with the generic drug on price, either directly or through an authorized generic version. As subsequent generic drugs launch, a generic-only market typically forms, with competition among generics driving pricing. When multiple generic drugs are available, customers usually substitute between the generics only—not the branded drug—and solicit bids exclusively from generic drug suppliers.

Teva's proposed acquisition of Allergan's generic pharmaceutical business will lessen current or future competition by reducing the number of current or future suppliers in the pharmaceutical markets for one or more strengths of seventy-nine pharmaceutical products. Those markets fall into three categories: (1) Current competition between Teva and Allergan; (2) future competition between Teva and Allergan in an existing generic market; and (3) future competition between Teva and Allergan in a future generic market (*i.e.,* the generic market has not yet formed and only the branded drug is on the market). Absent a remedy, the proposed acquisition would reduce the number of suppliers in each market as indicated below.

- Current Competition Between Teva and Allergan, 2-to-1 Supplier Consolidation
  - Armodafinil Oral Tablet, 200 mg
  - Desogestrel/Ethinyl Estradiol Oral Tablet, 0.025/0.1 mg then 0.025/0.125 mg then 0.025/0.15 mg (AB-rated to Cyclessa)
  - Estazolam Oral Tablet, 1 mg
  - Estazolam Oral Tablet, 2 mg
  - Ethinyl Estradiol/Ethynodiol Diacetate Oral Tablet, 0.035/1mg (AB-rated to Demulen 1/35)
  - Ethinyl Estradiol/Norethindrone Oral Tablet, 0.035/1mg (AB-rated to Tri-Norinyl 28-Day)
  - Ethinyl Estradiol/Norethindrone Acetate/Ferrous Fumarate Oral Tablet, 0.02/0.03/0.035/1/1/1 mg (AB-rated to Estrostep FE)
  - Metoclopramide HCl Oral Tablet, 5 mg
  - Trimipramine Maleate Oral Capsule, 25 mg
  - Trimipramine Maleate Oral Capsule, 50 mg
  - Trimipramine Maleate Oral Capsule, 100 mg

- Current Competition Between Teva and Allergan, 3-to-2 Supplier Consolidation
  - Budesonide Inhalation Suspension, 0.25 mg/2 mL
  - Budesonide Inhalation Suspension, 0.5 mg/2 mL
  - Clarithromycin Extended Release Oral Tablet, 500 mg
  - Clonidine HCl Extended Release Transdermal Film, 0.1 mg/24 hr
  - Clonidine HCl Extended Release Transdermal Film, 0.2 mg/24 hr
  - Clonidine HCl Extended Release Transdermal Film, 0.3 mg/24 hr
  - Cyclosporine Oral Solution, 100 mg/mL
  - Desmopressin Acetate Oral Tablet, 0.1 mg
  - Desogestrel/Ethinyl Estradiol/Ethinyl Estradiol Oral Tablet, 0.15/0.02 mg/0.01 mg (AB-rated to Mircette)
  - Disopyramide Phosphate Oral Capsule, 100 mg
  - Disopyramide Phosphate Oral Capsule, 150 mg
  - Estradiol Oral Tablet, 0.5 mg
  - Estradiol Oral Tablet, 1 mg
  - Estradiol Oral Tablet, 2 mg
  - Ethinyl Estradiol/Levonorgestrel Oral Tablet, 0.02/0.1mg (AB-rated to Levlite-28)
  - Ethinyl Estradiol/Levonorgestrel Oral Tablet 0.03/0.04/0.03/0.05/0.075/0.125 mg (AB-rated to Triphasil-28)
  - Ethinyl Estradiol/Norethindrone Oral Tablet, 0.035/0.5mg (AB-rated to Modicon 28)
  - Ethinyl Estradiol/Norgestrel Oral Tablet, 0.03/0.3mg (AB-rated to Lo/Ovral-28)
  - Fludarabine Lyopholized Vial Injection, 50 mg
  - Fluocinonide Topical Cream, 0.05%
  - Flutamide Oral Capsule, 125 mg
  - Griseofulvin Microcrystalline Oral Liquid Suspension, 125 mg/5 mL
  - Metoclopramide HCl Oral Tablet, 10 mg
  - Mirtazapine Oral Disintegrating Tab, 15 mg
  - Mirtazapine Oral Disintegrating Tab, 30 mg
  - Mirtazapine Oral Disintegrating Tab, 45 mg
  - Nabumetone Oral Tablet, 500 mg
  - Nabumetone Oral Tablet, 750 mg
  - Nortriptyline HCl Oral Capsule, 10 mg
  - Nortriptyline HCl Oral Capsule, 25 mg
  - Nortriptyline HCl Oral Capsule, 50 mg
  - Nortriptyline HCl Oral Capsule, 75 mg
  - Tamoxifen Citrate Oral Tablet, 10 mg
  - Tamoxifen Citrate Oral Tablet, 20 mg
  - Trimethoprim Oral Tablet, 100 mg

- Current Competition Between Teva and Allergan, 4-to-3 Supplier Consolidation
  - Acitretin Oral Capsule, 17.5 mg
  - Amphetamine Aspartate/Amphetamine Sulfate/Dextroamphetamine Saccharate/Dextroamphetamine Sulfate Oral Capsule, 5 mg
  - Amphetamine Aspartate/Amphetamine Sulfate/Dextroamphetamine Saccharate/Dextroamphetamine Sulfate Oral Capsule, 10 mg
  - Amphetamine Aspartate/Amphetamine Sulfate/Dextroamphetamine Saccharate/Dextroamphetamine Sulfate Oral Capsule, 15 mg
  - Amphetamine Aspartate/Amphetamine Sulfate/Dextroamphetamine Saccharate/Dextroamphetamine Sulfate Oral Capsule, 20 mg
  - Amphetamine Aspartate/Amphetamine Sulfate/Dextroamphetamine Saccharate/Dextroamphetamine Sulfate Oral Capsule, 25 mg
  - Amphetamine Aspartate/Amphetamine Sulfate/Dextroamphetamine Saccharate/

Dextroamphetamine Sulfate Oral Capsule, 30 mg
- Carbidopa/Levodopa Oral Tablet, 10/100 mg
- Carbidopa/Levodopa Oral Tablet, 25/100 mg
- Carbidopa/Levodopa Oral Tablet, 25/250 mg
- Cyclosporine Oral Capsule, 25 mg
- Cyclosporine Oral Capsule, 100 mg
- Desmopressin Acetate Oral Tablet, 0.2 mg
- Dexmethylphenidate HCl Extended Release Oral Capsule, 5 mg
- Dexmethylphenidate HCl Extended Release Oral Capsule, 10 mg
- Dexmethylphenidate HCl Extended Release Oral Capsule, 20 mg
- Dextroamphetamine Sulfate Extended Release Oral Capsule, 5 mg
- Dextroamphetamine Sulfate Extended Release Oral Capsule, 10 mg
- Dextroamphetamine Sulfate Extended Release Oral Capsule, 15 mg
- Diazepam Oral Tablet, 2 mg
- Diazepam Oral Tablet, 5 mg
- Diazepam Oral Tablet, 10 mg
- Epirubicin Injection Vial 50 mg/25 mL
- Epirubicin Injection Vial 200 mg/100 mL
- Ethinyl Estradiol/Levonorgestrel Oral Tablet, 0.02/0.01/0.1mg (AB-rated to Lo Seasonique)
- Ethinyl Estradiol/Norethindrone Acetate Oral Tablet, 0.02/1mg (AB-rated to Loestrin 21 1/20)
- Ethinyl Estradiol/Norethindrone Acetate Oral Tablet, 0.03/1.5mg (AB-rated to Loestrin 21 1.5/30)
- Glyburide/Metformin HC1 Oral Tablet, 1.25/250 mg
- Glyburide/Metformin HCl Oral Tablet, 2.5/500 mg
- Glyburide/Metformin HCl Oral Tablet, 5/500 mg
- Hydroxyzine Pamoate Oral Capsule, 25 mg
- Hydroxyzine Pamoate Oral Capsule, 50 mg
- Levalbuterol HCl Inhalation Solution, 0.0103%
- Levalbuterol HCl Inhalation Solution, 0.0210%
- Levalbuterol HCl Inhalation Solution, 0.042%
- Minocycline HCl Oral Capsule, 50 mg
- Minocycline HCl Oral Capsule, 75 mg
- Minocycline HCl Oral Capsule, 100 mg
- Nitrofurantoin Oral Capsules, 50 mg
- Nitrofurantoin Oral Capsules, 100 mg
- Propofol Injection Emulsion, 10 mg/mL 20 mL vial
- Propofol Injection Emulsion, 10 mg/mL 50 mL vial
- Propofol Injection Emulsion, 10 mg/mL 100 mL vial
- Propranolol HCl Oral Tablet, 10 mg
- Propranolol HCl Oral Tablet, 20 mg
- Propranolol HCl Oral Tablet, 40 mg
- Propranolol HCl Oral Tablet, 80 mg

• Current Competition Between Teva and Allergan, 5-to-4 Supplier Consolidation
- Acitretin Oral Capsule, 10 mg
- Acitretin Oral Capsule, 25 mg
- Alendronate Sodium Oral Tablet, 35 mg
- Buspirone HCl Oral Tablet, 15 mg
- Clozapine Oral Tablet, 25 mg
- Clozapine Oral Tablet, 100 mg
- Drospirenone/Ethinyl Estradiol Oral Tablet, 3/0.03 mg (AB-rated to Yasmin-28)
- Ethinyl Estradiol/Levonorgestrel Oral Tablet, 0.02/0.1 mg (AB-rated to Alesse-28)
- Ethinyl Estradiol/Levonorgestrel Oral Tablet, 0.03/0.15 mg (AB-rated to Nordette)
- Ethinyl Estradiol/Levonorgestrel Oral Tablet, 0.03/0.01/0.15 mg (AB-rated to Seasonique)
- Ethinyl Estradiol/Norethindrone Acetate/Ferrous Fumarate Oral Tablet, 0.02/1 mg (AB-rated to Loestrin FE 1/20)
- Ethinyl Estradiol/Norethindrone Acetate/Ferrous Fumarate Oral Tablet, 0.03/1.5 mg (AB-rated to Loestrin FE 1.5/30)
- Norethindrone Oral Tablet, 0.35 mg (AB-rated to Micronor 28)
- Norethindrone Oral Tablet, 0.35 mg (AB-rated to Nor-QD)

• Future Competition Between Teva and Allergan in an Existing Generic Market, 3-to-2 Supplier Consolidation
- Budesonide Inhalation Suspension, 1 mg/2 mL
- Fluocinonide Cream Emulsified Base 0.05%
- Methylphenidate HCl Extended Release Capsule, 20 mg
- Methylphenidate HCl Extended Release Capsule, 30 mg
- Methylphenidate HCl Extended Release Capsule, 40 mg

• Future Competition Between Teva and Allergan in an Existing Generic Market, 4-to-3 Supplier Consolidation
- Aspirin/Dipyridamole Extended Release Oral Capsule 25/200 mg

• Future Competition Between Teva and Allergan in an Existing Generic Market, 5-to-4 Supplier Consolidation
- Benzoyl Peroxide/Clindamycin Phosphate Gel, 5%/1%
- Clozapine Oral Tablet, 200 mg
- Methotrexate Injection, 25 mg/mL in 2 mL vial
- Methotrexate Injection, 25 mg/mL in 10 mL vial
- Methylphenidate HCl Extended Release Tablet, 18 mg
- Methylphenidate HCl Extended Release Tablet, 27 mg
- Methylphenidate HCl Extended Release Tablet, 36 mg
- Methylphenidate HCl Extended Release Tablet, 54 mg
- Tobramycin Inhalant Solution, 300 mg/5 mL

• Future Competition Between Teva and Allergan in a Future Generic Market, 2-to-1 Supplier Consolidation
- Methylphenidate HCl Extended Release Capsule, 10 mg
- Ramelteon Tablet, 8 mg

• Future Competition Between Teva and Allergan in a Future Generic Market, 3-to-2 Supplier Consolidation
- Buprenorphine/Naloxone Buccal Film, 12/3 mg
- Buprenorphine/Naloxone Buccal Film, 4/1 mg
- Ethinyl Estradiol/Etonogestrel Vaginal Ring 0.015mg/24hr; 0.012mg/24hr
- NAB Paclitaxel Injectable Suspension, 100 mg/vial
- Phentermine HCl/Topiramate Extended Release Capsule, 11.25/69 mg
- Phentermine HCl/Topiramate Extended Release Capsule, 15/92 mg
- Phentermine HCl/Topiramate Extended Release Capsule, 3.75/23 mg
- Phentermine HCl/Topiramate Extended Release Capsule, 7.5/46 mg
- Rotigotine Transdermal Patch, 1 mg
- Rotigotine Transdermal Patch, 2 mg
- Rotigotine Transdermal Patch, 3 mg
- Rotigotine Transdermal Patch, 4 mg
- Rotigotine Transdermal Patch, 6 mg
- Rotigotine Transdermal Patch, 8 mg

• Future Competition Between Teva and Allergan in a Future Generic Market, 4-to-3 Supplier Consolidation
- Buprenorphine/Naloxone Buccal Film, 2/0.5 mg
- Buprenorphine/Naloxone Buccal Film, 8/2 mg
- Dienogest/Estradiol Valerate and Estradiol Valerate Oral Tablet, 3 mg, 2/2 mg, 3/2 mg, 1 mg (AB-rated to Natazia)
- Ethinyl Estradiol/Levonorgestrel Oral Tablet, 0.02/0.15 mg; 0.025/0.15 mg; 0.03 mg/0.15 mg; 0.01 mg (AB-rated to Quartette)
- Ezetimibe/Simvastatin Tablets, 10/10 mg
- Ezetimibe/Simvastatin Tablets, 10/20 mg
- Ezetimibe/Simvastatin Tablets, 10/40 mg
- Ezetimibe/Simvastatin Tablets, 10/80 mg

- Imiquimod Topical Cream, 3.75%
- Four pipeline products [2]

• Future Competition Between Teva and Allergan in a Future Generic Market, 5-to-4 Supplier Consolidation

- Dexmethylphenidate HCl Extended Release Oral Capsule, 25 mg
- Dexmethylphenidate HCl Extended Release Oral Capsule, 35 mg
- Fentanyl Buccal Tablet, 100 mcg
- Fentanyl Buccal Tablet, 200 mcg
- Fentanyl Buccal Tablet, 400 mcg
- Fentanyl Buccal Tablet, 600 mcg
- Fentanyl Buccal Tablet, 800 mcg
- Metformin HCl/Saxagliptin Extended Release Tablet, 500/5 mg
- Metformin HCl/Saxagliptin Extended Release Tablet, 1000/2.5 mg
- Metformin HCl/Saxagliptin Extended Release Tablet, 1000/5 mg

b. API Supply and Competition in Pharmaceutical Markets

APIs are central inputs in the manufacture of finished dose form pharmaceutical products. API supply sources must be designated in a drug's FDA marketing authorization. Switching to a non-designated API source requires a drug maker to supplement its New Drug Application or ANDA, a process that can take as long as two years or even more. Consequently, a generic drug manufacturer's API supply options are limited to the sources qualified under its ANDA. If only one API supplier is qualified under an ANDA, the ANDA holder has no immediate recourse if its designated API supplier elects to raise its prices or refuse to supply.

Teva is world's largest API supplier and supplies API to Allergan's competitors in a number of generic markets. The proposed acquisition may lessen current or future competition in fifteen pharmaceutical products markets by creating the incentive and ability for Teva to foreclose rival suppliers of fifteen newly acquired Allergan pharmaceutical products by withholding supply of the following eight Teva API products:

- Betamethasone dipropionate API;
- Betamethasone valerate API;
- Clobetasol propionate API;
- Desonide API;
- Fluocinolone API;
- Fluorouracil API;
- Probenecid API; and
- Triamcinolone acetonide API.

The fifteen downstream pharmaceutical markets in which competition would be lessened as a result of the acquisition are:

- Betamethasone dipropionate augmented ointment, 0.05%;
- Betamethasone dipropionate cream, 0.05%;
- Betamethasone dipropionate lotion, 0.05%;
- Betamethasone dipropionate ointment, 0.05%;
- Betamethasone valerate cream, 0.1%;
- Betamethasone valerate ointment, 0.1%;
- Clobetasol propionate shampoo, 0.05%;
- Clobetasol propionate ointment, 0.05%;
- Desonide cream, 0.05%;
- Probenecid tablets, 500 mg;
- Probenecid/colchicine tablets, 500 mg/0.5 mg;
- Nystatin/triamcinolone acetonide cream, 100,000 units/gm/0.1%;
- Nystatin/triamcinolone acetonide ointment, 100,000 units/gm/0.1%; and
- Two pipeline products.[3]

II. Entry

Entry into these pharmaceutical markets would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the proposed acquisition. Introducing generic pharmaceutical products is costly and lengthy due to drug development times and regulatory requirements, including approval by the FDA. Additionally, it can take up to two years for an API manufacturer to qualify as a new API supplier for a generic pharmaceutical product, leaving the generic pharmaceutical product with no alternative to its existing qualified API supplier or suppliers.

III. Effects

The proposed acquisition likely would cause significant anticompetitive harm by eliminating current or future competition in markets for one or more strengths of seventy-nine pharmaceutical products where the parties currently sell or are developing generic drugs. In each of these markets, Teva and Allergan are two of a limited number of current or likely future suppliers in the United States. Customers and competitors have observed that the price of generic pharmaceutical products decreases with new entry even after several suppliers have entered the market. Removal of an independent generic pharmaceutical supplier from the relevant markets in which Teva and Allergan currently compete would result in significantly higher prices post-acquisition. Similarly, the elimination of a future independent competitor would prevent the price decreases that are likely to result from the firm's entry. Thus, absent a remedy, the proposed acquisition would likely result in significantly higher prices for these generic drugs.

Additionally, the proposed acquisition likely would cause competitive harm in markets for fifteen pharmaceutical products in which Teva supplies API for a generic pharmaceutical product that currently competes or will compete in the near future with an Allergan generic pharmaceutical product. Those generic pharmaceutical markets already have or will have a limited number of competitors, some of which are supplied API by Teva. Teva has the ability to foreclose these competitors by denying them API from their only approved source. Post-acquisition, Teva would have the incentive to foreclose one or more competitors because the lost API sales would be less than the recouped profits on additional sales gained from the foreclosed competitor(s) and the increased prices. Such foreclosure would harm consumers because market concentration and price would result in significantly higher prices.

IV. The Consent Agreement

The remedy reflected in the proposed Consent Agreement would eliminate the likely anticompetitive effects of the proposed acquisition by requiring the parties to divest rights and assets related to the pharmaceutical products in each relevant market. The acquirers are: Mayne Pharma Group Ltd. (''Mayne''), Impax Laboratories, Inc. (''Impax''), Dr. Reddy's Laboratories Ltd. (''Dr. Reddy's''), Sagent Pharmaceuticals, Inc. (''Sagent''), Cipla Limited (''Cipla''), Zydus Worldwide DMCC (''Zydus''), Mikah Pharma LLC (''Mikah''), Perrigo Pharma International D.A.C. (''Perrigo''), Aurobindo Pharma USA, Inc. (''Aurobindo''), Prasco LLC (''Prasco''), and 3M Company (''3M'') (collectively, the ''Acquirers''). The parties must

[2] Teva's and Allergan's independent development projects for two overlapping pharmaceutical products are not public, and their existence is confidential business information. But for the proposed acquisition, certain strengths of the Teva and Allergan products would likely compete in four future markets. To preserve the confidentiality of these development programs, the specific future markets in which these products would compete are not identified in this document, and references to these products have been redacted from the public version of the Complaint.

[3] Allergan has not yet made public the development of two pharmaceutical products that would likely compete with products for which Teva supplies API. To preserve the confidentiality of these Allergan development programs, the specific markets in which these likely future products would compete are not identified in this document, and references to these products have been redacted from the public version of the Complaint.

divest the products no later than ten days after the acquisition.

The Commission's goal in evaluating possible acquirers of divested assets is to maintain the competitive environment that existed prior to the acquisition. The Commission thoroughly reviewed the assets to be divested, the transitional services to be provided by Teva, and the capabilities and plans of each Acquirer. The interim monitors, who will oversee the divestiture process, have worked closely with Commission staff to ensure the viability of the divestiture and anticipate logistical and technical challenges. Additionally, Teva—in conjunction with the Acquirers, Allergan, and interim monitors—has prepared a comprehensive divestiture plan to guide the process of transferring the divested products to their new proposed owners. If the Commission determines that an Acquirer is not acceptable, or that the manner of the divestitures is not acceptable, the parties must unwind the sale or release of rights to that Acquirer and divest the products to a Commission-approved acquirer within six months of the date the Order becomes final. In that circumstance, the Commission may appoint a trustee to divest the products if the parties fail to divest the products as required.

The proposed Consent Agreement contains provisions to help ensure the divestitures are successful. The parties must take all action to maintain the economic viability, marketability, and competitiveness of the divestiture products until they are divested. The parties must provide transitional services to the Acquirers to assist them in establishing independent manufacturing capabilities. These transitional services include technical assistance to manufacture the divestiture products in substantially the same manner and quality employed or achieved by the parties, as well as advice and training from knowledgeable employees. The goal of the transitional services is to ensure that the acquirers will be able to operate independently of the parties in the manufacture and sale of the divested products. The proposed Consent Agreement also requires the parties to supply product to the Acquirers so that the Acquirers can market them independently while the parties transfer the associated technology to the production facilities of the Acquirer or its chosen third-party manufacturer(s). The Consent Agreement allows sufficient time to complete the manufacturing transfers, and for products in development, to gain FDA approval before completing manufacturing transfers. To ensure that the buyers of divestiture products for which Teva or Allergan supply API will have access to adequate supplies of reasonably priced API until they are able to qualify alternative suppliers, the proposed Consent Agreement requires Teva to supply API for up to four years after closing at prices not to exceed those set forth in binding letters of intent, recently executed by Teva and the buyers. Nothing in the Consent Agreement precludes the buyers from sourcing other divestiture product inputs from Teva on a negotiated basis.

In addition, to address the anticompetitive effects likely to arise in the fifteen pharmaceutical markets where Teva supplies API to Allergan competitors, the Consent Agreement requires Teva to give API customers in those markets the option of entering into long-term API supply contracts. Teva must notify each affected API customer of the option to enter a contract within ten days of consummating the proposed acquisition, and such customers may exercise their options at any point up to three years after the date of the Consent Agreement. Any such API supply contracts executed pursuant to the option shall be renewable for up three years after the date of the Consent Agreement, which will give the customers sufficient time to qualify alternative API suppliers if they wish to do so.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

Statement of the Federal Trade Commission in the Matter of Teva Pharmaceuticals Industries Ltd. and Allergan plc

The Commission has accepted a proposed consent order in connection with Teva Pharmaceutical Industries Ltd.'s proposed acquisition of the generic pharmaceutical business of Allergan plc. We believe the consent order remedies the anticompetitive effects that would otherwise likely result from this transaction by requiring the divestiture of nearly 80 drug products to buyers that appear well positioned to replicate the competition that would have occurred absent the merger. The consent order includes a number of safeguards to help achieve our remedial goals.

Both Teva and Allergan are global pharmaceutical companies that are among the largest suppliers of generic pharmaceuticals in the United States. Teva is currently the largest generic drug company in the United States, with an overall generic market share of approximately 13%; Allergan is third, accounting for approximately 9% of generic sales.[1] Although this merger combines two large sellers of generic drugs, the generic pharmaceutical industry as a whole remains relatively unconcentrated. Over two hundred firms sell generic drugs in the United States and the five largest suppliers account only for about half of overall generic sales. Following this transaction, the combined firm will likely have a 22% share of industry-wide sales across all generic product markets.

Despite the industry's relatively low concentration, the Commission appreciates that the price, quality, and availability of generic pharmaceutical products have a significant impact on American consumers' daily lives and on healthcare costs nationwide. We therefore looked closely at every possible aspect of this transaction that could result in competitive harm. We examined not only particular product overlaps but also whether the combination between Teva and Allergan would result in other adverse consequences to competition. Our comprehensive investigation included the review of extensive documents from the merging parties and other industry players as well as interviews with dozens of customers and more than 50 competitors. We concluded that the substantial divestitures required by the consent order resolve the competitive concerns resulting from the transaction.

The Complaint and Remedy

As detailed in our complaint, we have reason to believe that, absent a remedy, the transaction would likely substantially reduce competition in 79 markets for pharmaceutical products, including oral contraceptives, steroidal medications, mental health drugs, and many other products. These markets include individual strengths of pharmaceutical products where Teva and Allergan currently offer competing products as well as products where there would likely be future competition absent the merger because one or both of the parties are developing competing products.[2] To remedy the likely

[1] This market share data is based on 2014 IMS gross sales data.

[2] In addition to selling finished pharmaceutical products, Teva and Allergan also sell active pharmaceutical ingredients (API) to many third-party drug manufacturers, including parties that will now compete with the merged entity. Where the number of competitors in the finished product market is limited, the Commission determined that this vertical relationship could raise competitive

Continued

anticompetitive effects in each of the relevant markets, the consent order requires the divestiture of the products and related assets to specific acquirers that the Commission has closely vetted and approved. Where at least one dosage strength raised a competitive concern, we required Teva to divest all strengths. These divestitures, and the other relief contained in the proposed consent order, are designed to maintain competition in the relevant markets.

In settling this case, we rely on the Commission's extensive experience with divestitures in the pharmaceutical industry, including prior divestitures involving Teva and Allergan and have structured the divestitures in a way to minimize potential risks. This includes breaking the divested products into smaller packages to ease the load on any single buyer and requiring Teva to divest the easier-to-divest product of the overlapping products whenever possible. We also undertook an extensive review process to ensure that the divestiture buyers are acceptable and have the resources they need to compete successfully in the relevant markets. The buyers have identified third-party contract research organizations or contract manufacturers they intend to use and provided us with executed contracts. We involved interim monitors early in the divestiture negotiation process to ensure a smooth divestiture process and harmonize Teva's technological transfer plans with those of the acquirors of the divested assets. And we are requiring Teva to dedicate a full-time organization to implement the technology transfers and other measures necessary to effectuate the divestitures.

Other Potential Theories of Harm

In assessing whether the combination of the parties' generic businesses would harm competition or create a firm with a greater ability to engage in anticompetitive conduct, we evaluated three additional potential theories of harm beyond individual product overlaps.

First, we considered whether the merger would likely lead to anticompetitive effects from the bundling of generic products. Although both Teva and Allergan have broad generic drug portfolios today, the evidence did not show that the breadth of their portfolios significantly affects their ability to win business in individual drug product markets. Nor have they been able to use their portfolios to foreclose smaller competitors. Even with one of the broadest generic product portfolios in the industry, Teva's overall share of U.S. generic prescriptions has steadily declined from 2010 to 2015, and the share of total prescriptions filled by the five largest generic suppliers has similarly fallen during this period. Generic sales occur at the individual product level, and customers sometimes even break up purchases by specific strengths to obtain more favorable pricing. As a result, smaller firms with much smaller portfolios compete head-to-head against larger generic firms and are the leading suppliers in the markets for many individual generic treatments. Additionally, purchasers actively seek to diversify their supplier base by sourcing from smaller suppliers. On the facts here, we concluded that anticompetitive effects arising from the merged company's portfolio of products are unlikely to occur.

Second, we examined whether the merger would likely decrease incentives to challenge the patents held by brand-name pharmaceutical companies and bring new generic drugs to market. The regulatory framework governing generic pharmaceuticals, the Hatch-Waxman Act, provides specific procedures for identifying and resolving patent disputes related to new generic drugs. Under the Hatch-Waxman Act, a company seeking to introduce a new generic drug may file what is commonly known as a ''Paragraph IV challenge'' to a brand-name pharmaceutical product's patent. This filing triggers a process, including potential litigation, to resolve patent issues surrounding the proposed generic product's entry into the marketplace.

We considered whether the merger would likely result in fewer or less effective Paragraph IV challenges, but the evidence did not support such a conclusion. A major incentive to file Paragraph IV challenges is the 180-day exclusivity period awarded to the first generic drug that the Food and Drug Administration approves in a market. The financial rewards associated with this ''first-to-file'' exclusivity period provide a strong incentive for generic drug companies of all sizes to challenge brand drug patents and litigate against brand drug companies. Indeed, first-to-file Paragraph IV challenges are not concentrated among a small group of firms. To the contrary, many firms, including small ones, have been active and successful first filers. In 2014, for example, twenty-five different companies were the first to file Paragraph IV challenges. For eight of those companies, that was their very first Paragraph IV challenge. Thus, while Teva and Allergan have actively filed Paragraph IV challenges, we found no evidence that either one has been better positioned to win the first-to-file race or that they have substantially greater incentives or ability to succeed in Paragraph IV challenges than many other generic companies. Nor did we see evidence that a merger between the two would diminish the combined firm's incentive to continue to pursue Paragraph IV challenges.

Finally, we analyzed whether the proposed transaction might dampen incentives to develop new generic products. For example, certain types of generic drugs are especially difficult to develop. For the most part, however, the parties' in-house technical capabilities to develop complex generic drugs do not overlap. And to the extent that there are complex products for which both companies have engaged in development efforts, we found that there are a number of other firms with similar capabilities such that the transaction would not substantially lessen competition. Moreover, generic firms, including the merging parties, often partner with third parties (*e.g.,* specialized contract development and manufacturing organizations) to obtain the technical capability to develop complex generic drugs. These types of partnership options will remain after the merger. The consent order addresses individual markets where the merger was likely to harm competition, including markets for difficult-to-develop products that are currently in the parties' pipelines.

Conclusion

We therefore concluded that the proposed merger is unlikely to produce anticompetitive effects beyond the markets discussed above. That conclusion is necessarily limited to the facts of this case. Another set of facts presented by a different transaction might lead us to find that there are competitive concerns that extend beyond markets for individual pharmaceutical products.

The extensive investigation and detailed consent order reflect the Commission's dedication to ensuring that pharmaceutical markets, including generic markets, remain competitive. We will continue to take enforcement actions, where appropriate, to ensure that any merger or acquisition complies with the antitrust laws and does not

concerns in markets for finished drug products by creating the incentive and ability for Teva to raise prices or withhold supply where third parties source from the merged firm. To address these concerns, the order requires Teva to provide affected customers with the option of entering into long-term API supply contracts to ensure that they have an adequate supply of API until they are able to qualify alternative suppliers.

undermine competition in the pharmaceutical industry.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2016–18562 Filed 8–4–16; 8:45 am]

BILLING CODE 6750–01–P

FEDERAL TRADE COMMISSION

[File No. 1623034, Docket No. C–4580]

Very Incognito Technologies, Inc., Doing Business as Vipvape

AGENCY: Federal Trade Commission.

ACTION: Consent order.

SUMMARY: The Commission has approved a final consent order in this matter, settling alleged violations of federal law prohibiting deceptive acts or practices. The attached Analysis to Aid Public Comment describes both the allegations in the Complaint and the terms of the Decision and Order.

DATES: Issued on June 21, 2016.

SUPPLEMENTARY INFORMATION:

Analysis of Agreement Containing Consent Order To Aid Public Comment

The Federal Trade Commission (''FTC'' or ''Commission'') has approved a final consent order applicable to Very Incognito Technologies, Inc. dba Vipvape (''Vipvape'').

The consent order was placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period became part of the public record. After the public comment period, the Commission reviewed the agreement and the comments received, and determined to make the proposed order final.

This matter concerns allegedly false representations that Vipvape made to consumers concerning its participation in the Asia-Pacific Economic Cooperation (''APEC'') Cross Border Privacy Rules (''CBPR'') system. The APEC CBPR system is a voluntary, enforceable mechanism that certifies a company's compliance with the principles in the CBPR and facilitates privacy-respecting transfers of data amongst APEC member economies. The APEC CBPR system is based on nine data privacy principles: Preventing harm, notice, collection limitation, use choice, integrity, security safeguards, access and correction, and accountability. Companies that seek to participate in the APEC CBPR system must undergo a review by an APEC-recognized Accountability Agent, which certifies companies that meet the standards.

Companies under the FTC's jurisdiction are eligible to apply for APEC CBPR certification. The names of certified companies are posted on a public-facing Web site, *www.cbprs.org.* Companies must re-apply annually in order to retain their status as current participants in the APEC CBPR system. A company that falsely claims APEC CBPR participation may be subject to an enforcement action based on the FTC's deception authority under Section 5 of the FTC Act.

Vipvape makes and distributes hand-held vaporizers. According to the Commission's complaint, Vipvape has set forth on its Web site, *https://www.vipvape.com/content/legal/warranty/privacy*, privacy policies and statements about its practices, including statements related to its participation in the APEC CBPR system.

The Commission's complaint alleges that Vipvape falsely represented that it was a participant in the APEC CBPR system when, in fact, it never sought or obtained certification.

Part I of the order prohibits Vipvape from making misrepresentations about its participation in any privacy or security program sponsored by a government or any self-regulatory or standard-setting organization, including, but not limited to, the APEC CBPR system.

Parts II through VI of the order are reporting and compliance provisions. Part II requires acknowledgment of the order and dissemination of the order now and in the future to persons with responsibilities relating to the subject matter of the order. Part III ensures notification to the FTC of changes in corporate status and mandates that Vipvape submit an initial compliance report to the FTC. Part IV requires Vipvape to retain documents relating to its compliance with the order for a five-year period. Part V mandates that Vipvape make available to the FTC information or subsequent compliance reports, as requested. Part VI is a provision that ''sunsets'' the order on June 21, 2036, with certain exceptions.

The purpose of this analysis, which was placed on the Commission Web site on May 4, 2016, was to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the complaint or order or to modify the order's terms in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2016–18566 Filed 8–4–16; 8:45 am]

BILLING CODE 6750–01–P

FEDERAL TRADE COMMISSION

[File No. 161–0102]

Mylan N.V.; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the complaint and the terms of the consent orders—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before August 29, 2016.

ADDRESSES: Interested parties may file a comment at *https://ftcpublic.commentworks.com/ftc/mylanmedaconsent* online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write ''In the Matter of Mylan N.V., File No. 161–0102—Consent Agreement'' on your comment and file your comment online at *https://ftcpublic.commentworks.com/ftc/mylanmedaconsent* by following the instructions on the web-based form. If you prefer to file your comment on paper, write ''In the Matter of Mylan N.V., File No. 161–0102—Consent Agreement'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Christina Perez (202–326–2350), Bureau of Competition, 600 Pennsylvania Avenue NW., Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing consent orders to cease and desist, having been filed with and accepted, subject to final

approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for July 27, 2016), on the World Wide Web, at *http://www.ftc.gov/os/actions.shtm.*

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before August 29, 2016. Write ''In the Matter of Mylan N.V., File No. 161–0102—Consent Agreement'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at *http://www.ftc.gov/os/publiccomments.shtm.* As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any ''[t]rade secret or any commercial or financial information which . . . is privileged or confidential,'' as discussed in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c).[1] Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/mylanmedaconsent* by following the instructions on the web-based form. If this Notice appears at *http://www.regulations.gov/#!home,* you also may file a comment through that Web site.

If you file your comment on paper, write ''In the Matter of Mylan N.V., File No. 161–0102—Consent Agreement'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Web site at *http://www.ftc.gov* to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before August 29, 2016. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at *http://www.ftc.gov/ftc/privacy.htm.*

Analysis of Agreement Containing Consent Orders To Aid Public Comment

The Federal Trade Commission (''Commission'') has accepted, subject to final approval, an Agreement Containing Consent Orders (''Consent Agreement'') from Mylan N.V. (''Mylan'') that is designed to remedy the anticompetitive effects resulting from Mylan's acquisition of Meda AB (''Meda''). Under the terms of the proposed Consent Agreement, Mylan is required to divest all of its rights and assets related to 400 mg and 600 mg generic felbamate tablets to Alvogen Pharma US, Inc. (''Alvogen''), and to return all of its marketing rights and ownership interests in generic carisoprodol tablets to Indicus Pharma LLC (''Indicus'') the abbreviated new drug application owner for this product.

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again evaluate the proposed Consent Agreement, along with the comments received, to make a final decision as to whether it should withdraw from the proposed consent Agreement or make final the Decision and Order (''Order'').

Pursuant to a public offer to the shareholders of Meda announced on February 10, 2016, Mylan intends to acquire 100% of the issued and outstanding shares of Meda for a total equity value at announcement of approximately $7.2 billion. The Commission alleges in its Complaint that the proposed acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, by lessening current competition in the markets for 400 mg and 600 mg generic felbamate tablets and future competition in the market for 250 mg generic carisoprodol tablets in the United States. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be eliminated by the proposed acquisition.

I. The Products and Structure of the Markets

The proposed acquisition would reduce the number of current suppliers in the markets for 400 mg and 600 mg generic felbamate tablets and reduce the number of future suppliers in the market for 250 mg generic carisoprodol tablets.

Generic felbamate tablets treat severe refractory epilepsy and are available in 400 mg and 600 mg strengths. Three firms—Mylan, Meda, and Amneal Pharmaceuticals LLC—sell generic felbamate in the United States. A fourth firm, CorePharma LLC, has received U.S. Food and Drug Administration (''FDA'') approval for each strength of generic felbamate tablets, but it is not yet on the market.

Generic carisoprodol is a muscle relaxer that works by blocking pain sensations between the nerves and the brain. Two firms market generic carisoprodol tablets: Meda and Vensun Pharmaceuticals. Mylan owns the U.S.

[1] In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

marketing rights to a generic carisoprodol product that was recently approved by the FDA. Once it begins marketing generic carisoprodol, Mylan likely would have been the third supplier of generic carisoprodol tablets. Mylan is one of a limited number of suppliers capable of entering the United States market in the near future.

II. Entry

Entry into the three relevant markets would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the proposed acquisition. The combination of drug development times and regulatory requirements, including approval by the United States Food and Drug Administration (''FDA''), is costly and lengthy.

III. Effects

The proposed acquisition likely would cause significant anticompetitive harm to consumers by eliminating competition between Mylan and Meda in the markets for 400 mg and 600 mg generic felbamate tablets. Market participants characterize generic felbamate tablets as commodity products, and prices are inversely correlated with the number of competitors in each market. As the number of suppliers offering a therapeutically equivalent drug increases, the price for that drug generally decreases due to the direct competition between the existing suppliers and each additional supplier. The proposed acquisition would combine two of three companies offering the 400 mg and 600 mg strengths of generic felbamate tablets, likely leading consumers to pay higher prices.

In addition, the proposed acquisition likely would cause significant anticompetitive harm to consumers by eliminating future competition that would otherwise have occurred in the 250 mg generic carisoprodol market if Mylan and Meda remained independent. The evidence shows that anticompetitive effects are likely to result from the proposed acquisition due to the elimination of an additional independent entrant in the market for 250 mg generic carisoprodol. Customers expect that the price of this pharmaceutical product will decrease with new entry by Mylan. Thus, absent a remedy, the proposed acquisition will likely cause U.S. consumers to pay significantly higher prices for 250 mg generic carisoprodol tablets.

IV. The Consent Agreement

The proposed Consent Agreement remedies the competitive concerns raised by the acquisition in the markets at issue by requiring Mylan to divest all its rights and assets relating to 400 mg and 600 mg generic felbamate tablets to Alvogen. Founded in 2009, Alvogen is an international pharmaceutical company with commercial operations in thirty-four countries. In addition, the proposed Consent Agreement requires Mylan to return its rights to market generic carisoprodol tablets in the United States to Indicus, the abbreviated new drug application owner for this product.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the proposed acquisition. If the Commission determines that Alvogen is not an acceptable acquirer, or that the manner of the divestitures is not acceptable, the proposed Order requires Mylan to unwind the sale of rights to Alvogen and then divest the products to a Commission-approved acquirer within six months of the date the Order becomes final. The proposed Order further allows the Commission to appoint a trustee in the event the parties fail to divest the products as required.

The proposed Consent Agreement and Order contain several provisions to help ensure that the divestitures are successful. The proposed Order requires that Mylan transfer its manufacturing technology for felbamate to Alvogen and provide transitional services to assist Alvogen in establishing its manufacturing capabilities and securing all of the necessary FDA approvals. The transitional services include technical assistance to manufacture the product in substantially the same manner and quality employed or achieved by Mylan, and advice and training from knowledgeable employees of Mylan. In addition, Mylan must supply Alvogen with 400 mg and 600 mg generic felbamate tablets until Alvogen is able to manufacture generic felbamate successfully in commercial quantities.

To remedy competitive concerns raised by the acquisition in the market for generic 250 mg carisoprodol tablets, the proposed Order requires Mylan to terminate its agreement with Indicus that gives Mylan the exclusive right to market and sell in the United States all strengths of carisoprodol tablets manufactured by Indicus. Indicus has existing relationships with suppliers of generic drugs that it can and expects to use to replace Mylan as its marketing partner for its carisoprodol products.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2016–18563 Filed 8–4–16; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9098–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—April Through June 2016

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published from April through June 2016, relating to the Medicare and Medicaid programs and other programs administered by CMS.

FOR FURTHER INFORMATION CONTACT: It is possible that an interested party may need specific information and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing contact persons to answer general questions concerning each of the addenda published in this notice.

Addenda	Contact	Phone number
I CMS Manual Instructions	Ismael Torres	(410) 786–1864
II Regulation Documents Published in the **Federal Register**	Terri Plumb	(410) 786–4481
III CMS Rulings	Tiffany Lafferty	(410) 786–7548
IV Medicare National Coverage Determinations	Wanda Belle, MPA	(410) 786–7491
V FDA-Approved Category B IDEs	John Manlove	(410) 786–6877

Addenda	Contact	Phone number
VI Collections of Information	Mitch Bryman	(410) 786–5258
VII Medicare-Approved Carotid Stent Facilities	Sarah Fulton, MHS	(410) 786–2749
VIII American College of Cardiology—National Cardiovascular Data Registry Sites	Sarah Fulton, MHS	(410) 786–2749
IX Medicare's Active Coverage-Related Guidance Documents	JoAnna Baldwin, MS	(410) 786–7205
X One-Time Notices Regarding National Coverage Provisions	JoAnna Baldwin, MS	(410) 786–7205
XI National Oncologic Positron Emission Tomography Registry Sites	Stuart Caplan, RN, MAS	(410) 786–8564
XII Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities	Linda Gousis, JD	(410) 786–8616
XIII Medicare-Approved Lung Volume Reduction Surgery Facilities	Sarah Fulton, MHS	(410) 786–2749
XIV Medicare-Approved Bariatric Surgery Facilities	Sarah Fulton, MHS	(410) 786–2749
XV Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials	Stuart Caplan, RN, MAS	(410) 786–8564
All Other Information	Annette Brewer	(410) 786–6580

SUPPLEMENTARY INFORMATION:

I. Background

The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs and coordination and oversight of private health insurance. Administration and oversight of these programs involves the following: (1) Furnishing information to Medicare and Medicaid beneficiaries, health care providers, and the public; and (2) maintaining effective communications with CMS regional offices, state governments, state Medicaid agencies, state survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, National Association of Insurance Commissioners (NAIC), health insurers, and other stakeholders. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act) and Public Health Service Act. We also issue various manuals, memoranda, and statements necessary to administer and oversee the programs efficiently.

Section 1871(c) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every 3 months in the **Federal Register**.

II. Format for the Quarterly Issuance Notices

This quarterly notice provides only the specific updates that have occurred in the 3-month period along with a hyperlink to the full listing that is available on the CMS Web site or the appropriate data registries that are used as our resources. This is the most current up-to-date information and will be available earlier than we publish our quarterly notice. We believe the Web site list provides more timely access for beneficiaries, providers, and suppliers. We also believe the Web site offers a more convenient tool for the public to find the full list of qualified providers for these specific services and offers more flexibility and ''real time'' accessibility. In addition, many of the Web sites have listservs; that is, the public can subscribe and receive immediate notification of any updates to the Web site. These listservs avoid the need to check the Web site, as notification of updates is automatic and sent to the subscriber as they occur. If assessing a Web site proves to be difficult, the contact person listed can provide information.

III. How To Use the Notice

This notice is organized into 15 addenda so that a reader may access the subjects published during the quarter covered by the notice to determine whether any are of particular interest. We expect this notice to be used in concert with previously published notices. Those unfamiliar with a description of our Medicare manuals should view the manuals at *http://www.cms.gov/manuals*.

Dated: July 27, 2016.

Kathleen Cantwell,

Director, Office of Strategic Operations and Regulatory Affairs.

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Publication Dates for the Previous Four Quarterly Notices

We publish this notice at the end of each quarter reflecting information released by CMS during the previous quarter. The publication dates of the previous four Quarterly Listing of Program Issuances notices are: August 3, 2015 (80 FR 45980) November 13, 2015 (80 FR 70218), February 4, 2016 (81 FR 6009) and May 9, 2016 (81 FR 28072). We are providing only the specific updates that have occurred in the 3-month period along with a hyperlink to the website to access this information and a contact person for questions or additional information.

Addendum I: Medicare and Medicaid Manual Instructions (April through June 2016)

The CMS Manual System is used by CMS program components, partners, providers, contractors, Medicare Advantage organizations, and State Survey Agencies to administer CMS programs. It offers day-to-day operating instructions, policies, and procedures based on statutes and regulations, guidelines, models, and directives. In 2003, we transformed the CMS Program Manuals into a web user-friendly presentation and renamed it the CMS Online Manual System.

How to Obtain Manuals

The Internet-only Manuals (IOMs) are a replica of the Agency's official record copy. Paper-based manuals are CMS manuals that were officially released in hardcopy. The majority of these manuals were transferred into the Internet-only manual (IOM) or retired. Pub 15-1, Pub 15-2 and Pub 45 are exceptions to this rule and are still active paper-based manuals. The remaining paper-based manuals are for reference purposes only. If you notice policy contained in the paper-based manuals that was not transferred to the IOM, send a message via the CMS Feedback tool.

Those wishing to subscribe to old versions of CMS manuals should contact the National Technical Information Service, Department of Commerce, 5301 Shawnee Road, Alexandria, VA 22312 Telephone (703-605-6050). You can download copies of the listed material free of charge at: http://cms.gov/manuals.

How to Review Transmittals or Program Memoranda

Those wishing to review transmittals and program memoranda can access this information at a local Federal Depository Library (FDL). Under the FDL program, government publications are sent to approximately 1,400 designated libraries throughout the United States. Some FDLs may have arrangements to transfer material to a local library not designated as an FDL. Contact any library to locate the nearest FDL. This information is available at http://www.gpo.gov/libraries/

In addition, individuals may contact regional depository libraries that receive and retain at least one copy of most federal government publications, either in printed or microfilm form, for use by the general public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library. CMS publication and transmittal numbers are shown in the listing entitled Medicare and Medicaid Manual Instructions. To help FDLs locate the materials, use the CMS publication and transmittal numbers. For example, to find the manual for Medicare Internet Only Manual Publication 100-04 Chapter 26 – Completing and Processing Form CMS-1500 Data Set (CMS-Pub. 100-04) Transmittal No. 3490.

Addendum I lists a unique CMS transmittal number for each instruction in our manuals or program memoranda and its subject number. A transmittal may consist of a single or multiple instruction(s). Often, it is necessary to use information in a transmittal in conjunction with information currently in the manual. For the purposes of this quarterly notice, we list only the specific updates to the list of manual instructions that have occurred in the 3-month period. This information is available on our website at www.cms.gov/Manuals.

Transmittal Number	Manual/Subject/Publication Number
Medicare General Information (CMS-Pub. 100-01)	
99	Medicare Fee-for-Service Change Request Correction and Rescind Process
100	Medicare Fee-for-Service Change Request Correction and Rescind Process Change Management Process (Electronic Change Information Management Portal
Medicare Benefit Policy (CMS-Pub. 100-02)	
222	Revisions to Private Contracting/Opt-Out Manual Sections Due to the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) Nonparticipating Physicians or Practitioners Who Opt-Out of Medicare Physicians or Practitioners Who Choose to Opt-Out of Medicare Opt-Out Relationship to Noncovered Services Maintaining Information on Opt-Out Physicians Informing Medicare Managed Care Plans of the Identity of the Opt-Out Physicians or Practitioners Emergency and Urgent Care Situations Mandatory Claims Submission Cancellation of Opt-Out

	Early Termination of Opt-Out Appeal Claims Denial Notices to Opt-Out Physicians and Practitioners
223	Clarification of Inpatient Psychiatric Facilities (IPF) Requirements for Certification, Recertification and Delayed/Lapsed Certification and Recertification
224	Update to Pub. 100-02, Chapter 11 End-Stage Renal Disease (ESRD) for Calendar Year (CY) 2016
Medicare National Coverage Determination (CMS-Pub. 100-03)	
191	Stem Cell Transplantation for Multiple Myeloma, Myelofibrosis, Sickle Cell Disease, and Myelodysplastic Syndromes
192	Percutaneous Left Atrial Appendage Closure (LAAC)
193	Stem Cell Transplantation for Multiple Myeloma, Myelofibrosis, Sickle Cell Disease, and Myelodysplastic Syndromes Stem Cell Transplantation9Formerly 110.8.1)(Various Effective Dates Below)
Medicare Claims Processing (CMS-Pub. 100-04)	
3490	Medicare Internet Only Manual Publication 100-04 Chapter 26 – Completing and Processing Form CMS-1500 Data Set
3491	Payment for Purchased Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Furnished to Medicare Beneficiaries Residing Outside the U.S. - Expatriate Beneficiaries
3492	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3493	Payment Change for Group 3 Complex Rehabilitative Power Wheelchair Accessories and Seat and Back Cushions under Section 2 of the Patient Access and Medicare Protection Act (PAMPA)
3494	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity Instruction
3495	Indian Health Services (IHS) Hospital Payment Rates for Calendar Year 2016
3496	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3497	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3498	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3499	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3500	Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP): Additional Instructions for the Implementation of Round 2 Recompete of the DMEPOS CBP and National Mail Order (NMO) Recompete Payment of a Part of a DMEPOS Item Payment for Capped Rental Items Payment for Inexpensive or Routinely Purchased Items Payment for Repair and Replacement of Beneficiary-Owned Equipment
3501	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3502	Making Principal Diagnosis Codes Mandatory for Notice of Election (NOE) to be Accepted Completing the Uniform (Institutional Provider) Bill (Form CMS 1450) for Hospice Election Service Intensity Add-on (SIA) Payments Frequency of Billing and Same Day Billing
3503	Billing of Vaccine Services on Hospice Claims Payer Only Codes Utilized by Medicare Hospice Claims for Vaccine Services Billing Requirements Claims Submitted to MACs Using Institutional Formats Payment for Pneumococcal Pneumonia Virus, Influenza Virus, and Hepatitis B Virus Vaccines and Their Administration on Institutional Claims Institutional Claims Submitted by Home Health Agencies and Hospice Payment Procedures for Renal Dialysis Facilities (RDF)
3504	Revision of the Method to Calculate the Length of Stay (LOS) Edit for Continuous Invasive Mechanical Ventilation for Greater than 96 Consecutive Hours Medicare Code Editor (MCE)
3505	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3506	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3507	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3508	JW Modifier: Drug amount discarded/not administered to any patient Discarded Drugs and Biologicals
3509	Stem Cell Transplantation for Multiple Myeloma, Myelofibrosis, Sickle Cell Disease, and Myelodysplastic Syndromes Stem Cell Transplantation Billing for Stem Cell Transplantation Billing for Autologous Stem Cell Transplants Billing for Allogeneic Stem Cell Transplants Stem Cell Transplantation
3510	Updates to Pub. 100-04, Chapters 1 and 16 to Correct Remittance Advice Messages Claims Processing Instructions for Payment Jurisdiction An A/B MAC (B) Receives a Claim for Services that are in Another A/B MAC (B)'s Payment Jurisdiction An A/B MAC (B) Receives a Claim for Services that are in a DME Payment Jurisdiction A DME MAC Receives a Claim for Services that are in an A/B MAC (B) Payment Jurisdiction An A/B MAC (B) Receives a Claim for an RRB Beneficiary An A/B MAC (B) or DME MAC Receives a Claim for a UMWA Beneficiary A DME MAC receives a Paper Claim with Items or Services that are in Another DME MAC's Payment Jurisdiction Deported Medicare Beneficiaries Processing Claims for Services of Participating Physicians or Suppliers Charges for Missed Appointments

	Coding That Results from Processing Noncovered Charges Handling Incomplete or Invalid Claims A/B MAC (B) Data Element Requirements Conditional Data Element Requirements for A/B MACs and DMEMACs A/B MAC (B) Specific Requirements for Certain Specialties/Services General Explanation of Payment Assignment Required Physician Notification of Denials Reasons for Denial - Physician Office Laboratories Out-of-Compliance
3511	Changes to the Fiscal Intermediary Shared System (FISS) Inpatient Provider Specific File (PSF) for Low-Volume Hospital Payment Adjustment Factor and New Inpatient Prospective Payment System (IPPS) Pricer Output Field for Islet Isolation Add-on Payment A/Provider Specific File Procedure for Medicare Contractors to Perform and Record Outlier Reconciliation Adjustments
3512	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3513	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3514	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3515	Percutaneous Left Atrial Appendage Closure (LAAC)
3516	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3517	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity Instruction
3518	Quarterly Healthcare Common Procedure Coding System (HCPCS) Drug/Biological Code Changes - July 2016 Update
3519	Corrections to Chapter 1 of the Medicare Claims Processing Manual Claims Submitted for Items or Services Furnished to Medicare Beneficiaries in State or Local Custody Under a Penal Authority Application to Special Claim Type Payer Only Codes Utilized by Medicare
3520	2016 Durable Medical Equipment Prosthetics, Orthotics, and Supplies Healthcare Common Procedure Coding System (HCPCS) Code Jurisdiction List
3521	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3522	Update to Internet-Only-Manual Publication 100-04, Chapter 18, Section 30.6 Screening Pap Smears: Diagnoses Codes
3523	July 2016 Update of the Hospital Outpatient Prospective Payment System (OPPS) Billing Instructions for IMRT Planning and Delivery
3524	July 2016 Integrated Outpatient Code Editor (I/OCE) Specifications Version 17.2
3525	Common Edits and Enhancements Modules (CEM) Code Set Update
3526	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3527	Claim Status Category and Claim Status Codes Update
3528	Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - July CY 2016 Update
3529	Instructions for Downloading the Medicare ZIP Code File for October 2016
3530	JW Modifier: Drug amount discarded/not administered to any patient Discarded Drugs and Biologicals
3531	July 2016 Update of the Ambulatory Surgical Center (ASC) Payment System
3532	Annual Update of the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM)
3533	Payments to Home Health Agencies That Do Not Submit Required Quality Data
3534	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3535	Payment Change for Group 3 Complex Rehabilitative Power Wheelchairs Accessories and Seat and Back Cushions under Section 2 of the Patient Access and Medicare Protection Act (PAMPA)
3536	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
3537	Corrections to Chapter 1 of the Medicare Claims Processing Manual Claims Submitted for Items or Services Furnished to Medicare Beneficiaries in State or Local Custody Under a Penal Authority Application to Special Claim Types Payer Only Codes Utilized by Medicare
3538	JW Modifier: Drug amount discarded/not administered to any patient Discarded Drugs and Biologicals
3539	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3540	Billing of Vaccine Services on Hospice Claims Hospice Claims for Vaccine Services Billing Requirements Claims Submitted to MACs Using Institutional Formats Payment for Pneumococcal Pneumonia Virus, Influenza Virus, and Hepatitis B Virus Vaccines and Their Administration on Institutional Claims Institutional Claims Submitted by Home Health Agencies and Hospices Payment Procedures for Renal Dialysis Facilities (RDF)
3541	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3542	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3543	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3544	New Physician Specialty Code for Dentist Physician Specialty Codes
3545	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3546	October Quarterly Update to 2016 Annual Update of HCPCS Codes Used for Skilled Nursing Facility (SNF) Consolidated Billing (CB) Enforcement
3547	New Physician Specialty Code for Dentist
3548	Issued to a specific audience, not posted to Internet/Intranet due to

	Confidentiality of Instruction
3549	Pub. 100-04, Chapter 29 – Appeals of Claims Decisions Update: Revisions to Timeliness Requirements for Forwarding Misfiled Appeal Requests, Reconsideration Request Form, and Guidelines for Writing Appeals Correspondence Glossary CMS Decisions Subject to the Administrative Appeals Process Who May Appeal Steps in the Appeals Process: Overview Where to Appeal Conditions and Examples That May Establish Good Cause for Late Filing by Beneficiaries Amount in Controversy General Requirements Principles for Determining Amount in Controversy Parties to an Appeal How to Make and Revoke an Appointment Appeals of Claims Involving Excluded Providers, Physicians, or Other Suppliers Reading Levels General Information Filing a Request for Redetermination Time Limit for Filing a Request for Redetermination The Redetermination The Redetermination Decision Dismissals Medicare Redetermination Notice (For Partly or Fully Unfavorable Redeterminations Filing a Request for a Reconsideration Time Limit for Filing a Request for a Reconsideration Contractor Responsibilities - General QIC Jurisdictions Tracking Cases Requests for an ALJ Hearing
3550	New Waived Tests
3551	July Quarterly Update for 2016 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule
3552	July 2016 Update of the Hospital Outpatient Prospective Payment System (OPPS)
3553	New Condition Code for Reporting Home Health Episodes With No Skilled Visits
3554	Quarterly Update for the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) - October 2016
3555	Medicare Part A Skilled Nursing Facility (SNF) Prospective Payment System (PPS) Pricer Update FY 2017

Medicare Secondary Payer (CMS-Pub. 100-05)	
117	None Remote Identity Proofing (RIDP) and Multi-Factor Authentication (MFA) for Electronic Correspondence Referral System (ECRS) Web Users
118	Individuals Not Subject to the Limitation on Medicare Secondary Payment (MSP)
Medicare Financial Management (CMS-Pub. 100-06)	
266	Notice of New Interest Rate for Medicare Overpayments and Underpayments -3rd Qtr Notification for FY 2016
267	Notice of New Interest Rate for Medicare Overpayments and Underpayments -3rd Qtr Notification for FY 2016
268	New Physician Specialty Code for Dentist
269	New Physician Specialty Code for Dentist Physician/Limited License Physician Specialty Codes
Medicare State Operations Manual (CMS-Pub. 100-07)	
154	Revisions to the State Operations Manual (SOM) – Chapter 2 Exit Conference A Introductory Remarks B Ground Rules C Presentation of Finding D Closure Limitations on Technical Assistance Afforded by Surveyors
155	Revisions to the State Operations Manual (SOM) –Chapter 5 Survey Exit Conference and Report to the Provider/Supplier Task 7: Exit Conference
156	Post-Survey Certification Actions for Nursing Homes Survey Protocol for Long Term Care Facilities - Part I/IV Deficiency Categorization/E. Psychosocial Outcome Severity Guide
157	Revisions to the State Operations Manual (SOM) - Appendix PP – Guidance to Surveyors for Long Term Care Facilities
Medicare Program Integrity (CMS-Pub. 100-08)	
643	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
644	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
645	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
646	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
647	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
648	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
649	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
650	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
651	Medical Review of Skilled Nursing Facility Prospective Payment System (SNF PPS) Bills
652	Issued to a specific audience, not posted to Internet/Intranet due to

	Confidentiality of Instruction
653	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
654	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)	
	None
Medicare Quality Improvement Organization (CMS- Pub. 100-10)	
25	QIO Manual Chapter 11 - Hospital Payment Monitoring Program (HPMP)
26	QIO Manual Chapter 2 – Eligibility
27	QIO Manual Chapter 12 "Communications, Outreach, and Program-related Information Activities"
Medicare End Stage Renal Disease Network Organizations (CMS Pub 100-14)	
	None
Medicaid Program Integrity Disease Network Organizations (CMS Pub 100-15)	
	None
Medicare Managed Care (CMS-Pub. 100-16)	
121	Chapter 4, Benefits and Beneficiary Protections General Requirements Basic Rule Exceptions to Requirements for MA plans to Cover FFS Benefits Types of Benefits Hospice Coverage Uniformity Anti-Discrimination Review for Discrimination and Steering Confidentiality Multiple Plan Offerings and Benefit Caps Payment for Investigational Device Exemption (IDE) Studies Return to Enrollee's Home Skilled Nursing Facility (SNF) Therapy Caps and Exceptions
122	Chapter 14, Contract Determinations and Appeals
Medicare Business Partners Systems Security (CMS-Pub. 100-17)	
	None
Demonstrations (CMS-Pub. 100-19)	
142	Affordable Care Act Bundled Payments for Care Improvement Initiative - Recurring File Updates Models 2 and 4 July 2016 Updates
143	Implementing Payment Changes for FCIIIP (Frontier Community Health Integration Project), Mandated by Section 123 of MIPPA 2008 and as Amended by Section 3126 of the ACA of 2010 (This CR Rescinds and Replaces CR8683)
144	Issued to a specific audience, not posted to Internet/ Intranet to Confidentiality of Instruction
145	Update to the Common Working File Edits for G9678 - Oncology Care Model Service
146	Oncology Care Model (OCM) Monthly Enhanced Oncology Services (MEOS) Payment Implementation
147	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
148	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
149	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
One Time Notification (CMS-Pub. 100-20)	
1641	Issued to a specific audience, not posted to Internet/ Intranet to Sensitivity of Instruction
1642	Implementation of the Award for Jurisdiction A Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) Workload
1643	Issued to a specific audience, not posted to Internet/ Intranet to Sensitivity of Instruction
1644	Reclassification of Certain Durable Medical Equipment HCPCS Codes Included in Competitive Bidding Programs (CBP) from the Inexpensive and Routinely Purchased Payment Category to the Capped Rental Payment Category
1645	Analysis of the Combined Common Edits/Enhancements Module (CCEM) 3rd Party Software
1646	Upgrade (Jaspersoft) reporting software for the Combined Common Edits/Enhancement Module (CCEM)
1647	Payment Change for Group 3 Complex Rehabilitative Power Wheelchairs Accessories and Seat and Back Cushions under Section 2 of the Patient Access and Medicare Protection Act (PAMPA) for Home Health Claims
1648	Issued to a specific audience, not posted to Internet/ Intranet to Sensitivity of Instruction
1649	Phase 2 of Updating the Fiscal Intermediary Shared System (FISS) to Make Payment for Drugs and Biologicals Services for Outpatient Prospective Payment System (OPPS) Providers
1650	Shared System Enhancement 2015: Archive/Remove Inactive Medicare Demonstration Projects
1651	National Provider Identifier Crosswalk System (NPICS) Retirement Analysis Only - Engage Shared Systems Maintainers and Medicare Administrative Contractors (MACs) in Meetings and Correspondence Related to the NPICS Retirement with the Stakeholders
1652	Analysis Only: To Obtain a Rough Order of Magnitude (ROM) from Durable Medical Equipment Medicare Administrative Contractors (DME MACs), GDIT/VMS, the National Supplier Clearinghouse (NSC) and the Common Electronic Data Interchange (CEDI) Contractor to Develop and Implement a Process for DME MAC Provider Self-Service Internet Portal Authentication of Medicare Providers Using EDI Enrollment Data Elements
1653	New State Code for AZ, ID, NY, and WV
1654	System Changes to Implement Section 231 of the Consolidated Appropriations Act, 2016, Temporary Exception for Certain Severe Wound Discharges From Certain Long-Term Care Hospitals (LTCHs)
1655	Recurring calls with the Fiscal Intermediary Shared System (FISS) for any in-depth discussions
1656	Issued to a specific audience, not posted to Internet/ Intranet to Sensitivity of Instruction
1657	Issuing Continuing Compliance Letters to Specific Providers and Suppliers
1658	Coding Revisions to National Coverage Determinations
1659	Convert Assembler Code to COBOL or Best Coding Language to Improve

	MCS System Maintainability and Sustainability, Analysis only.
1660	Shared Savings Program (SSP) Accountable Care Organization (ACO) Qualifying Stay Edits
1661	Issued to a specific audience, not posted to Internet/ Intranet to Sensitivity of Instruction
1662	Issued to a specific audience, not posted to Internet/ Intranet to Sensitivity of Instruction
1663	Issued to a specific audience, not posted to Internet/ Intranet to Confidentiality of Instruction
1664	Reporting Medicare Administrative Contractor (MAC) Provider Education Website Analytic Data to the Provider Customer Service Program Contractor Information Database (PCID)
1665	Coding Revisions to National Coverage Determinations (NCDs)
1666	Issued to a specific audience, not posted to Internet/ Intranet to Sensitivity of Instruction
1667	Issued to a specific audience, not posted to Internet/ Intranet to Sensitivity of Instruction
1668	National Provider Identifier Crosswalk System (NPICS) Retirement Analysis Only - Engage Shared Systems Maintainers and Medicare Administrative Contractors (MACs) in Meetings and Correspondence Related to the NPICS Retirement with the Stakeholders
1669	Guidance on Implementing System Edits for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)
1670	Shared System Enhancement 2014 – Identification of Fiscal Intermediary Standard System (FISS) Obsolete Reports – Analysis Only
Medicare Quality Reporting Incentive Programs (CMS- Pub. 100-22)	
57	Payments to Home Health Agencies That Do Not Submit Required Quality Data
Information Security Acceptable Risk Safeguards (CMS-Pub. 100-25)	
	None

Addendum II: Regulation Documents Published in the Federal Register (April through June 2016)

Regulations and Notices

Regulations and notices are published in the daily **Federal Register**. To purchase individual copies or subscribe to the **Federal Register,** contact GPO at www.gpo.gov/fdsys. When ordering individual copies, it is necessary to cite either the date of publication or the volume number and page number.

The **Federal Register** is available as an online database through GPO Access. The online database is updated by 6 a.m. each day the **Federal Register** is published. The database includes both text and graphics from Volume 59, Number 1 (January 2, 1994) through the present date and can be accessed at http://www.gpoaccess.gov/fr/index.html. The following website http://www.archives.gov/federal-register/ provides information on how to access electronic editions, printed editions, and reference copies.

This information is available on our website at: http://www.cms.gov/quarterlyproviderupdates/downloads/Regs-2Q16QPU.pdf

For questions or additional information, contact Terri Plumb (410-786-4481).

Addendum III: CMS Rulings (April through June 2016)

CMS Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, private health insurance, and related matters.

The rulings can be accessed at http://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings. For questions or additional information, contact Tiffany Lafferty (410-786-7548).

Addendum IV: Medicare National Coverage Determinations (April through June 2016)

Addendum IV includes completed national coverage determinations (NCDs), or reconsiderations of completed NCDs, from the quarter covered by this notice. Completed decisions are identified by the section of the NCD Manual (NCDM) in which the decision appears, the title, the date the publication was issued, and the effective date of the decision. An NCD is a determination by the Secretary for whether or not a particular item or service is covered nationally under the Medicare Program (title XVIII of the Act), but does not include a determination of the code, if any, that is assigned to a particular covered item or service, or payment determination for a particular covered item or service. The entries below include information concerning completed decisions, as well as sections on program and decision memoranda, which also announce decisions or, in some cases, explain why it was not appropriate to issue an NCD. Information on completed decisions as well as pending decisions has also been posted on the CMS website. For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available at: www.cms.gov/medicare-coverage-database/. For questions or additional information, contact Wanda Belle, MPA (410-786-7491).

Title	NCDM Section	Transmittal Number	Issue Date	Effective Date
Percutaneous Left Atrial Appendage Closure (LAAC)	NCD 20.34	R192	05/06/2016	02/08/2016
Stem Cell Transplantation for Multiple Myeloma, Myelofibrosis, Sickle Cell Disease, and Myelodysplastic Syndromes	NCD 110.23	R191	04/29/2016	01/27/2016

Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (April through June 2016)

Addendum V includes listings of the FDA-approved investigational device exemption (IDE) numbers that the FDA assigns. The listings are organized according to the categories to which the devices are assigned (that is, Category A or Category B), and identified by the IDE number. For the purposes of this quarterly notice, we list only the specific updates to the Category B IDEs as of the ending date of the period covered by this notice and a contact person for questions or additional information. For questions or additional information, contact John Manlove (410-786-6877).

Under the Food, Drug, and Cosmetic Act (21 U.S.C. 360c) devices fall into one of three classes. To assist CMS under this categorization process, the FDA assigns one of two categories to each FDA-approved investigational device exemption (IDE). Category A refers to experimental IDEs, and Category B refers to non-experimental IDEs. To obtain more information about the classes or categories, please refer to the notice published in the April 21, 1997 **Federal Register** (62 FR 19328).

IDE	Device	Start Date
G160051	Brainsway Deep TMS System utilizing the H2-coil	04/13/2016
G160053	Closing the Loop on Tremor: A Responsive Deep Brain Stimulator for the Treatment of Essential Tremor	04/14/2016
G160058	True Beam, True Beam STx, Edge	04/14/2016
G160056	Allurion Elipse Device	04/15/2016
G160054	Repetitive Transcanial Magnetic Stimulation (rTMS) for Obsessive-Compulsive Disorder	04/20/2016
G160061	Spatz3 Adjustable Balloon System	04/20/2016
G160065	iNod Biopsy Needle, iNod Ultrasound Catheter, iNod Ultrasound Imaging System, iNod Motor Drive Unit, iNod Sled	04/21/2016
G160063	HEMOBLAST Bellows Hemostatic Agent	04/22/2016
G160064	Sight Sciences VISCO 360 Viscosurgical System	04/22/2016
G160074	MADIT S-ICD Clinical Study	04/26/2016
G160067	NeoChord Artificial Chordae Delivery System, Model DS1000	04/27/2016
G140102	ThermoCool SmartTouch SF Catheter	04/27/2016
G160066	Embosphere Microspheres	04/27/2016
G160071	NeuroBlate System	04/29/2016
G160072	Influence of Cooling duration on Efficacy in Cardiac Arrest Patients (ICECAP) trial	04/29/2016
G160073	MED-EL Synchrony cochlear implant with the FLEX28 electrode array	04/29/2016
G160077	Orbera Intragastric Balloon	05/04/2016
G160078	SJM MRI Diagnostic Imaging Registry	05/05/2016
G160081	WIRION Embolic Protection System (EPS)	05/06/2016
BB16430	DryThaw-MTS1-C	05/08/2016
G120246	Exablate Transcranial MRGFUS Thalmotomy Treatment	05/13/2016
G150199	Model SC9 Posterior Chamber Intraocular Lens	05/13/2016
G160082	DBS Leads, Activa PC Stimulator, DBS Extension	05/14/2016
G160084	Revanesse Ultra+ (with lidocaine)	05/17/2016
G040175	Relay Thoracic Stend Graft with Transport Delivery System	05/20/2016

IDE	Device	Start Date
	for treatment of thoracic aortic aneurysms.	
G160087	Aspen System	05/25/2016
G150241	Ellipse ICD and Durata and Optisure high voltage lead system	05/25/2016
G160013	Bio Ventrix Revivent TC System	05/25/2016
G160089	NovoTTF-100M System	05/26/2016
G160092	Bioness StimRouter Neuromodulation System, StimRouter Lead Kit, StimRouter Surgical Tool Kit, StimRouter Clinician Kit, StimRouter User Kit	06/01/2016
G160093	OVT	06/01/2016
G160094	TSolution One TKA	06/01/2016
G160049	EnligHTN Renal Denervation System	06/02/2016
G160001	Covera Vascular Covered Stent	06/03/2016
G160107	ZiftLift System	06/14/2016
G160105	therascreen BRAF V600E RGQ PCR Kit	06/15/2016
G160109	Covera Vascular Covered Stent	06/22/2016
G160111	MET Exon 14 Skipping Test	06/22/2016
G150137	JUVEDERM VOLUMA XC	06/22/2016
G160060	ClariCore Biopsy System	06/22/2016
G160110	TIVUS System, Multidirectional TIVUS Catheter (also referred as TIVUS Catheter), TIVUS Console	06/23/2016
G160113	SAFE - PCI in STEMI for Seniors	06/24/2016

Addendum VI: Approval Numbers for Collections of Information (April through June 2016)

All approval numbers are available to the public at Reginfo.gov. Under the review process, approved information collection requests are assigned OMB control numbers. A single control number may apply to several related information collections. This information is available at www.reginfo.gov/public/do/PRAMain. For questions or additional information, contact Mitch Bryman (410-786-5258).

Addendum VII: Medicare-Approved Carotid Stent Facilities, (April through June 2016)

Addendum VII includes listings of Medicare-approved carotid stent facilities. All facilities listed meet CMS standards for performing carotid artery stenting for high risk patients. On March 17, 2005, we issued our decision memorandum on carotid artery stenting. We determined that carotid artery stenting with embolic protection is reasonable and necessary only if performed in facilities that have been determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes. We have created a list of minimum standards for facilities modeled in part on professional society statements on competency. All facilities must at least meet our standards in order to receive coverage for carotid artery stenting for high risk patients. For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available at: http://www.cms.gov/MedicareApprovedFacilitie/CASF/list.asp#TopOfPage For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Facility	Provider Number	Effective Date	State
The following facilities are new listings for this quarter.			
South Georgia Medical Center 2501 N. Patterson Street Valdosta, GA 31602	1306896253	04/12/2016	GA
Baptist Memorial Hospital – North Mississippi (Baptist North Mississippi) 2301 South Lamar Boulevard Oxford, MS 38655	250034	04/12/2016	MS
Aurora Medical Center - Oshkosh 855 North Westhaven Drive Oshkosh, WI 54904	060112	04/21/2016	WI
The following facility has editorial changes (in bold).			
FROM: Mercy General Health Partners **TO: Mercy Health Partners** 1500 East Sherman Boulevard Muskegon, MI 49444	23-0066	12/21/2005	MI

Addendum VIII: American College of Cardiology's National Cardiovascular Data Registry Sites (April through June 2016)

Addendum VIII includes a list of the American College of Cardiology's National Cardiovascular Data Registry Sites. We cover implantable cardioverter defibrillators (ICDs) for certain clinical indications, as long as information about the procedures is reported to a central registry. Detailed descriptions of the covered indications are available in the NCD. In January 2005, CMS established the ICD Abstraction Tool through the Quality Network Exchange (QNet) as a temporary data collection mechanism. On October 27, 2005, CMS announced that the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) ICD Registry satisfies the data reporting requirements in the NCD. Hospitals needed to transition to the ACC-NCDR ICD Registry by April 2006.

Effective January 27, 2005, to obtain reimbursement, Medicare NCD policy requires that providers implanting ICDs for primary prevention clinical indications (that is, patients without a history of cardiac arrest or spontaneous arrhythmia) report data on each primary prevention ICD procedure. Details of the clinical indications that are covered by Medicare

and their respective data reporting requirements are available in the Medicare NCD Manual, which is on the CMS website at http://www.cms.hhs.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=99&sortByDID=1&sortOrder=ascending&itemID=CMS014961

A provider can use either of two mechanisms to satisfy the data reporting requirement. Patients may be enrolled either in an Investigational Device Exemption trial studying ICDs as identified by the FDA or in the ACC-NCDR ICD registry. Therefore, for a beneficiary to receive a Medicare-covered ICD implantation for primary prevention, the beneficiary must receive the scan in a facility that participates in the ACC-NCDR ICD registry. The entire list of facilities that participate in the ACC-NCDR ICD registry can be found at www.ncdr.com/webncdr/common

For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available by accessing our website and clicking on the link for the

American College of Cardiology's National Cardiovascular Data Registry at: www.ncdr.com/webncdr/common. For questions or additional information, contact Sarah Fulton, MHS (410 786 2749).

Facility	City	State
The following facilities are new listings for this quarter.		
Memorial Hermann Sugar Land	Sugar Land	TX
Tennova-North Knoxville Medical Center	Powell	TN
Wichita Ambulatory Surgery Center	Wichita	KS
Alexandria Ambulatory Surgery Center	Alexandria	LA
Baytown Ambulatory Surgery Center	Baytown	TX
Watertown Medical Center, LLC	Watertown	WI
Nason Medical Center, LLC	Roaring Spring	PA
Trios Health	Kennewick	WA
Memorial Hermann Pearland	Pearland	TX
North Metro Medical Center	Jacksonville	AZ
Ohio Valley General Hospital	McKees Rocks	PA
HHC ASC, LLC	St. Louis	MO
St. Bernard Parish Hospital	Chalmette	LA
Palms of Pasadena Hospital	St. Petersburg	FL
Melrose-Wakefield Hospital	Melrose	MA
Saint Anne's Hospital	Fall River	MA
United Hospital System	Kenosha	WI
Watsonville Community Hospital	Watsonville	CA
Bristol Regional Medical Center	Bristol	TN
UPMC McKeesport	McKeesport	PA
Lafayette General Southwest	Lafayette	LA

Addendum IX: Active CMS Coverage-Related Guidance Documents (April through June 2016)

CMS issued a guidance document on November 20, 2014 titled "Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development Document". Although CMS has several policy vehicles relating to evidence development activities including the investigational device exemption (IDE), the clinical trial policy, national coverage determinations and local coverage determinations, this guidance document is principally intended to help the public understand CMS's implementation of coverage with evidence development (CED) through the national coverage determination process. The document is available at http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27. There are no additional Active CMS Coverage-Related Guidance Documents for the 3-month period. For questions or additional information, contact JoAnna Baldwin, MS (410-786-7205).

Addendum X: List of Special One-Time Notices Regarding National Coverage Provisions (April through June 2016)

There were no special one-time notices regarding national coverage provisions published in the 3-month period. This information is available at www.cms.hhs.gov/coverage. For questions or additional information, contact JoAnna Baldwin, MS (410-786 7205).

Addendum XI: National Oncologic PET Registry (NOPR) (April through June 2016)

Addendum XI includes a listing of National Oncologic Positron Emission Tomography Registry (NOPR) sites. We cover positron emission tomography (PET) scans for particular oncologic indications when they are performed in a facility that participates in the NOPR.

In January 2005, we issued our decision memorandum on **positron emission tomography** (PET) scans, which stated that CMS would cover PET scans for particular oncologic indications, as long as they were performed in the context of a clinical study. We have since recognized the National Oncologic PET Registry as one of these clinical studies. Therefore, in order for a beneficiary to receive a Medicare-covered PET scan, the beneficiary must receive the scan in a facility that participates in the registry. There were no additions, deletions, or editorial changes to the listing of National Oncologic Positron Emission Tomography Registry (NOPR) in the 3-month period. This information is available at http://www.cms.gov/MedicareApprovedFacilitie/NOPR/list.asp#TopOfPage.

For questions or additional information, contact Stuart Caplan, RN, MAS (410-786-8564).

Addendum XII: Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities (April through June 2016)

Addendum XII includes a listing of Medicare-approved facilities that receive coverage for ventricular assist devices (VADs) used as destination therapy. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy. On October 1, 2003, we issued our decision memorandum on VADs for the clinical indication of destination therapy. We determined that VADs used as destination therapy are reasonable and necessary only if performed in facilities that have been determined to have the experience and infrastructure to ensure optimal patient outcomes. We established facility standards and an application process. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy.

We are providing only the specific updates to the list of Medicare-approved facilities that meet our standards that have occurred in the 3-month period. This information is available at http://www.cms.gov/MedicareApprovedFacilitie/VAD/list.asp#TopOfPage. For questions or additional information, contact Linda Gousis, JD, (410-786-8616).

Facility	Provider Number	Date Approved	State
The following facilities are new listings for this quarter.			
Saint Cloud Hospital 1406 Sixth Avenue North Saint Cloud, MN 56303	240036	04/13/2016	MN
Lubbock County Hospital District 602 Indiana Avenue Lubbock, TX 79415	450686	06/17/2016	TX
Fresno Community Hospital and Medical Center 2823 Fresno Street Fresno, CA 93721	1104906569	11/05/2014	CA
The following facility is being removed as of this quarter.			
Albany Medical Center Hospital 43 New Scotland Avenue Albany, NY	33-0013	11/06/2013	NY

Addendum XIII: Lung Volume Reduction Surgery (LVRS) (April through June 2016)

Addendum XIII includes a listing of Medicare-approved facilities that are eligible to receive coverage for lung volume reduction surgery. Until May 17, 2007, facilities that participated in the National Emphysema Treatment Trial were also eligible to receive coverage. The following three types of facilities are eligible for reimbursement for Lung Volume Reduction Surgery (LVRS):

- National Emphysema Treatment Trial (NETT) approved (Beginning 05/07/2007, these will no longer automatically qualify and can qualify only with the other programs);
- Credentialed by the Joint Commission (formerly, the Joint Commision on Accreditation of Healthcare Organizations (JCAHO)) under their Disease Specific Certification Program for LVRS; and
- Medicare approved for lung transplants.

Only the first two types are in the list. There were no updates to the listing of facilities for lung volume reduction surgery published in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilitie/LVRS/list.asp#TopOfPage. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (April through June 2016)

Addendum XIV includes a listing of Medicare-approved facilities that meet minimum standards for facilities modeled in part on professional society statements on competency. All facilities must meet our standards in order to receive coverage for bariatric surgery procedures. On February 21, 2006, we issued our decision memorandum on bariatric surgery procedures. We determined that bariatric surgical procedures are reasonable and necessary for Medicare beneficiaries who have a body-mass index (BMI) greater than or equal to 35, have at least one co-morbidity related to obesity and have been previously unsuccessful with medical treatment for obesity. This decision also stipulated that covered bariatric surgery procedures are reasonable and necessary only when performed at facilities that are: (1) certified by the American College of Surgeons (ACS) as a Level 1 Bariatric Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery (ASBS) as a Bariatric Surgery Center of Excellence (BSCOE) (program standards and requirements in effect on February 15, 2006).

There were no additions, deletions, or editorial changes to Medicare-approved facilities that meet CMS's minimum facility standards for bariatric surgery that have been certified by ACS and/or ASMBS in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilitie/BSF/list.asp#TopOfPage. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (April through June 2016)

There were no FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the 3-month period.

This information is available on our website at www.cms.gov/MedicareApprovedFacilitie/PETDT/list.asp#TopOfPage. For questions or additional information, contact Stuart Caplan, RN, MAS (410-786-8564).

[FR Doc. 2016–18546 Filed 8–4–16; 8:45 am]
BILLING CODE 4120–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10243]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid 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 (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 a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by September 6, 2016.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 *or* Email: *OIRA_submission@omb.eop.gov.*

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' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*.
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*
3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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 (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-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 that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Testing Experience and Functional Tools: Functional Assessment Standardized Items (FASI) Based on the CARE Tool; *Use:* In 2012, CMS funded a project entitled, Technical Assistance to States for Testing Experience and Functional Tools (TEFT) Grants. One component of this demonstration is to amend and test the reliability of a setting-agnostic, interoperable set of data elements, called ''items,'' that can support standardized assessment of individuals across the continuum of care. Items that were created for use in post-acute care settings using the Continuity Assessment Record and Evaluation (CARE) tool have been adopted, modified, or supplemented for use in community-based long-term services and supports (CB–LTSS) programs. This project will test the reliability and validity of the function-related assessment items, now referred to as Functional Assessment Standardized Items (FASI), when applied in community settings, and in various populations: Elders (65 years and older); younger adults (18–64) with physical disabilities; and adults of any age with intellectual or developmental disabilities, with severe mental illness, or with traumatic brain injury.

Individual-level data will be collected two times using the TEFT FASI Item Set. The first data collection effort will collect data that can be analyzed to evaluate the reliability and validity of the FASI items when used with the five waiver populations. Assessors will conduct functional assessments in client homes using the TEFT FASI Item Set. Changes may be recommended to individual TEFT FASI items, to be made prior to releasing the TEFT FASI items for use by the states. The FASI Field Test Report will be released to the public.

The second data collection will be conducted by the states to demonstrate their use of the FASI data elements. The assessment data could be used by the states for multiple purposes. They may use the standardized items to determine individual eligibility for state programs, or to help determine levels of care within which people can receive services, or other purposes. In the second round of data collection, states will demonstrate their proposed uses, manage their FASI data collection and conduct their own analysis, to the extent they propose to do such tasks. The states have been funded under the demonstration grant to conduct the round 2 data collection and analysis. These states will submit reports to CMS describing their experience in the Round 2 data collection, including the items they collected, how they planned to use the data, and the types of challenges and successes they encountered in doing so. The reports may be used by CMS in their evaluation of the TEFT grants.

Subsequent to the publication of our 60-day **Federal Register** notice (May 2, 2016; 81 FR 26235), we have made several minor modifications to the form. The changes are intended to further protect participant identification and improve the response efficiency by removing several checkboxes that we were using for item screening purposes. The instructions were revised accordingly. The revisions have no impact on our 60-day burden estimates. *Form Number:* CMS–10243 (OMB control number: 0938–1037); *Frequency:* On occasion; *Affected Public:* Individuals and Households; *Number of Respondents:* 5,650; *Total Annual Responses:* 5,650; *Total Annual Hours:* 2,825. (For policy questions regarding this collection contact Allison Weaver at 410–786–4924.)

Dated: August 2, 2016.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2016–18664 Filed 8–4–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3335–N]

Medicare Program; Request for Nominations for Members for the Medicare Evidence Development & Coverage Advisory Committee

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: This notice announces the request for nominations for membership on the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC). Among other duties, the MEDCAC provides advice and guidance to the Secretary of the Department of Health and Human Services (the Secretary) and the Administrator of the Centers for Medicare & Medicaid Services (CMS) concerning the adequacy of scientific evidence available to CMS in making coverage determinations under the Medicare program.

The MEDCAC reviews and evaluates medical literature and technology assessments, and hears public testimony on the evidence available to address the impact of medical items and services on health outcomes of Medicare beneficiaries.

DATES: Nominations must be received by Tuesday, September 6, 2016.

ADDRESSES: You may mail nominations for membership to the following address: Centers for Medicare & Medicaid Services, Center for Clinical Standards and Quality, Attention: Maria Ellis, 7500 Security Boulevard, Mail Stop: S3–02–01, Baltimore, MD 21244 or send via email to *MEDCACnomination@cms.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Maria Ellis, Executive Secretary for the MEDCAC, Centers for Medicare & Medicaid Services, Center for Clinical Standards and Quality, Coverage and Analysis Group, S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244 or contact Ms. Ellis by phone (410–786–0309) or via email at *Maria.Ellis@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Secretary signed the initial charter for the Medicare Coverage Advisory Committee (MCAC) on November 24, 1998. A notice in the **Federal Register** (63 FR 68780) announcing establishment of the MCAC was published on December 14, 1998. The MCAC name was updated to more accurately reflect the purpose of the committee and on January 26, 2007, the Secretary published a notice in the **Federal Register** (72 FR 3853), announcing that the Committee's name changed to the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC). The current Secretary's Charter for the MEDCAC is available on the CMS Web site at: *http://www.cms.hhs.gov/FACA/Downloads/medcaccharter.pdf,* or you may obtain a copy of the charter by submitting a request to the contact listed in the **FOR FURTHER INFORMATION** section of this notice.

The MEDCAC is governed by provisions of the Federal Advisory Committee Act, Pub. L. 92–463, as amended (5 U.S.C. App. 2), which sets forth standards for the formulation and use of advisory committees, and is authorized by section 222 of the Public Health Service Act as amended (42 U.S.C. 217A).

We are requesting nominations for candidates to serve on the MEDCAC. Nominees are selected based upon their individual qualifications and not solely as representatives of professional associations or societies. We wish to ensure adequate representation of the interests of both women and men, members of all ethnic groups, and physically challenged individuals. Therefore, we encourage nominations of qualified candidates who can represent these interests.

The MEDCAC consists of a pool of 100 appointed members including: 94 at-large standing members (6 of whom are patient advocates), and 6 representatives of industry interests. Members generally are recognized authorities in clinical medicine including subspecialties, administrative medicine, public health, biological and physical sciences, epidemiology and biostatistics, clinical trial design, health care data management and analysis, patient advocacy, health care economics, medical ethics or other relevant professions.

The MEDCAC works from an agenda provided by the Designated Federal Official. The MEDCAC reviews and evaluates medical literature and technology assessments, and hears public testimony on the evidence available to address the impact of medical items and services on health outcomes of Medicare beneficiaries. The MEDCAC may also advise the Centers for Medicare & Medicaid Services (CMS) as part of Medicare's ''coverage with evidence development'' initiative.

II. Provisions of the Notice

As of January 2017, there will be 31 membership terms expiring. Of the 31 memberships expiring, 3 are industry representatives, 1 is a patient advocate, and the remaining 27 membership openings are for the at-large standing MEDCAC membership.

All nominations must be accompanied by curricula vitae. Nomination packages should be sent to Maria Ellis at the address listed in the **ADDRESSES** section of this notice. Nominees are selected based upon their individual qualifications. Nominees for membership must have expertise and experience in one or more of the following fields:

- Clinical medicine including subspecialties
- Administrative medicine
- Public health
- Biological and physical sciences
- Epidemiology and biostatistics
- Clinical trial design
- Health care data management and analysis
- Patient advocacy
- Health care economics
- Medical ethics
- Other relevant professions

We are looking particularly for experts in a number of fields. These include cancer screening, genetic testing, clinical epidemiology, psychopharmacology, screening and diagnostic testing analysis, and vascular surgery. We also need experts in biostatistics in clinical settings, dementia treatment, minority health, observational research design, stroke epidemiology, and women's health.

The nomination letter must include a statement that the nominee is willing to serve as a member of the MEDCAC and appears to have no conflict of interest that would preclude membership. We are requesting that all curricula vitae include the following:

- Date of birth
- Place of birth
- Social security number
- Title and current position
- Professional affiliation
- Home and business address
- Telephone and fax numbers
- Email address
- List of areas of expertise

In the nomination letter, we are requesting that nominees specify

whether they are applying for a patient advocate position, for an at-large standing position, or as an industry representative. Potential candidates will be asked to provide detailed information concerning such matters as financial holdings, consultancies, and research grants or contracts in order to permit evaluation of possible sources of financial conflict of interest. Department policy prohibits multiple committee memberships. A federal advisory committee member may not serve on more than one committee within an agency at the same time.

Members are invited to serve for overlapping 2-year terms. A member may continue to serve after the expiration of the member's term until a successor is named. Any interested person may nominate one or more qualified persons. Self-nominations are also accepted. Individuals interested in the representative positions must include a letter of support from the organization or interest group they would represent.

Dated: July 26, 2016.

Kate Goodrich,

Director, Center for Clinical Standards and Quality, Centers for Medicare & Medicaid Services.

[FR Doc. 2016–18545 Filed 8–4–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10340 and CMS–10630]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid 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 any of the following subjects: 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 October 4, 2016.

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' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*.

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

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–10340 Collection of Encounter Data From: Medicare Advantage Organizations, Section 1876 Cost HMOS/CMPS, Section 1833 Health Care Prepayment Plans (HCPPS), and PACE Organizations

CMS–10630 The PACE Organization (PO) Monitoring and Audit Process in 42 CFR part 460

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:* Revision of a currently approved collection; *Title of Information Collection:* Collection of Encounter Data From: Medicare Advantage Organizations, Section 1876 Cost HMOS/CMPS, Section 1833 Health Care Prepayment Plans (HCPPS), and PACE Organizations; *Use:* We collect encounter data or data on each item or service delivered to enrollees of Medicare Advantage (MA) plans offered by MA organizations. The MA organizations currently obtain this data from providers. We collect this information using standard transaction forms and code sets. We will use the data for determining risk adjustment factors for payment, updating the risk adjustment model, calculating Medicare DSH percentages, Medicare coverage purposes, and quality review and improvement activities. The data is also used to verify the accuracy and validity of the costs claimed on cost reports. For PACE organizations, encounter data would serve the same purpose it does related to the MA program and would be submitted in a similar manner. *Form Number:* CMS–10340 (OMB control number: 0938–1152); *Frequency:* Weekly, bi-weekly, and monthly; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 691; *Total Annual Responses:* 18,854,605; *Total Annual Hours:* 54,054. (For policy questions regarding this collection contact Michael Massimini at 410–786–1566.)

2. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* The PACE Organization (PO) Monitoring and Audit Process in 42 CFR part 460; *Use:* Historically, the Programs of All-Inclusive Care for the Elderly (PACE) audit protocols have been included in the Medicare Advantage (MA) and Medicare Part D audit protocol's information collection request (CMS–10191, OMB 0938–1000). However, in examining previous submissions, we do not believe that including it with the MA and Part D audit protocols allowed for an accurate representation of the PACE burden. Due to PACE audits being substantially different from our MA and Part D audits, we have separated the PACE audit protocols from the MA and Part D protocols and created this information collection request which seeks OMB approval under a new control number.

POs are required to comply with all PACE program requirements. The growth of these PACE organizations forced CMS to develop an audit strategy to ensure we continue to obtain meaningful audit results. As a result, CMS' audit strategy reflected a move to a more targeted, data-driven and outcomes-based audit approach. We focused on high-risk areas that have the greatest potential for participant harm.

CMS has developed an audit protocol and will post it to the CMS Web site each year for use by POs to prepare for their audit. The data collected for audit is detailed in this protocol and the exact fields are located in the record layouts, at the end of the protocol. In addition, a questionnaire will be distributed as part of our audit. This questionnaire is also included in this package. *Form Number:* CMS–10630 (OMB control number: 0938–New); *Frequency:* Yearly; *Affected Public:* Private sector (Business or other for-profits and Not-for-profits institutions); *Number of Respondents:* 72; *Total Annual Responses:* 72; *Total Annual Hours:* 12,960. (For policy questions regarding this collection contact Caroline Zeman at 410–786–0116.)

Dated: August 2, 2016.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2016–18662 Filed 8–4–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Cellular, Tissue, and Gene Therapies Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Cellular, Tissue, and Gene Therapies Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. At least one portion of the meeting will be closed to the public.

DATES: The meeting will be held on September 7, 2016, from 1 p.m. to 4 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FOR FURTHER INFORMATION CONTACT: Janie Kim or Denise Royster, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Silver Spring, MD 20993–0002, 301–796–9016 or 240–402–8158, *Janie.kim@fda.hhs.gov* or *Denise.royster@fda.hhs.gov*; or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting. For those unable to attend in person, the meeting will also be available via Webcast. The Webcast will be available at the following link: *https://collaboration.fda.gov/ctgtac0916/.*

SUPPLEMENTARY INFORMATION:

Agenda: On September 7, 2016, the committee will meet by teleconference. In open session, the committee will hear updates of research programs in the Gene Transfer and Immunogenicity Branch, Division of Cellular and Gene Therapies, Office of Cellular, Tissue, and Gene Therapies, Center for Biologics Evaluation and Research.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: On September 7, 2016, from 1 p.m. to 2:20 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before August 23, 2016. Oral presentations from the public will be scheduled between approximately 2:20 p.m. to 3:20 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before August 15, 2016. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by August 16, 2016.

Closed Committee Deliberations: On September 7, 2016, from 3:20 p.m. to 4 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss reports of intramural research programs and make recommendations regarding personnel staffing decisions.

Persons attending FDA's advisory committee meetings are advised that the

Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Janie Kim at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 1, 2016.

Janice M. Soreth,

Acting Associate Commissioner, Special Medical Programs.

[FR Doc. 2016–18560 Filed 8–4–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Pediatric Master Protocols; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), in collaboration with the University of Maryland Center of Excellence in Regulatory Science and Innovation, is announcing a public workshop titled, ''Pediatric Master Protocols''. The objective of the workshop is to discuss regulatory and scientific concerns related to pediatric master protocols and clinical trial design considerations for these protocols. In addition, applications of pediatric master protocols to specific pediatric therapeutic areas will be presented.

DATES: The public workshop will be held on September 23, 2016, from 8:30 a.m. to 4:30 p.m.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

FOR FURTHER INFORMATION CONTACT: Audrey Thomas, Office of Regulatory Science and Innovation, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4220, Silver Spring, MD 20993–0002, 301–796–3520, *Audrey.Thomas@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The purpose of this public workshop is to provide an opportunity for relevant stakeholders including: Clinicians and scientists from FDA and other government Agencies, academia, nonprofit organizations, and industry to discuss use of pediatric master protocols for development of medical products for children. Specifically, the workshop will present the current status of pediatric protocol development in the United States, considerations for pediatric protocol development internationally, and development of international consortia in this area. Clinical trial design considerations and the preliminary steps needed for development of pediatric master protocols, including the role of in vitro diagnostic tests, will also be discussed. Finally, examples of pediatric master protocol development for medical products with no, partial, and full extrapolation of data from adults to children will be presented. The workshop will include two panel sessions for interaction and discussion among the speakers and attendees.

Agenda: The agenda is available at *http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm507079.htm* (FDA has verified the Web site address, but FDA is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**).

Registration: There is a registration fee to attend this public workshop in-person. Seats are limited and registration will be on a first-come, first-served basis. To register, please complete registration online at *http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm507079.htm* (FDA has verified the Web site address, but FDA is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**). There will be no onsite registration. The costs of registration, to attend in-person, for different categories of attendees are as follows:

Category	Cost
Industry Representative	$50
Nonprofit Organization and Academic Other Than University of Maryland	50
University of Maryland, College Park and Baltimore	0
Federal Government	0

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. There is no registration fee for access to the workshop via the Webcast, but registration is still required. Information regarding registration and access to the Webcast link is available at *http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm507079.htm.* If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview.* (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Accommodations: Attendees are responsible for their own hotel accommodations. If you need special accommodations while at FDA's White Oak Campus due to a disability, please contact Shari Solomon at *Shari.Solomon@fda.hhs.gov* at least 7 days in advance.

Dated: August 1, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–18555 Filed 8–4–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

National Mammography Quality Assurance Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the National Mammography Quality Assurance Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory

issues. The meeting will be open to the public.

DATES: The meeting will be held Thursday, September 15, 2016, from 8:30 a.m. to 4:30 p.m.

ADDRESSES: Hilton Washington, DC North/Gaithersburg, Salons A, B, C and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301–977–8900. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FOR FURTHER INFORMATION CONTACT: S.J. Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1643, Silver Spring, MD 20993, *Sara.Anderson@fda.hhs.gov,* 301–796–7047, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The Committee will discuss and make recommendations on:

- Compliance Analysis. This presentation will be focused on Mammography Quality Standards Act (MQSA) current compliance trends, such as how most compliance cases originate. Input from the committee on any trends seen in the analysis, why the trends may be occurring, and possible actions will be sought.
- Inspection Enhancement Project. This presentation will describe a proposal to use the inspection program to enhance image quality. FDA is seeking committee input on anticipated facility questions related to the proposal.
- The approved alternative standard American College of Radiology Full Field Digital Mammography Quality Control Manual. The manual's contents will be explained and FDA will ask the committee's advice on facility roll-out strategies.
- Issues related to breast density. A presentation of current issues followed by a committee discussion on how these issues might effect a possible MQSA requirement for reporting breast density.
- Future challenges for MQSA, such as the role of synthesized 2D images. FDA is seeking committee input on this challenge as well as what future challenges MQSA might encounter.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before September 7, 2016. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before August 30, 2016. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by August 31, 2016.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Artair Mallett at 301 796–9638 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 1, 2016.

Janice M. Soreth,

Acting Associate Commissioner, Special Medical Programs.

[FR Doc. 2016–18592 Filed 8–4–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than September 6, 2016.

ADDRESSES: Submit your comments, including the ICR title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: The Teaching Health Center Graduate Medical Education (THCGME) Program Eligible Resident/Fellow FTE Chart.

OMB No. 0915–0367—Revision.

Abstract: The Teaching Health Center Graduate Medical Education (THCGME) Program, section 340H of the Public

Health Service (PHS) Act, was established by section 5508 of Public Law 111–148. Public Law 114–10, the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) provided continued funding for the THCGME Program. THCGME Program awards payment for both direct and indirect expenses to support training for primary care residents in community-based ambulatory patient care settings. THCGME Program Eligible Resident/Fellow FTE Chart, published in the THCGME Funding Opportunity Announcements (FOAs), is a means for determining the number of eligible resident/fellow full-time equivalents (FTEs) in an applicant's primary care residency program. The current THCGME Program Eligible Resident/Fellow FTE Chart received OMB clearance on September 16, 2013. HRSA is revising the chart to provide clearer projections over a longer period of time.

Need and Proposed Use of the Information: The THCGME Program Eligible Resident/Fellow FTE Chart requires applicants to provide data related to the size and/or growth of the residency program over previous academic years, the number of residents enrolled in the program during the baseline academic year, and a projection of the program's proposed expansion over the next 5 academic years. It is imperative that applicants complete this chart and provide evidence of a planned expansion, as per the statute, THCGME funding may only be used to support an expanded number of residents in a residency program or to establish a new residency training program. Utilization of a chart to gather this important information has decreased the number of errors in the eligibility review process resulting in a more accurate review and funding process. In the proposed revisions, the content of the information collected has not changed; however, the order in which the information is presented on the chart has been modified to provide clearer projections over a longer period of time. This extended time frame would allow programs the flexibility to project the variations that occur during the natural expansion and scaling up of residency programs. This would better equip HRSA to make more accurate future funding projections.

Likely Respondents: Teaching Health Centers applying for THCGME funding through a THCGME FOA, which may include new applicants and existing awardees.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Teaching Health Center GME Program Eligible Resident/Fellow FTE Chart	90	1	90	1	90
Total	90		90		90

Jackie Painter,

Senior Advisor, Division of the Executive Secretariat.

[FR Doc. 2016–18609 Filed 8–4–16; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 Neurological Disorders and Stroke Special Emphasis Panel; R21: Rapid Assessment of Zika Virus (ZIKV) Complications.

Date: August 15, 2016.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Ana Olariu, Ph.D., Scientific Review Administrator, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3204, MSC 9529, Bethesda, MD 20892–9529, 301–496–9223, *Ana.olariu@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 Neurological Disorders and Stroke Special Emphasis Panel; FTD CWOW Review.

Date: August 23–24, 2016.

Time: 8:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel and Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Ernest Lyons, Ph.D., Scientific Review Administrator, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3204, MSC 9529, Bethesda, MD 20892–9529, 301–496–4056, *lyonse@ninds.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: August 1, 2016.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–18551 Filed 8–4–16; 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 (5 U.S.C. App.), 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: AIDS and AIDS Related Research.

Date: August 9, 2016.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Mark P. Rubert, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, 301–435–1775, *rubertm@csr.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: Center for Scientific Review Special Emphasis Panel; PAR Panel: Methods for HIV Prevention Packages.

Date: August 9, 2016.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Shalanda A. Bynum, Ph.D., MPH, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3206, Bethesda, MD 20892, 301–755–4355, *bynumsa@csr.nih.gov*.

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: Center for Scientific Review Special Emphasis Panel; Member Conflict: AIDS and Related Research Applications.

Date: August 9, 2016.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Robert Freund, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5216, MSC 7852, Bethesda, MD 20892, 301–435–1050, *freundr@csr.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: Center for Scientific Review Special Emphasis Panel; PAR14–066: SPF Macaque Colonies.

Date: August 12, 2016.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Shiv A. Prasad, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5220, MSC 7852, Bethesda, MD 20892, 301–443–5779, *prasads@csr.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. 93.306, 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: August 1, 2016.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–18548 Filed 8–4–16; 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 (5 U.S.C. App.), 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 NIAID Clinical Trial Implementation Grant (R01).

Date: September 1, 2016

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health RM 5C100, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Lynn Rust, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3G42A National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892–9823, (240) 669–5069, *lrust@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: August 1, 2016.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–18550 Filed 8–4–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Public Comment on the Proposed Changes to the NIH Guidelines for Human Stem Cell Research and the Proposed Scope of an NIH Steering Committee's Consideration of Certain Human-Animal Chimera Research

SUMMARY: The National Institutes of Health (NIH) is requesting public comment on a proposal to amend Section IV and Section V of the NIH Guidelines for Human Stem Cell Research and on the proposed scope of certain human-animal chimera research that will be considered internally by an NIH steering committee to provide programmatic input to the director of the relevant NIH Institute(s) or Center(s) or equivalent NIH officials responsible for funding decisions.

DATES: Written comments must be received by the NIH on or before September 6, 2016 in order to be considered.

ADDRESSES: Public comments may be entered at: *http://grants.nih.gov/grants/rfi/rfi.cfm?ID=57*. Comments may also be mailed to: Office of Science Policy, National Institutes of Health, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892, 301–496–9838. Comments will be made publicly available. Comments received, including any

personal information, will be posted without change to *http://grants.nih.gov/grants/rfi/responses_57.cfm*.

SUPPLEMENTARY INFORMATION: On July 7, 2009, the NIH issued the NIH Guidelines for Human Stem Cell Research (''Guidelines'') 74 FR 32170 (July 7, 2009) to implement Executive Order 13505 (March 9, 2009), as it pertains to NIH-funded stem cell research, to establish policy and procedures under which the NIH will fund such research, and help ensure that NIH-funded research in this area is ethically responsible, scientifically worthy, and conducted in accordance with applicable law.

Since the Guidelines were issued in 2009, growing knowledge and advancement of stem cell biology has created new research opportunities. Some scientists are exploring strategies for growing human tissue and organs in animals through the introduction of human pluripotent cells into early stage embryos of non-human vertebrate animals. These experimental designs raise questions regarding where the human cells might go in the developing animal and how they might function, such as whether the human cells might contribute to the central nervous system and affect the cognition of the animal.

While considering these issues, on September 23, 2015, the NIH issued a funding moratorium (*http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-158.html*) on ''NIH Research Involving Introduction of Human Pluripotent Cells into Non-Human Vertebrate Animal Pre-Gastrulation Embryos.'' The NIH subsequently held a workshop with experts on November 6, 2015, to review the state of the science and discuss animal welfare issues.

The workshop illustrated that while there are significant challenges to creating chimeric models, there is clear interest and potential in producing animal models with human tissues or organs for studying human development, disease pathology, and eventually organ transplantation. In the interest of moving the field forward while preserving the NIH's opportunity to provide continuing assessment and oversight of this emerging area of research, the NIH has decided to establish a steering committee to provide programmatic input to the director of the relevant NIH Institute(s) or Center(s) (or equivalent NIH official responsible for funding decisions) on certain human-animal chimera research proposals. The committee will be composed of federal employees. The committee is expected to consider and offer the director of the relevant NIH Institute(s) or Center(s) (or equivalent NIH official responsible for funding decisions) programmatic input on factors, such as, (1) the characteristics of the human cells to be introduced (including potency and any modifications of those cells); (2) characteristics of the recipient animal (*e.g.,* species, stage of development, and any modifications that affect location or function of human cells); (3) other data relevant to the likely effects on the animal (*e.g.,* changes in cognition, behavior, or physical appearance); (4) planned monitoring (including animal welfare assessments); and (5) any staging of proposed research (*e.g.,* assessing the outcome of a particular experiment before conducting a further experiment). This internal programmatic work will be conducted independent of, and in addition to, the usual peer review procedures for research at the NIH. The relevant IC director(s) will consider the input from the steering committee, in addition to other NIH programmatic input, as well as the funding recommendations and evaluations of the initial Scientific Review Group and the relevant Institute or Center's Advisory Council or Board. The committee will also monitor trends in this general field of research and the use of new technologies, and may provide such analysis and advice to the NIH leadership.

The NIH also proposes to revise the Guidelines to expand the existing prohibition on introducing human pluripotent stem cells into blastocyst stage nonhuman primate embryos to include pre-blastocyst stage nonhuman primate embryos; and to expand the prohibition on research involving the breeding of animals where the introduction of hESCs or human induced pluripotent stem cells may contribute to the germ line to include any human cells that may result in the formation of human gametes.

Therefore, NIH is requesting public comment on:

(1) The following proposed changes to the Guidelines.

Sections IV and V of the Guidelines currently state:

IV. Research Using hESCs and/or Human Induced Pluripotent Stem Cells That, Although the Cells May Come From Eligible Sources, Is Nevertheless Ineligible for NIH Funding

This section governs research using hESCs and human induced pluripotent stem cells, *i.e.,* human cells that are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers. Although the cells may come from eligible sources, the following uses of these cells are nevertheless ineligible for NIH funding, as follows:

A. Research in which hESCs (even if derived from embryos donated in accordance with these Guidelines) or human induced pluripotent stem cells are introduced into non-human primate blastocysts.

B. Research involving the breeding of animals where the introduction of hESCs (even if derived from embryos donated in accordance with these Guidelines) or human induced pluripotent stem cells may contribute to the germ line.

V. Other Research Not Eligible for NIH Funding

A. NIH funding of the derivation of stem cells from human embryos is prohibited by the annual appropriations ban on funding of human embryo research (Section 509, Omnibus Appropriations Act, 2009, Pub. L. 111–8, 3/11/09), otherwise known as the Dickey Amendment.

B. Research using hESCs derived from other sources, including somatic cell nuclear transfer, parthenogenesis, and/or IVF embryos created for research purposes, is not eligible for NIH funding.

The NIH is proposing to amend the Guidelines as follows:

IV. Research Not Eligible for NIH Funding:

A. Research in which human pluripotent stem cells are introduced into non-human primate embryos up through the end of the blastocyst stage, is not eligible for funding.

B. Research involving the breeding of animals where the introduction of human cells may contribute to the germ line, is not eligible for funding.

C. NIH funding of the derivation of stem cells from human embryos is prohibited by the annual appropriations limitations on the funding of human embryo research (see *e.g.* Section 508, Omnibus Appropriations Act, 2016, Pub. L.114–113, 12/18/15), otherwise known as the Dickey Amendment.

D. Research using hESCs derived from other sources, including somatic cell nuclear transfer, parthenogenesis, and/or IVF embryos created for research purposes, is not eligible for NIH funding.

(2) The NIH is also requesting public comment on the proposed scope of research (*e.g.,* grant applications, contract proposals, intramural research protocols, etc.) to be considered by an NIH steering committee to provide programmatic input to the director of the relevant Institute or Center (or equivalent NIH official responsible for funding decisions). The NIH proposes the scope of research include research in which:

a. Human pluripotent cells are introduced into non-human vertebrate embryos, up through the end of the gastrulation stage, or

b. human cells are introduced into post-gastrulation non-human mammals (excluding rodents), such that there could be either a substantial contribution or a substantial functional

modification to the animal brain by the human cells.

While the NIH seeks public comment on the proposed changes to the Guidelines, and on the proposed scope for an NIH steering committee's consideration of certain research, NOT–OD–15–158 will remain in effect.

Dated: July 28, 2016.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

[FR Doc. 2016–18601 Filed 8–4–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 Heart, Lung, and Blood Institute, Special Emphasis Panel, Pediatric Heart Network Data Coordinating Centers (U24).

Date: August 30, 2016.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 7182, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Susan Wohler Sunnarborg, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA National, Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7182, Bethesda, MD 20892 *sunnarborgsw@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: July 29, 2016.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–18549 Filed 8–4–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2016–0640]

Eighth Coast Guard District; Interim Outer Continental Shelf Risk-Based Resource Allocation Methodology

AGENCY: Coast Guard, DHS.

ACTION: Notice of availability and request for comments.

SUMMARY: The Coast Guard announces the availability of an interim risk based resource allocation methodology for inspections of certain Outer Continental Shelf (OCS) units in the Eighth Coast Guard District (D8) area of responsibility (AOR). This interim methodology will be implemented for a five-month trial period beginning August 1, 2016. After the trial period, the methodology will be finalized within D8 and submitted to Coast Guard Headquarters (CG–CVC) for consideration at the national level.

DATES: Comments and related material must be received by the Coast Guard on or before September 6, 2016.

ADDRESSES: You may submit comments identified by docket number USCG–2016–0640 or view documents mentioned in this notice as being available in the docket using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: For information about this document call or email Steve Sutton, Coast Guard; telephone 202-671–2151, email *steve.sutton@uscg.mil.*

SUPPLEMENTARY INFORMATION:

Discussion

This interim risk based resource allocation methodology is intended to improve implementation of the requirements contained in 33 CFR 140.101(c), 143.120(c), and 143.210(a) by employing interagency consultation and by establishing increased focus on the industrial mission and regulatory compliance and casualty data. It builds upon the risk based matrix created for foreign Mobile Offshore Drilling Units (MODU), which was published in the **Federal Register** (76 FR 39885) by the Coast Guard in 2011 by applying similar principles to other OCS units and adding consultation with the Bureau of Safety and Environmental Enforcement (BSEE). This methodology will reallocate Coast Guard inspection resources from lower risk, fixed interval activities to higher risk activities prior to commencing an industrial mission. The Coast Guard will periodically evaluate MODUs and OCS facilities that either perform drilling or well-workover or are due for a Coast Guard regulatory inspection to assign an inspection priority and scope using risk matrices. For example, under this methodology Coast Guard inspection resources previously used to conduct an annual Certificate of Compliance inspection of a lower risk stacked MODU may be reallocated to conduct a higher risk inspection of any MODU or OCS facility with a drilling rig prior to commencement of drilling.

Outreach to the Offshore Operator's Committee

On June 8, 2016, the Coast Guard conducted outreach to the offshore Operators' Committee at its annual general meeting in Houston, TX. The presentation, presentation script, and transcript of questions and answers from this outreach are available on the docket where indicated under **ADDRESSES**.

Public Participation and Request for Comments

We encourage you to submit comments (or related material) on the interim risk based resource allocation methodology for inspection of OCS units in the D8 AOR. We will consider all submissions and may adjust our action based on your comments, although we do not anticipate a written response to comments. If you submit a comment, please include the docket number for this notice, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice of availability, and all public comments, are in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted to the docket.

We accept anonymous comments. All comments received will be posted

without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

This notice is issued under authority of 5 U.S.C. 552(a).

Dated: August 1, 2016.

D.R. Callahan,

Rear Admiral, U.S. Coast Guard, Commander, Eighth Coast Guard District.

[FR Doc. 2016–18590 Filed 8–4–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0103]

Agency Information Collection Activities: Request for Information

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: 30-Day notice and request for comments; Extension of an existing collection of information.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Passenger List/Crew List (Form I–418). CBP is proposing that this information collection be extended with no change to the burden hours or to the information collected. This document is published to obtain comments from the public and affected agencies.

DATES: Written comments should be received on or before September 6, 2016 to be assured of consideration.

ADDRESSES: Interested persons are invited to submit written comments on this proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Paperwork Reduction Act Officer, U.S. Customs and Border Protection, Regulations and Rulings, Office of Trade, 90 K Street NE., 10th Floor, Washington, DC 20229–1177, or via email (*CBP_PRA@cbp.dhs.gov*). Please note contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs please contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP Web site at *https://www.cbp.gov/.* For additional help: *https://help.cbp.gov/app/home/search/1.*

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** (81 FR 33543) on May 26, 2016, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10. CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Public Law 104–13; 44 U.S.C. 3507). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates 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, including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual costs to respondents or record keepers from the collection of information (total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for OMB approval. All comments will become a matter of public record. In this document, CBP is soliciting comments concerning the following information collection:

Title: Passenger List/Crew List.

OMB Number: 1651–0103.

Form Number: Form I–418.

Abstract: CBP Form I–418 is prescribed by CBP, for use by masters, owners, or agents of vessels in complying with Sections 231 and 251 of the Immigration and Nationality Act (INA). This form is filled out upon arrival of any person by commercial vessel at any port within the United States from any place outside the United States. The master or commanding officer of the vessel is responsible for providing CBP officers at the port of arrival with lists or manifests of the persons on board such conveyances. CBP is currently working to allow for electronic submission of the information on CBP Form I–418. This form is provided for in 8 CFR 251.1 and 251.3. A copy of CBP Form I–418 can be found at *https://www.cbp.gov/newsroom/publications/forms?title=i-418&=Apply.*

Current Actions: CBP proposes to extend the expiration date of this information collection with no change to the burden hours or to the information collected.

Type of Review: Extension (without change).

Affected Public: Businesses.

Estimated Number of Respondents: 48,000.

Estimated Time per Respondent: 1 hour.

Estimated Total Annual Hours: 48,000.

Dated: August 1, 2016.

Seth Renkema,

Branch Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection.

[FR Doc. 2016–18547 Filed 8–4–16; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2015–0029; OMB No. 1660–0141]

Agency Information Collection Activities: Submission for OMB Review; Comment Request; Controlled Equipment Request Form

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency (FEMA) will submit the information collection abstracted below to the Office of Management and Budget for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995. The submission will describe the nature of the information collection, the categories of respondents, the estimated burden (*i.e.,* the time, effort and resources used by respondents to respond) and cost, and the actual data collection instruments FEMA will use.

DATES: Comments must be submitted on or before September 6, 2016.

ADDRESSES: Submit written comments on the proposed information collection

to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the Desk Officer for the Department of Homeland Security, Federal Emergency Management Agency, and sent via electronic mail to *oira.submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be made to Director, Records Management Division, 500 C Street SW., Washington, DC 20472–3100, or email address *FEMA-Information-Collections-Management@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: This proposed information collection previously published in the **Federal Register** on May 24, 2016, at 81 FR 32769, with a 60 day public comment period. No comments were received. The purpose of this notice is to notify the public that FEMA will submit the information collection abstracted below to the Office of Management and Budget for review and clearance.

Collection of Information

Title: Controlled Equipment Request Form.

Type of information collection: Extension, without change, of a currently approved information collection.

OMB Number: 1660–0141.

Form Titles and Numbers: FEMA Form 087–0–0–1, Controlled Equipment Request Form.

Abstract: This form was developed to collect required information as part of the implementation of Executive Order 13688: Federal Support for Local Law Enforcement Equipment Acquisition, issued January 16, 2015, which established a Prohibited Equipment List and a Controlled Equipment List and identified actions that can improve Federal support for the appropriate use, acquisition, and transfer of controlled equipment by state, local, tribal, territorial, and private grant recipients.

Affected Public: Business or other for-profit; State, Local, or Tribal Government.

Estimated Number of Respondents: 175.

Estimated Total Annual Burden Hours: 131 hours.

Estimated Cost: The estimated annual cost to respondents for the hour burden is $3,877.60. There are no annual costs to respondents' operations and maintenance costs for technical services. There are no annual start-up or capital costs. The cost to the Federal Government is $759.40.

Dated: August 1, 2016.

Richard W. Mattison,

Records Management Program Chief, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2016–18640 Filed 8–4–16; 8:45 am]

BILLING CODE 9111–46–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2015–0017]

Information Sharing and Analysis Organization

AGENCY: Department of Homeland Security.

ACTION: Notice of public forum and request for public comment.

SUMMARY: This Notice announces a fourth public meeting for the Information Sharing and Analysis Organization (ISAO) Standards Organization (SO) on August 31 and September 1, 2016 in Tysons, VA. Additionally, this notice announces a second request for public comment on draft products produced by the ISAO SO. This is the second iteration of draft products that will be used in the development of voluntary standards for Information Sharing and Analysis Organizations (ISAOs) as they relate to E.O. 13691. These drafts have been updated, revised and consolidated from the first drafts released in May 2016.

DATES: The ISAO SO Public Forum will be held on August 31 and September 1, 2016 in Tysons, VA. The comment period for the second iteration of the SO draft voluntary standards for ISAOs will be open until Friday, August 5, 2016. Comments will continue to be accepted after this date, but may not be reflected until later iterations of draft standards documents.

FOR FURTHER INFORMATION CONTACT: If you have questions concerning the draft voluntary standards documents, please contact the ISAO Standards Organization at *Contact@ISAO.org.*

SUPPLEMENTARY INFORMATION:

Background and Purpose

On February 13, 2015, President Obama signed E.O. 13691 intended to enable and facilitate ''private companies, nonprofit organizations, and executive departments and agencies . . . to share information related to cybersecurity risks and incidents and collaborate to respond in as close to real time as possible.''

In accordance with E.O. 13691, DHS has entered into a cooperative agreement with a non-governmental ISAO SO led by the University of Texas at San Antonio with support from the Logistics Management Institute (LMI) and the Retail Cyber Intelligence Sharing Center (R–CISC). The ISAO SO is working with existing information sharing organizations, owners and operators of critical infrastructure, relevant agencies, and other public and private sector stakeholders to identify a common set of voluntary standards or guidelines for the creation and functioning of ISAOs.

As part of this collaborative, transparent, and industry-driven process, the ISAO SO has established six working groups to assist in the development of voluntary standards. As part of the standards development process, the ISAO SO hosts public forums. This notice is to provide further information regarding the August 31 and September 1, 2016 public forum in Tysons, VA.

Additionally, this notice is to request comment on the Standards Organization's draft products. These drafts consolidate previous separate documents, comments and newly developed material. Your participation in this comment process is highly encouraged to ensure all equities are being met. To join a working group or to find out how else you can best participate, please visit *www.ISAO.org* or email *Contact@ISAO.org.*

Meeting Details

To view the agenda and further details on the corresponding August 31 and September 1, 2016 in person meeting in Tysons, VA, please visit *www.ISAO.org.* These meetings will be held at LMI Headquarters (7940 Jones Branch Drive, Tysons, VA).

Submitting Written Comments

The second draft documents can be found and comments submitted directly to the ISAO SO at *https://www.ISAO.org/products/drafts/.* This method is preferred by the ISAO SO.

You may also submit written comments to the docket using one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov.* Although this is not a rulemaking action, comments are being submitted to the Federal eRulemaking Portal in an effort to provide transparency to the general public.

(2) *Email: Contact@ISAO.org.* Include the docket number in the subject line of the message.

(3) *Mail:* ISAO Standards Organization, c/o LMI, 1777 NE. Loop 410, Suite 808, San Antonio, TX 78217–5217.

To avoid duplication, please use only one of these four methods. All comments must either be submitted to the online docket on or before August 5, 2016, or reach the Docket Management Facility by that date.

Comments may be submitted directly to the ISAO SO using the method described above after August 5, 2016. However, these comments may not be reflected until later iterations of draft standards documents.

References

Executive Order 13691 can be found at: *https://www.whitehouse.gov/the-press-office/2015/02/13/executive-order-promoting-private-sector-cybersecurity-information-shari.*

For additional information about the ISAO SO, draft products, and how you can best participate in the standards development process, please go to *www.ISAO.org* or email *Contact@ISAO.org.*

Authority: 6 U.S.C. 131–134; 6 CFR 29; E.O.13691.

Dated: August 1, 2016.

Andy Ozment,

Assistant Secretary, Cybersecurity and Communications, National Protection and Programs Directorate, Department of Homeland Security.

[FR Doc. 2016–18557 Filed 8–4–16; 8:45 am]

BILLING CODE 9110–9P–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–HQ–IA–2016–0098: FXIA16710900000–156–FF09A30000]

Endangered Species; Marine Mammals; Receipt of Applications for Permit

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications for permit.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on the following applications to conduct certain activities with endangered species, marine mammals, or both. With some exceptions, the Endangered Species Act (ESA) and Marine Mammal Protection Act (MMPA) prohibit activities with listed species unless Federal authorization is acquired that allows such activities.

DATES: We must receive comments or requests for documents on or before September 6, 2016. We must receive requests for marine mammal permit public hearings, in writing, at the address shown in the **ADDRESSES** section by September 6, 2016.

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

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments on Docket No. FWS–HQ–IA–2016–0098.
- *U.S. mail or hand-delivery:* Public Comments Processing, Attn: Docket No. FWS–HQ–IA–2016–0098; U.S. Fish and Wildlife Service Headquarters, MS: BPHC; 5275 Leesburg Pike, Falls Church, VA 22041–3803.

When submitting comments, please indicate the name of the applicant and the PRT# you are commenting on. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see the Public Comments section below for more information).

Viewing Comments: Comments and materials we receive will be available for public inspection on *http://www.regulations.gov*, or by appointment, between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays, at the U.S. Fish and Wildlife Service, Division of Management Authority, 5275 Leesburg Pike, Falls Church, VA 22041–3803; telephone 703–358–2095.

FOR FURTHER INFORMATION CONTACT: Brenda Tapia, (703) 358–2104 (telephone); (703) 358–2281 (fax); *DMAFR@fws.gov* (email).

SUPPLEMENTARY INFORMATION:

I. Public Comment Procedures

A. How do I request copies of applications or comment on submitted applications?

Send your request for copies of applications or comments and materials concerning any of the applications to the contact listed under **ADDRESSES**. Please include the **Federal Register** notice publication date, the PRT-number, and the name of the applicant in your request or submission. We will not consider requests or comments sent to an email or address not listed under **ADDRESSES**. If you provide an email address in your request for copies of applications, we will attempt to respond to your request electronically.

Please make your requests or comments as specific as possible. Please confine your comments to issues for which we seek comments in this notice, and explain the basis for your comments. Include sufficient information with your comments to allow us to authenticate any scientific or commercial data you include.

The comments and recommendations that will be most useful and likely to influence agency decisions are: (1) Those supported by quantitative information or studies; and (2) Those that include citations to, and analyses of, the applicable laws and regulations. We will not consider or include in our administrative record comments we receive after the close of the comment period (see **DATES**) or comments delivered to an address other than those listed above (see **ADDRESSES**).

B. May I review comments submitted by others?

Comments, including names and street addresses of respondents, will be available for public review at the street address listed under **ADDRESSES**. The public may review documents and other information applicants have sent in support of the application unless our allowing viewing would violate the Privacy Act or Freedom of Information Act. 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.

II. Background

To help us carry out our conservation responsibilities for affected species, and in consideration of section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), and the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), along with Executive Order 13576, ''Delivering an Efficient, Effective, and Accountable Government,'' and the President's Memorandum for the Heads of Executive Departments and Agencies of January 21, 2009—Transparency and Open Government (74 FR 4685; January 26, 2009), which call on all Federal agencies to promote openness and transparency in Government by disclosing information to the public, we invite public comment on these permit applications before final action is taken. Under the MMPA, you may request a hearing on any MMPA application received. If you request a hearing, give specific reasons why a hearing would be appropriate. The holding of such a hearing is at the discretion of the Service Director.

III. Permit Applications

A. Endangered Species

Applicant: Duke University, Durham, NC; PRT–92458B

The applicant requests a permit to import biological samples from wild kakapo (*strigops habroptilus*) for the purpose of scientific research. This notification covers activities to be conducted by the applicant over a 2-year period.

Multiple Applicants

The following applicants each request a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Applicant: Edwin Andrew, Frederica, DE; PRT–00500C

Applicant: Guy Maranga, Neponsit, NY; PRT–98444B

Applicant: Donald Bitz, West Palm Beach, FL; PRT–00209C

Applicant: Christopher Sibert, Midland, TX; PRT–98815B

B. Endangered Marine Mammals and Marine Mammals

Applicant: University of California, Santa Cruz, CA; PRT–83954B

The applicant requests a permit to import blood and tissue samples collected from wild polar bears in Manitoba, Canada, for purposes of scientific research. The goal of this study is to create an improved reference genome for polar bears (*Ursus maritimus*) and investigate the genetic diversity and unique adaptations of polar bears. Samples to be imported have been collected under Manitoba Wildlife Research permits for a study assessing the status of the wild population for conservation and ecological purposes. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Passion Planet, London, UK; PRT–01370C

The applicant requests a permit for Level B Harassment of northern sea otters (*Enhydra lutris kenyoni*) and southern sea otters (*Enhydra lutris nereis*) for purposes of photography for educational and commercial purposes. Filming will occur along the Washington State and California State coastlines. The filming is part of a documentary explaining the importance of sea otters to marine ecosystems. This notification covers activities to be conducted by the applicant over a 2-year period.

Concurrent with publishing this notice in the **Federal Register**, we are forwarding copies of the above applications to the Marine Mammal Commission and the Committee of Scientific Advisors for their review.

Brenda Tapia,

Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.

[FR Doc. 2016–18587 Filed 8–4–16; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[167A2100DD/AAKC001030/A0A501010.999900]

Rate Adjustments for Indian Irrigation Projects

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of proposed rate adjustments.

SUMMARY: The Bureau of Indian Affairs (BIA) owns or has an interest in irrigation projects located on or associated with various Indian reservations throughout the United States. We are required to establish irrigation assessment rates to recover the costs to administer, operate, maintain, and rehabilitate these projects. We request your comments on the proposed rate adjustments.

DATES: Interested parties may submit comments on the proposed rate adjustments on or before *October 4, 2016.*

ADDRESSES: All comments on the proposed rate adjustments must be in writing and addressed to: Yulan Jin, Chief, Division of Water and Power, Office of Trust Services, Mail Stop 4637–MIB, 1849 C Street NW., Washington, DC 20240, Telephone (202) 219–0941.

FOR FURTHER INFORMATION CONTACT: For details about a particular irrigation project, please use the tables in **SUPPLEMENTARY INFORMATION** section to contact the regional or local office where the project is located.

SUPPLEMENTARY INFORMATION: The first table in this notice provides contact information for individuals who can give further information about the irrigation projects covered by this notice. The second table provides the current 2015 irrigation assessment rates, the proposed rates for Calendar Year (CY) 2016, and proposed rates for subsequent years where these rates are available.

What is the meaning of the key terms used in this notice?

In this notice:

Administrative costs means all costs we incur to administer our irrigation projects at the local project level and is a cost factor included in calculating your operation and maintenance assessment. Costs incurred at the local project level do not normally include Agency, Region, or Central Office costs unless we state otherwise in writing.

Assessable acre means lands designated by us to be served by one of our irrigation projects, for which we collect assessments in order to recover costs for the provision of irrigation service. (See *total assessable acres.*)

BIA means the Bureau of Indian Affairs.

Bill means our statement to you of the assessment charges and/or fees you owe the United States for administration, operation, maintenance, and/or rehabilitation. The date we mail or hand-deliver your bill will be stated on it.

Costs means the costs we incur for administration, operation, maintenance, and rehabilitation to provide direct support or benefit to an irrigation facility. (See administrative costs, operation costs, maintenance costs, and rehabilitation costs).

Customer means any person or entity to whom or to which we provide irrigation service.

Due date is the date on which your bill is due and payable. This date will be stated on your bill.

I, me, my, you and *your* means all persons or entities that are affected by this notice.

Irrigation project means a facility or portion thereof for the delivery, diversion, and storage of irrigation water that we own or have an interest in, including all appurtenant works. The term ''irrigation project'' is used interchangeably with irrigation facility, irrigation system, and irrigation area.

Irrigation service means the full range of services we provide customers of our irrigation projects. This includes our activities to administer, operate, maintain, and rehabilitate our projects in order to deliver water.

Maintenance costs means costs we incur to maintain and repair our irrigation projects and associated equipment and is a cost factor included in calculating your operation and maintenance assessment.

Operation and maintenance (O&M) assessment means the periodic charge you must pay us to reimburse costs of administering, operating, maintaining, and rehabilitating irrigation projects

consistent with this notice and our supporting policies, manuals, and handbooks.

Operation or operating costs means costs we incur to operate our irrigation projects and equipment and is a cost factor included in calculating your O&M assessment.

Past due bill means a bill that has not been paid by the close of business on the 30th day after the due date as stated on the bill. Beginning on the 31st day after the due date, we begin assessing additional charges accruing from the due date.

Rehabilitation costs means costs we incur to restore our irrigation projects or features to original operating condition or to the nearest state which can be achieved using current technology and is a cost factor included in calculating your O&M assessment.

Responsible party means an individual or entity that owns or leases land within the assessable acreage of one of our irrigation projects and is responsible for providing accurate information to our billing office and paying a bill for an annual irrigation rate assessment.

Total assessable acres means the total acres served by one of our irrigation projects.

Water delivery is an activity that is part of the irrigation service we provide our customers when water is available.

We, us, and *our* means the United States Government, the Secretary of the Interior, the BIA, and all who are authorized to represent us in matters covered under this notice.

Does this notice affect me?

This notice affects you if you own or lease land within the assessable acreage of one of our irrigation projects or if you have a carriage agreement with one of our irrigation projects.

Where can I get information on the regulatory and legal citations in this notice?

You can contact the appropriate office(s) stated in the tables for the irrigation project that serves you, or you can use the Internet site for the Government Printing Office at *http://www.gpo.gov*.

Why are you publishing this notice?

We are publishing this notice to inform you that we propose to adjust our irrigation assessment rates. This notice is published in accordance with the BIA's regulations governing its operation and maintenance of irrigation projects, found at 25 CFR part 171. This regulation provides for the establishment and publication of the proposed rates for annual irrigation assessments as well as related information about our irrigation projects.

What authorizes you to issue this notice?

Our authority to issue this notice is vested in the Secretary of the Interior by 5 U.S.C. 301 and the Act of August 14, 1914 (38 Stat. 583; 25 U.S.C. 385). The Secretary has in turn delegated this authority to the Assistant Secretary—Indian Affairs under Part 209, Chapter 8.1A, of the Department of the Interior's Departmental Manual.

When will you put the rate adjustments into effect?

We will put the rate adjustments into effect for the CY 2016 and subsequent years where applicable.

How do you calculate irrigation rates?

We calculate annual irrigation assessment rates in accordance with 25 CFR part 171.500 by estimating the annual costs of operation and maintenance at each of our irrigation projects and then dividing by the total assessable acres for that particular irrigation project. The result of this calculation for each project is stated in the rate table in this notice.

What kinds of expenses do you consider in determining the estimated annual costs of operation and maintenance?

Consistent with 25 CFR part 171.500, these expenses include the following:

(a) Salary and benefits for the project engineer/manager and project employees under the project engineer/manager's management or control;

(b) Materials and supplies;

(c) Vehicle and equipment repairs;

(d) Equipment costs, including lease fees;

(e) Depreciation;

(f) Acquisition costs;

(g) Maintenance of a reserve fund available for contingencies or emergency costs needed for the reliable operation of the irrigation facility infrastructure;

(h) Maintenance of a vehicle and heavy equipment replacement fund;

(i) Systematic rehabilitation and replacement of project facilities;

(j) Carriage Agreements for the transfer of project water through irrigation facilities owned by others.

(j) Any water storage fees for non-BIA-owned reservoirs, as applicable,

(j) Contingencies for unknown costs and omitted budget items; and

(k) Other expenses we determine necessary to properly perform the activities and functions characteristic of an irrigation project.

When should I pay my irrigation assessment?

We will mail or hand-deliver your bill notifying you (a) the amount you owe to the United States and (b) when such amount is due. If we mail your bill, we will consider it as being delivered no later than 5 business days after the day we mail it. You should pay your bill by the due date stated on the bill.

What information must I provide for billing purposes?

All responsible parties are required to provide the following information to the billing office associated with the irrigation project where you own or lease land within the project's assessable acreage or to the billing office associated with the irrigation project with which you have a carriage agreement:

(1) The full legal name of person or entity responsible for paying the bill;

(2) An adequate and correct address for mailing or hand delivering our bill; and

(3) The taxpayer identification number or Social Security number of the person or entity responsible for paying the bill.

Why are you collecting my taxpayer identification number or Social Security number?

Public Law 104–134, the Debt Collection Improvement Act of 1996, requires that we collect the taxpayer identification number or Social Security number before billing a responsible party and as a condition to servicing the account.

What happens if I am a responsible party but I fail to furnish the information required to the billing office responsible for the irrigation project within which I own or lease assessable land or for which I have a carriage agreement?

If you are late paying your bill because of your failure to furnish the required information listed above, you will be assessed interest and penalties as provided below, and your failure to provide the required information will not provide grounds for you to appeal your bill or any penalties assessed.

What can happen if I do not provide the information required for billing purposes?

We can refuse to provide you irrigation service.

If I allow my bill to become past due, could this affect my water delivery?

Yes. 25 CFR 171.545(a) states: ''We will not provide you irrigation service until: (1) Your bill is paid; or (2) You make arrangement for payment pursuant to § 171.550 of this part.'' If we do not receive your payment before the close of business on the 30th day after the due date stated on your bill, we will send you a past due notice. This past due notice will have additional information concerning your rights. We will consider your past due notice as delivered no later than 5 business days after the day we mail it. We follow the procedures provided in 31 CFR 901.2, ''Demand for Payment,'' when demanding payment of your past due bill.

Are there any additional charges if I am late paying my bill?

Yes. We will assess you interest on the amount owed, using the rate of interest established annually by the Secretary of the United States Treasury (Treasury) to calculate what you will be assessed. You will not be assessed this charge until your bill is past due. However, if you allow your bill to become past due, interest will accrue from the original due date, not the past due date. Also, you will be charged an administrative fee of $12.50 for each time we try to collect your past due bill. If your bill becomes more than 90 days past due, you will be assessed a penalty charge of 6 percent per year, which will accrue from the date your bill initially became past due. Pursuant to 31 CFR 901.9, ''Interest, penalties and administrative costs,'' as a Federal agency, we are required to charge interest, penalties, and administrative costs in accordance with 31 U.S.C. 3717.

What else will happen to my past due bill?

If you do not pay your bill or make payment arrangements to which we agree, we are required to send your past due bill to the Treasury for further action. Under the provisions of 31 CFR 901.1, ''Aggressive agency collection activity,'' Federal agencies should consider referring debts that are less than 180 days delinquent, and we must send any unpaid annual irrigation assessment bill to Treasury no later than 180 days after the original due date of the bill.

Who can I contact for further information?

The following tables are the regional and project/agency contacts for our irrigation facilities.

Project name	Project/agency contacts
Northwest Region Contacts	
Stanley Speaks, Regional Director, Bureau of Indian Affairs, Northwest Regional Office, 911 NE. 11th Avenue, Portland, OR 97232–4169, Telephone: (503) 231–6702.	
Flathead Irrigation Project	Ernest Moran, Superintendent, Pete Plant, Irrigation Project Manager, P.O. Box 40, Pablo, MT 59855, Telephones: (406) 675–2700 ext. 1300, Superintendent; (406) 745–2661 ext. 2, Project Manager.
Fort Hall Irrigation Project	David Bollinger, Irrigation Project Manager, Building #2, Bannock Ave., Fort Hall, ID 83203–0220, Telephone: (208) 238–6264.
Wapato Irrigation Project	David Shaw, Superintendent, Larry Nelson, Acting Project Administrator, P.O. Box 220, Wapato, WA 98951–0220, Telephone: (509) 865–2421, Superintendent; (509) 877–3155, Acting Project Administrator.
Rocky Mountain Region Contacts	
Darryl LaCounte, Regional Director, Bureau of Indian Affairs, Rocky Mountain Regional Office, 316 North 26th Street, Billings, MT 59101, Telephone: (406) 247–7943.	
Blackfeet Irrigation Project	Thedis Crowe, Superintendent, Greg Tatsey, Irrigation Project Manager, Box 880, Browning, MT 59417, Telephones: (406) 338–7544, Superintendent; (406) 338–7519, Irrigation Project Manager.
Crow Irrigation Project	Vianna Stewart, Superintendent, Karl Helvik, Acting Irrigation Project Manager, P.O. Box 69, Crow Agency, MT 59022, Telephones: (406) 638–2672, Superintendent; (406) 247–7469, Acting Irrigation Project Manager.
Fort Belknap Irrigation Project	John St. Pierre, Superintendent, Vacant, Irrigation Project Manager, (Project operations & maintenance contracted to Tribes), R.R.1, Box 980, Harlem, MT 59526, Telephones: (406) 353–2901, Superintendent; (406) 353–8454, Irrigation Project Manager (Tribal Office).
Fort Peck Irrigation Project	Howard Beemer, Superintendent, Huber Wright, Acting Irrigation Project Manager, P.O. Box 637, Poplar, MT 59255, Telephones: (406) 768–5312, Superintendent; (406) 653–1752, Irrigation Project Manager.
Wind River Irrigation Project	Norma Gourneau, Superintendent, Karl Helvik, Acting Irrigation Project Manager, P.O. Box 158, Fort Washakie, WY 82514, Telephones: (307) 332–7810, Superintendent; (406) 247–7469, Acting Irrigation Project Manager.
Southwest Region Contacts	
William T. Walker, Regional Director, Bureau of Indian Affairs, Southwest Regional Office, 1001 Indian School Road, Albuquerque, NM 87104, Telephone: (505) 563–3100.	
Pine River Irrigation Project	Priscilla Bancroft, Superintendent, Vickie Begay, Irrigation Project Manager, P.O. Box 315, Ignacio, CO 81137–0315, Telephones: (970) 563–4511, Superintendent; (970) 563–9484, Irrigation Project Manager.
Western Region Contacts	
Bryan Bowker, Regional Director, Bureau of Indian Affairs, Western Regional Office, 2600 N. Central Ave., 4th Floor Mailroom, Phoenix, AZ 85004, Telephone: (602) 379–6600.	
Colorado River Irrigation Project	Kellie Youngbear Superintendent, Gary Colvin, Irrigation Project Manager, 12124 1st Avenue, Parker, AZ 85344, Telephone: (928) 669–7111.

Project name	Project/agency contacts
Duck Valley Irrigation Project	Joseph McDade, Superintendent, (Project operations & management compacted to Tribes), 2719 Argent Ave., Suite 4, Gateway Plaza, Elko, NV 89801, Telephone: (775) 738–5165; (208) 759–3100, (Tribal Office).
Yuma Project, Indian Unit	Irene Herder, Superintendent, 256 South Second Avenue, Suite D, Yuma, AZ 85364, Telephone: (928) 782–1202.
San Carlos Irrigation Project Indian Works and Joint Works.	Ferris Begay, Project Manager, Clarence Begay, Irrigation Manager, 13805 N. Arizona Boulevard, Coolidge, AZ 85128, Telephone: (520) 723–6225.
Uintah Irrigation Project	Bart Stevens Superintendent, Ken Asay, Irrigation System Manager, P.O. Box 130, Fort Duchesne, UT 84026, Telephone: (435) 722–4300, (435) 722–4344.
Walker River Irrigation Project	Robert Eben, Superintendent, 311 E. Washington Street, Carson City, NV 89701, Telephone: (775) 887–3500.

What irrigation assessments or charges are proposed for adjustment by this notice?

The rate table below contains the current rates for all irrigation projects where we recover costs of administering, operating, maintaining, and rehabilitating them. The table also contains the proposed rates for the CY 2016 and subsequent years where applicable. An asterisk immediately following the rate category notes the irrigation projects where rates are proposed for adjustment.

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Northwest Region Rate Table				
Project Name	Rate Category	Final 2015 Rate	Final 2016 Rate	Proposed 2017 Rate **
Flathead Irrigation Project (See Note #1)	Basic per acre – A *	$26.00	$26.00	$33.50
	Basic per acre – B *	$13.00	$13.00	$16.75
	Minimum Charge per tract	$75.00	$75.00	$75.00

Project Name	Rate Category	Final 2015 Rate	Proposed 2016 Rate
Fort Hall Irrigation Project	Basic per acre *	$49.00	$52.00
	Minimum Charge per tract *	$35.00	$37.00
Fort Hall Irrigation Project - Minor Units	Basic per acre *	$27.00	$31.00
	Minimum Charge per tract *	$35.00	$37.00
Fort Hall Irrigation Project – Michaud	Basic per acre *	$50.50	$55.00
	Pressure per acre *	$72.50	$83.00
	Minimum Charge per tract *	$35.00	$37.00
Wapato Irrigation Project – Toppenish/Simcoe Units	Minimum Charge per bill *	$24.00	$25.00
	Basic per acre *	$24.00	$25.00
Wapato Irrigation Project - Ahtanum Units	Minimum Charge per bill *	$25.00	$30.00
	Basic per acre *	$25.00	$30.00
Wapato Irrigation Project - Satus Unit	Minimum Charge per bill	$79.00	$79.00
	"A" Basic per acre	$79.00	$79.00
	"B" Basic per acre	$85.00	$85.00
Wapato Irrigation Project -	Minimum Charge per bill *	$75.00	$78.00

Additional Works	Basic per acre *	$75.00	$78.00
Wapato Irrigation Project - Water Rental	Minimum Charge	$86.00	$86.00
	Basic per acre	$86.00	$86.00

Rocky Mountain Region Rate Table

Project Name	Rate Category	Final 2015 Rate	Proposed 2016 Rate
Blackfeet Irrigation Project	Basic-per acre	$20.00	$20.00
Crow Irrigation Project – Willow Creek O&M (includes Agency, Lodge Grass #1, Lodge Grass #2, Reno, Upper Little Horn, and Forty Mile Units)	Basic-per acre *	$24.80	$26.00
Crow Irrigation Project – All Others (includes Bighorn, Soap Creek, and Pryor Units)	Basic-per acre *	$24.80	$26.00
Crow Irrigation Project - Two Leggins Unit	Basic-per acre	$14.00	$14.00
Crow Irrigation Two Leggins Drainage District	Basic-per acre	$2.00	$2.00
Fort Belknap Irrigation Project	Basic-per acre *	$15.00	$16.00
Fort Peck Irrigation Project	Basic-per acre	$26.00	$26.00
Wind River Irrigation Project – Units 2, 3 and 4	Basic-per acre *	$21.00	$22.50
Wind River Irrigation Project – Unit 6	Basic-per acre	$21.00	$21.00
Wind River Irrigation Project – LeClair District (See Note #2)	Basic-per acre *	$25.70	$47.00
Wind River Irrigation Project – Crow Heart Unit	Basic-per acre *	$14.00	$15.50
Wind River Irrigation Project – A Canal Unit	Basic-per acre *	$ 14.00	$15.50

Wind River Irrigation Project – Riverton Valley Irrigation District	Basic-per acre *	$21.00	$26.00

Southwest Region Rate Table			
Project Name	Rate Category	Final 2015 Rate	Proposed 2016 Rate
Pine River Irrigation Project	Minimum Charge per tract	$50.00	$50.00
	Basic-per acre *	$17.00	$18.00

Western Region Rate Table			
Project Name	Rate Category	Final 2015 Rate	Proposed 2016 Rate
Colorado River Irrigation Project	Basic per acre up to 5.75 acre-feet	$54.00	$54.00
	Excess Water per acre-foot over 5.75 acre-feet	$17.00	$17.00
Duck Valley Irrigation Project	Basic per acre *	$5.30	$6.30
Yuma Project, Indian Unit (See Note #3)	Basic per acre up to 5.0 acre-feet *	$108.50	$113.00
	Excess Water per acre-foot over 5.0 acre-feet	$24.50	$24.50
	Basic per acre up to 5.0 acre-feet (Ranch 5) *	$108.50	$113.00

Project Name	Rate Category	Final 2015 Rate	Final 2016 Rate	Proposed 2017 Rate **
San Carlos Irrigation Project (Joint Works) (See Note #4)	Basic per acre *	$35.00	$30.00	$25.00
	Proposed 2016 – 2017 Construction Water Rate Schedule:			
		Off Project Construction	On Project Construction – Gravity Water	On Project Construction – Pump Water
	Administrative Fee	$300.00	$300.00	$300.00
	Usage Fee	$250.00 per month	No Fee	$100.00 per acre foot
	Excess Water Rate †	$5.00 per 1,000 gal.	No Charge	No Charge
	† The excess water rate applies to all water used in excess of 50,000 gallons in any one month.			

Project Name	Rate Category	Final 2015 Rate	Proposed 2016 Rate
San Carlos Irrigation Project (Indian Works) (See Note#5)	Basic per acre *	$86.00	$81.00
Uintah Irrigation Project	Basic per acre	$18.00	$18.00
	Minimum Bill	$25.00	$25.00
Walker River Irrigation Project	Basic per acre	$31.00	$31.00

*	Notes irrigation projects where rates are proposed for adjustment
**	The requirement for a proposed 2017 Rate is only applicable to the Flathead and San Carlos Irrigation Projects due to their specific billing requirements.
Note #1	Federal Register Notice published April 29, 2016 established the final 2016 rate for the Flathead Irrigation Project (81 FR 25691). This notice proposes the 2017 rate for the Flathead Irrigation Project.
Note #2	The O&M rate varies yearly based upon the budget submitted by the LeClair District.
Note #3	The O&M rate for the Yuma Project, Indian Unit has two components. The first component is the O&M rate established by the Bureau of Reclamation (BOR), the owner and operator of the Project. The BOR rate for 2016 is proposed to be $110/acre. The second component is for the O&M rate established by BIA to cover administrative costs including billing and collections for the Project. The 2016 BIA rate is $3.00/acre.
Note #4	The construction water rate schedule proposes the fees assessed for use of irrigation water for non-irrigation purposes. Federal Register Notice published April 29, 2016 established the final 2016 rate for the SCIP-JW (81 FR 25691). This notice proposes the 2017 rate for the SCIP-JW.
Note #5	The proposed 2016 O&M rate for the San Carlos Irrigation Project – Indian Works has three components. The first component is the O&M rate established by the San Carlos Irrigation Project – Indian Works, the owner and operator of the Project; this rate is proposed to be $51 per acre. The second component is for the O&M rate established by the San Carlos Irrigation Project – Joint Works and is determined to be $25.00 per acre. The third component is the O&M rate established by the San Carlos Irrigation Project Joint Control Board and is proposed to be $5 per acre.

Consultation and Coordination With Tribal Governments (Executive Order 13175)

The Department of the Interior strives to strengthen its government-to-government relationship with Indian Tribes through a commitment to consultation with Indian Tribes and recognition of their right to self-governance and Tribal sovereignty. We have evaluated this notice under the Department's consultation policy and under the criteria of Executive Order 13175 and have determined there to be substantial direct effects on federally recognized Tribes because the irrigation projects are located on or associated with Indian reservations. To fulfill its consultation responsibility to Tribes and Tribal organizations, BIA communicates, coordinates, and consults on a continuing basis with these entities on issues of water delivery, water availability, and costs of administration, operation, maintenance, and rehabilitation of projects that concern them. This is accomplished at the individual irrigation project by project, agency, and regional representatives, as appropriate, in accordance with local protocol and procedures. This notice is one component of our overall coordination and consultation process to provide notice to, and request comments from, these entities when we adjust irrigation assessment rates.

Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (Executive Order 13211)

The proposed rate adjustments are not a significant energy action under the definition in Executive Order 13211. A Statement of Energy Effects is not required.

Regulatory Planning and Review (Executive Order 12866)

These proposed rate adjustments are not a significant regulatory action and do not need to be reviewed by the Office of Management and Budget under Executive Order 12866.

Regulatory Flexibility Act

These proposed rate adjustments are not a rule for the purposes of the Regulatory Flexibility Act because they establish ''a rule of particular applicability relating to rates.'' 5 U.S.C. 601(2).

Unfunded Mandates Reform Act of 1995

These proposed rate adjustments do not impose an unfunded mandate on State, local, or tribal governments in the aggregate, or on the private sector, of more than $100 million per year. The rule does not have a significant or unique effect on State, local, or Tribal governments or the private sector. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

Takings (Executive Order 12630)

These proposed rate adjustments do not effect a taking of private property or otherwise have ''takings'' implications under Executive Order 12630. The proposed rate adjustments do not deprive the public, state, or local governments of rights or property.

Federalism (Executive Order 13132)

Under the criteria in section 1 of Executive Order 13132, these proposed rate adjustments do not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement because they will not affect the States, the relationship between the national government and the States, or the distribution of power and responsibilities among various levels of government. A federalism summary impact statement is not required.

Civil Justice Reform (Executive Order 12988)

This notice complies with the requirements of Executive Order 12988. Specifically, in issuing this notice, the Department has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct, as required by section 3 of Executive Order 12988.

Paperwork Reduction Act of 1995

These proposed rate adjustments do not affect the collections of information which have been approved by the Office of Information and Regulatory Affairs, Office of Management and Budget, under the Paperwork Reduction Act of 1995. The OMB Control Number is 1076–0141 and expires June 30, 2019.

National Environmental Policy Act

The Department has determined that these proposed rate adjustments do not constitute a major Federal action significantly affecting the quality of the human environment and that no detailed statement is required under the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370(d)).

Dated: August 1, 2016.

Lawrence S. Roberts,

Principal Deputy Secretary—Indian Affairs.

[FR Doc. 2016–18642 Filed 8–4–16; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCON04000 L16100000.DP000]

Notice of Availability of the Final Environmental Impact Statement for Previously Issued Oil and Gas Leases in the White River National Forest, Colorado

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: In compliance with the National Environmental Policy Act of 1969, as amended (NEPA), the Bureau of Land Management (BLM) Colorado River Valley Field Office (CRVFO), located in Silt, Colorado, prepared a Final Environmental Impact Statement (EIS) that analyzes the environmental impacts of previous decisions to issue 65 leases on lands within the White River National Forest (WRNF) from 1995 to 2012.

DATES: The BLM will not issue a final decision on the proposal for a minimum of 30 days after the date that the Environmental Protection Agency publishes its Notice of Availability in the **Federal Register**.

ADDRESSES: Copies of the Previously Issued Oil and Gas Leases in the WRNF Final EIS are available for public inspection at the CRVFO, 2300 River Frontage Road, Silt, CO 81652. Interested persons may also review the Final EIS on the project Web site at *http://www.blm.gov/co/st/en/fo/crvfo.html.*

FOR FURTHER INFORMATION CONTACT: Greg Larson, Project Manager, at the address above, by telephone at 970–876–9000, or by email at *glarson@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, seven days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The BLM developed this EIS to address a NEPA deficiency identified by the Interior Board of Land Appeals (IBLA) related to the issuance of oil and gas leases on WRNF lands from 1995 to 2004. In 2007, the IBLA ruled that before including WRNF parcels in an oil and gas lease sale, the BLM must either formally adopt the NEPA analysis completed by the U.S. Forest Service (USFS) or conduct a NEPA analysis of its own (*Board of Commissioners of Pitkin County,* 173 IBLA 173 (2007)). The BLM canceled the three leases at issue in that case and has identified 65 additional leases with effective dates ranging from 1995 to 2012, which the BLM leased without either: (i) Adopting applicable USFS NEPA, or (ii) Preparing its own NEPA analysis. For these 65 existing leases, the most recent USFS decision to make these lands available for oil and gas leasing was analyzed in the 1993 USFS WRNF Oil and Gas Leasing EIS, which was reaffirmed in the 2002 WRNF Plan.

While the BLM obtained USFS consent before offering and subsequently issuing these 65 leases, it did not adopt the USFS' NEPA analysis or prepare its own analysis. As a result, the BLM determined that the issuance of the leases in question was not in compliance with applicable NEPA requirements, rendering the leases voidable. The BLM therefore determined that additional actions were necessary to either reaffirm, modify, or cancel those leases. As part of its determination of what additional action needs to be taken, the BLM determined that the WRNF NEPA analysis relevant to the 65 previously issued leases was no longer adequate due to changes in laws, regulations, policies and conditions since the earlier EIS was finalized in 1993. As a result, the BLM prepared this EIS, which analyzes the previous decisions to lease WRNF lands for oil and gas development.

Based on the analysis in the EIS, the BLM will determine whether these 65 leases should be cancelled, reaffirmed, or modified with additional or different terms. Distinct from this effort, the USFS has also been updating its 1993 Oil and Gas Leasing EIS to address future oil and gas leasing availability on the WRNF. The USFS released the Final EIS and Draft Record of Decision in December 2014. The Final USFS Record of Decision was signed in December 2015. The USFS EIS and ROD are forward-looking and do not directly affect the 65 previously issued leases; however, the information generated as part of that process was relevant to the BLM's analysis. As part of its process, the BLM has incorporated as much of the new USFS NEPA analysis of future oil and gas leasing on WRNF lands as possible into the BLM's analysis of the existing leases.

The BLM considered six alternatives in the Final EIS, including the *No Action Alternative.* The *No Action Alternative* would reaffirm the lease stipulations on the 65 leases as they were issued. Under this alternative, the BLM would take no action by continuing to administer the leases with their current stipulations. *Alternative 2* would address inconsistencies in some of the existing leases by adding stipulations identified in the 1993 WRNF EIS that should have been but were not attached to eight leases when they were issued. *Alternative 3* would modify the 65 leases to match the stipulations identified for future leasing in the 2014 USFS Final EIS Proposed Action. *Alternative 4* would modify or cancel the 65 leases to match the stipulations and availability decision for future leasing identified in the 2014 USFS Draft Record of Decision. In areas the USFS identified as open to future leasing, lease stipulations would be modified to track those found in the most recent decisions, and all or part of 25 existing leases in areas identified as closed to future leasing would be cancelled. *Alternative 5* would cancel all 65 leases.

For purposes of the Final EIS, the BLM identified a combination of Alternatives 2 and 4 as its Preferred Alternative. Under this alternative, the BLM would cancel in their entirety 25 leases that are not producing or committed to a unit or communitization agreement, and that overlap with the area identified as closed to future leasing by the USFS's Final Record of Decision (USFS 2015f). It would apply Alternative 4 stipulations (*i.e.,* those that were identified in the 2015 USFS Record of Decision) to the 13 undeveloped leases that are within parts of the WRNF identified as open to future leasing, and would apply *Alternative 2* stipulations (*i.e.,* those

identified in the 1993 WRNF EIS) to the 23 leases that are producing or committed to a unit agreement or communitization agreement. Four of these leases had previously been part of the Willow Creek Unit and are now expired. If the unit contraction associated with these 4 leases is overturned on appeal, those leases would be reauthorized and the *Alternative 2* stipulations would apply. As with *Alternative 4,* the BLM would offer the lessee the option of either accepting the new stipulations or having the lease in question cancelled. For undeveloped leases, cancellation would be accomplished through a BLM process and would require that the BLM reimburse any bonus bids and rental payments.

The BLM developed this Preferred Alternative to address public comments and concerns submitted in response to the Draft EIS, while acknowledging recent decisions by the USFS governing future oil and gas leasing on the WRNF. The Preferred Alternative also recognizes the adverse economic impacts to local governments and technical challenges for the BLM associated with any decision to cancel producing or committed leases.

The Draft EIS was released on November 20, 2015 (80 FR 72733), for a 49-day public comment period. During that period, the BLM held three public meetings in communities near the project area: Glenwood Springs, DeBeque and Carbondale, Colorado. The BLM received 60,515 comments during the formal comment period. The BLM worked with cooperating agencies (including the Environmental Protection Agency; USFS; the Colorado Department of Natural Resources, including Colorado Parks and Wildlife; Garfield, Mesa, Pitkin and Rio Blanco counties; the Cities of Glenwood Springs and Rifle, and the Towns of Carbondale, New Castle, Parachute and Silt) to prepare the Final EIS. The BLM also consulted with the U.S. Fish and Wildlife Service (Service) informally and through a Biological Assessment; the Service issued a consultation memorandum on May 19, 2016, concurring with the BLM effects determinations of ''may affect, but is not likely to adversely affect'' for Ute ladies'-tresses orchid, Colorado hookless cactus and its critical habitat, Western yellow-billed cuckoo, Green-lineage cutthroat trout, Colorado pikeminnow and its critical habitat, Razorback sucker and its critical habitat, Humpback chub and its critical habitat, Bonytail and its critical habitat, and Canada lynx. In addition, the BLM notified the Colorado State Historic Preservation Office (SHPO) via an informational letter that pursuant to the 2014 Protocol agreement between the BLM Colorado and the SHPO, this undertaking does not exceed any of the review thresholds that would require SHPO concurrence, and that there will be no adverse effect to historic properties. Finally, the BLM began tribal consultation for the project in April 2014 when the field manager sent a scoping letter via certified mail to the Ute Indian Tribe (Uintah and Ouray Reservation), Ute Mountain Ute Tribe, and Southern Ute Indian Tribe. Consultation and outreach continued through April 22, 2016, when the BLM sent the tribes a letter that identified the Preferred Alternative and summarized cultural resource records within the area of potential effect (including potential Traditional Cultural Properties). The letter also offered the opportunity for comments or clarifications. The BLM will continue to offer opportunities for the tribes to identify properties of possible traditional religious and cultural importance that may be affected by the alternatives and to express their concerns throughout the project as stipulated under EO 13175, November 6, 2000.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 40 CFR 1506.6, 40 CFR 1506.10

Ruth Welch,

BLM Colorado State Director.

[FR Doc. 2016–18542 Filed 8–4–16; 8:45 am]

BILLING CODE 4310–JB–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

[RR03510000, XXXR0680R1, RR171260120019400]

Notice of Intent To Prepare an Environmental Impact Report/ Environmental Impact Statement for the Pure Water San Diego Program, North City Project, San Diego County, California

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Reclamation and the City of San Diego will prepare a joint Environmental Impact Report/ Environmental Impact Statement to evaluate the effects of the North City Project, the first phase of the Pure Water San Diego Program (Pure Water Program). The Pure Water Program is a water and wastewater facilities plan to produce potable water from recycled water.

Interested parties are invited to comment on the scope of the environmental analysis and the proposed alternatives. Two public meetings are scheduled.

DATES: Please submit written comments on or before September 6, 2016.

Public meeting dates:

1. August 23, 2016, 6 p.m. to 7:30 p.m., Scripps Miramar Ranch Public Library.

2. August 25, 2016, 6:30 p.m. to 8 p.m., City of San Diego Public Utilities Department.

ADDRESSES: Send written comments to Doug McPherson, Southern California Area Office, Bureau of Reclamation, 27708 Jefferson Avenue, Suite 202, Temecula, CA 92590; or email to *dmcpherson@usbr.gov.*

Public meeting locations:

1. Scripps Miramar Ranch Public Library, 10301 Scripps Lake Drive, San Diego, CA.

2. City of San Diego Public Utilities Department, 9192 Topaz Way, San Diego, CA.

FOR FURTHER INFORMATION CONTACT: Doug McPherson, Southern California Area Office general telephone number 951–695–5310; or email *dmcpherson@usbr.gov.*

SUPPLEMENTARY INFORMATION: This notice is provided pursuant to the National Environmental Policy Act (NEPA) (42 U.S.C. 4332(2)(c)), and Department of the Interior regulations for implementation of NEPA (43 CFR part 46).

North City Project

The proposed project will expand the existing North City Water Reclamation Plant and construct an adjacent Advanced Water Purification Facility with a purified water pipeline to Miramar Reservoir. A project alternative would install a longer pipeline to deliver product water to the larger San Vicente reservoir.

Other project components include: A new pump station and forcemain to deliver additional wastewater to the North City Water Reclamation Plant, a brine discharge pipeline, and upgrades to the existing Metropolitan Biosolids Center to accommodate additional

biosolids from the increased treatment capacity at the North City Water Reclamation Plant.

A new electrical transmission line is proposed, connecting the North City Water Reclamation Plant to the future cogeneration facility at the Metropolitan Biosolids Center to deliver power for North City Project components. The electrical transmission line would cross Marine Corps Air Station Miramar and will require approval by the United States Marine Corps.

Background

On average, eighty-five percent (85%) of the City's water supply is imported from the Colorado River and northern California. This reliance on imported water causes San Diego to be vulnerable to supply shortages and price increases.

With few local water supply options, the City has explored potable and non-potable reuse options of treated wastewater. In 2011, the City started operating a one million gallon per day (MGD) demonstration scale advanced water purification facility at the North City Water Reclamation Plant site and confirmed that the purified water complied with all federal and state drinking water standards.

Pure Water San Diego Program

The Pure Water Program will ultimately produce 83 MGD of locally-controlled water, recycling a valuable and limited resource that is currently discharged to the Pacific ocean. The program will be implemented in phases over a 20-year period, grouped by geographical area: North City, Central Area and South Bay.

The North City Project will produce 30 MGD of purified water and is scheduled to be operational in 2021. The Central Area and/or South Bay projects are scheduled to be completed by December 31, 2035 and will produce a combined total up to 53 MGD.

The Pure Water Program will make San Diego more water independent while providing increased protection of the ocean environment. The City made a commitment to begin implementing the Pure Water Program in their application to renew the Clean Water Act § 301(h) modified ocean discharge permit for the Point Loma Wastewater Treatment Plant (NPDES permit no. CA0107409).

Authority

Federal assistance is authorized by the Reclamation Wastewater and Groundwater Study and Facilities Act of 1992 (Title XVI of Pub. L. 102–575). Section 1612, San Diego Area Water Reclamation Program, directs the Secretary of the Interior, in cooperation with the city of San Diego, to participate in the planning, design, and construction of demonstration and permanent facilities to reclaim and reuse water in the San Diego metropolitan service area. This authority is delegated to the Bureau of Reclamation. The Federal share of the costs of the facilities shall not exceed 25 per cent of the total. Federal Funds for the operation or maintenance of the project are not authorized.

Scoping Process

The City is filing a Notice of Preparation pursuant to the California Environmental Quality Act, and will hold two public scoping meetings. To avoid duplication with State and local procedures, we plan to use the scoping process initiated by the City. The Notice of Preparation, Notice of Scoping Meetings, and a proposed Scope of Work are available at *https://www.sandiego.gov/planning/programs/ceqa.*

The site proposed for the Advanced Water Purification Facility contains vernal pool habitat supporting endangered species. The City is preparing a Vernal Pool Habitat Conservation Plan to comply with the Endangered Species Act.

Pipeline alignments and/or drinking water service areas may include areas of low income and minority populations. Environmental justice issues are not anticipated, but will be evaluated. No known Indian Trust Assets are associated with the proposed action.

Written comments are requested to help identify alternatives and issues that should be analyzed. Federal, State and local agencies, tribes, and the general public are invited to participate in the environmental review process.

Public Disclosure

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.

Dated: July 29, 2016.

Jennifer McCloskey,

Acting Regional Director, Lower Colorado Region.

[FR Doc. 2016–18616 Filed 8–4–16; 8:45 am]

BILLING CODE 4332–90–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

[S1D1S SS08011000 SX064A000 167S180110; S2D2S SS08011000 SX064A000 16XS501520]

Notice of Proposed Information Collection; Request for Comments for 1029–0117

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Office of Surface Mining Reclamation and Enforcement (OSMRE) is announcing its intention to request renewed approval for the collection of information for Permit Applications—Minimum Requirements for Legal, Financial, Compliance, and Related Information. The information collection request has been forwarded to the Office of Management and Budget (OMB) for review and approval. The information collection request describes the nature of the information collection and the expected burden and cost.

DATES: OMB has up to 60 days to approve or disapprove the information collection but may respond after 30 days. Therefore, the public should submit comments to OMB by September 6, 2016, in order to be assured of consideration.

ADDRESSES: Comments may be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget, Department of the Interior Desk Officer, via email at *OIRA_submission@omb.eop.gov,* or by facsimile to (202) 395–5806. Also, please send a copy of your comments to John Trelease, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Ave. NW., Room 203—SIB, Washington, DC 20240, or electronically to *jtrelease@osmre.gov.* Please reference 1029–0117 in your correspondence.

FOR FURTHER INFORMATION CONTACT: To receive a copy of the information collection request contact John Trelease at (202) 208–2783, or electronically at *jtrelease@osmre.gov.* You may also review the information collection request online at *http://www.reginfo.gov.* Follow the instructions to review Department of the Interior collections under review by OMB.

SUPPLEMENTARY INFORMATION: OMB regulations at 5 CFR 1320, which implement provisions of the Paperwork

Reduction Act of 1995 (Pub. L. 104–13), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities [see 5 CFR 1320.8(d)]. OSMRE has submitted a request to OMB to approve the collection of information for 30 CFR part 778—Permit Applications—Minimum Requirements for Legal, Financial, Compliance, and Related Information. OSMRE is requesting a 3-year term of approval for this information collection activity.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this collection of information is displayed in 30 CFR 778.8 (1029–0117).

As required under 5 CFR 1320.8(d), a **Federal Register** notice soliciting comments on this collection of information was published on March 18, 2016 (81 FR 14888). No comments were received. This notice provides the public with an additional 30 days in which to comment on the following information collection activity:

Title: 30 CFR part 778—Permit Applications—Minimum Requirements for Legal, Financial, Compliance, and Related Information.

OMB Control Number: 1029–0117.

Summary: Section 507(b) of 30 U.S.C. 1201 provides that persons conducting coal mining activities submit to the regulatory authority all relevant information regarding ownership and control of the property affected, their compliance status and history. This information is used to ensure all legal, financial and compliance requirements are satisfied prior to issuance or denial of a permit.

Bureau Form Number: None.

Frequency of Collection: Once.

Description of Respondents: Surface coal mining permit applicants and State regulatory authorities.

Total Annual Responses: 1,091 Surface coal mining permit applicants and 448 State regulatory authorities.

Total Annual Burden Hours: 4,512.

Total Non-Wage Costs: $0.

Send comments on the agency need for the collection of information to perform its mission; the accuracy of our burden estimates; ways to enhance the quality, utility and clarity of the information collection; and ways to minimize the information collection burden on respondents, such as use of automated means of collection of the information, to the offices listed in the **ADDRESSES** section. Please refer to OMB control number 1029–0117 in all correspondence.

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.

Dated: August 1, 2016.

John A. Trelease,

Acting Chief, Division of Regulatory Support.

[FR Doc. 2016–18630 Filed 8–4–16; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140–0026]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Report of Theft or Loss of Explosives (ATF Form 5400.5)

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

ACTION: 30-day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), 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 was previously published in the **Federal Register** 81 FR 35062, on June 1, 2016, allowing for a 60-day comment period.

DATES: Comments are encouraged and will be accepted for an additional 30 days until September 6, 2016.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on 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 Jason Lynch, United States Bomb Data Center, 3750 Corporal Road, Redstone Arsenal, AL 35898, at email: *Jason.Lynch@ATF.gov.*

Written comments and/or suggestions can also be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503 or sent to *OIRA_submissions@omb.eop.gov.*

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:* Extension without change of a currently approved collection.

2. *The Title of the Form/Collection:* Report of Theft or Loss of Explosives.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number: ATF Form 5400.5.

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: Individuals or households, Not-for-profit institutions, Farms, Federal Government, and State, Local, or Tribal Government.

Abstract: According to 27 CFR 555.30(a) Any licensee or permittee who has knowledge or theft or loss of any explosive materials from his stock shall, within 24 hours of discovery, report the theft or loss by telephoning 1–800–800–3855 (nationwide toll free number) and on ATF F 5400.5, Report of Theft or Loss of Explosives, in accordance with the instructions on the form.

5. *An estimate of the total number of respondents and the amount of time*

estimated for an average respondent to respond: An estimated 300 respondents will take 1 hour and 48 minutes to complete the form.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 540 hours.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., Room 3E–405B, Washington, DC 20530.

Dated: August 2, 2016.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2016–18602 Filed 8–4–16; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

[OMB Number [1123–0013]]

Agency Information Collection Activities: Proposed eComments eCollection Requested; Notice of Non-Substantive Change Request to a Previously Approved Collection

AGENCY: Criminal Division, Department of Justice.

ACTION: Notice.

DATES: The notice is effective August 5, 2016.

SUMMARY: The United States Victims of State Sponsored Terrorism Fund, Department of Justice (DOJ), Criminal Division, submitted a non-substantive change request to an approved collection to the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: The Special Master, United States Victims of State Sponsored Terrorism Fund, or the Chief, Program Management and Training Unit, Asset Forfeiture and Money Laundering Section, Criminal Division, Department of Justice, 950 Pennsylvania Avenue NW, Washington, DC 20530–0001, telephone (202) 353–2046.

SUPPLEMENTARY INFORMATION: The Justice for United States Victims of State Sponsored Terrorism Act (Act), part of the Consolidated Appropriations Act of 2016, established the U.S. Victims of State Sponsored Terrorism Fund (Fund), overseen by a Special Master, to provide compensation to certain eligible individuals who were injured in acts of state sponsored terrorism. *See* 42 U.S.C. 10609. The Act required the Special Master to publish, within 60 days of his appointment by the Attorney General, a notice in the **Federal Register** specifying the procedure by which eligible United States persons may apply and establish eligibility for payment. *See id.* 10609(b)(2)(A). Under 42 U.S.C. 10609(c)(3)(A)(i), claimants with eligible final judgments and those Iran hostages taken and held hostage from the U.S. Embassy in Tehran, Iran, during the period beginning November 4, 1979, and ending January 20, 1981, if such person is identified as a member of the proposed class in case number 1:00–CV–03110 (EGS) of the United States District Court for the District of Columbia, and their spouses and children, have 90 days after the publication of the Fund's notice in the **Federal Register** to file an application for payment from the Fund. Accordingly, because claimants could apply for payment from the Fund upon the date of publication of the notice in the **Federal Register**, and for 90 days thereafter, the Fund developed an Application Form to assist with the claim filing.

On July 7, 2016, the Special Master submitted to OMB an emergency information collection request for the U.S. Victims of State Sponsored Terrorism Application Form in accordance with the Paperwork Reduction Act of 1995. On July 14, 2016, the Fund published its Notice in the **Federal Register** pursuant to 42 U.S.C. 10609(b)(2). Thus, under 42 U.S.C. 10609(c)(3)(A)(i), the Fund could begin to accept applications. On July 15, 2016, OMB approved the emergency information collection request, thereby authorizing the availability and use of the Application Form.

Part V of the Fund's Application Form, titled NOTICE TO INDIVIDUALS OF FILING OF CLAIM, specifically references a notice of filing claim for use by those applicants filing claims on behalf of deceased individuals and states that ''[t]he 'Additional Forms' page of the Fund Web site contains the notice [the Personal Representative] must provide to the required individuals.'' This notice of filing claim is required under part VII.2.a of the Fund's Notice published in the **Federal Register**, which requires that ''[a]ny purported Personal Representative must, before filing a claim, provide written notice of the claim to the immediate family of the decedent; to the executor, administrator, and beneficiaries of the decedent's will; and to any other persons who may reasonably be expected to assert an interest in an award or to have a cause of action to recover damages relating to the wrongful death of the decedent.'' The Fund inadvertently did not, however, include the notice of filing claim as part of the Application Form and request for emergency collection of information for review and approval by OMB. Both the emergency collection of information request and the Application Form were drafted expeditiously in order to coincide with the publication of the Notice in the **Federal Register** and also to meet the other strict statutory time frames in the Act, including being able to authorize initial payments by December 18, 2016, in accordance with 42 U.S.C. 10609(d)(2). Accordingly, on July 28, 2016, the Fund submitted a non-substantive change request to OMB for the notice of filing claim in order to clarify the already approved collection and complete the Application Form. The only aspect of the notice of filing claim that effected a change in the information collection was the inclusion of a drafted sample notice of filing claim for use by those applicants filing an application with the Fund on behalf of a deceased individual. The notice of filing claim for use by an applicant is not mandatory, but was prepared to assist those applying as Personal Representatives of deceased individuals to satisfy the written notice requirements in the Fund's Notice published in the **Federal Register**. The inclusion of the notice of filing claim with the Application Form did not add substantial burden hours to the information collection and was necessary to provide applicants a complete Application Form.

At present, the Fund is preparing the 60-day notice of information collection request to OMB in accordance with the Paperwork Reduction Act of 1995. The notice will allow 60 days for public comment preceding submission of the collection to OMB. The notice of filing claim will be included as part of that information collection request to OMB.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., 3E.405B, Washington, DC 20530.

Dated: August 1, 2016.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2016–18582 Filed 8–4–16; 8:45 am]

BILLING CODE 4410–14–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Judgment Under the Resource Conservation and Recovery Act

On August 1, 2016, the Department of Justice lodged a proposed Consent Judgment with the United States District Court for the Eastern District of New York in the lawsuit entitled *United States* v. *Nedjet Yetim, et al.,* Civil Action No. 14–0847.

The proposed consent judgment will resolve the United States' claims under Section 9006 of the Resource Recovery and Conservation Act, as amended, on behalf of the U.S. Environmental Protection Agency, against the following defendants: Rachelann Yetim, Black Realty, Inc., Fast Gasoline Station, Inc., TAG Gasoline, Inc., NGRV Realty Co., Inc., and Venus Bukey Realty, Inc. (the ''Rachelann Defendants''). The United States alleges that the Rachelann Defendants violated the regulations set forth at 40 CFR part 280, governing underground storage tanks (''USTs''), at three facilities—automobile fueling stations with USTs—that the Rachelann Defendants have owned and/or operated at the following locations:

1. 653 Hempstead Turnpike, Elmont, New York
2. 725 Wyandanch Ave, North Babylon, New York
3. 4305 Austin Blvd., Island Park, New York

The consent judgment requires the Rachelann Defendants to pay a civil penalty of $60,000, which was calculated after conducting an ability-to-pay analysis. The consent judgment also provides for injunctive relief, which will consist of maintaining compliance with the UST regulations and submission of reports demonstrating such compliance, to be implemented over the next three years at the Rachelann Defendants' facilities.

The publication of this notice opens a period for public comment on the proposed Consent Judgment. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *Nedjet Yetim, et al.,* D.J. Ref. No. 90–7–1–10743. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	Send them to:
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the proposed Consent Judgment may be examined and downloaded at this Justice Department Web site: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the proposed Consent Judgment upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $9.00 (25 cents per page reproduction cost) payable to the United States Treasury.

Robert E. Maher, Jr.,

Assistant Section Chief, Environmental Enforcement Section.

[FR Doc. 2016–18603 Filed 8–4–16; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Under the Clean Air Act

On August 1, 2016, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Eastern District of Missouri in *United States and the State of Missouri* v. *Lone Star Industries, Inc,.* Civil Action No. 16–206.

The Consent Decree settles claims brought by the United States and the State of Missouri for violations of the Clean Air Act, federal regulations promulgated thereunder, and various state regulations and permits at Defendant's cement manufacturing facility located in Cape Girardeau, Missouri. Under the Consent Decree, Defendant will undertake measures to correct the alleged violations, pay a civil penalty of $60,000 to the United States and State of Missouri, and perform a project to mitigate excess emissions associated with the violations.

The publication of this notice opens a period for public comment on the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States et al.* v. *Lone Star Industries, Inc.,* D.J. Ref. No. 90–5–2–1–09889/1. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	Send them to:
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department Web site: *https://www.justice.gov/enrd/consent-decrees.*

We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $12.5 (25 cents per page reproduction cost) payable to the United States Treasury.

Susan M. Akers,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2016–18561 Filed 8–4–16; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Employment and Training Administration

Agency Information Collection Activities; Comment Request; ETA 5130, Benefit Appeals Report; Extension With Revision (OMB Control No. 1205–0172). This Report Has Removed All Occurrences of Federal Emergency Unemployment Compensation Program, Which Expired on January 1, 2014

ACTION: Notice.

SUMMARY: The Department of Labor (DOL), Employment and Training Administration, is soliciting comments concerning a proposed extension for the authority to conduct the information collection request (ICR) titled, ''Benefits Appeals Report.'' This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.*

DATES: Consideration will be given to all written comments received by October 4, 2016.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free by contacting Stephanie Garcia by telephone at (202) 693–3207 (*this is not a toll-free number*) or by email at *Garcia.Stephanie@dol.gov.*

Submit written comments about, or request a copy of, this ICR by mail or courier to the U.S. Department of Labor, Employment and Training Administration, Room S–4524, 200 Constitution Avenue NW., Washington, DC 20210; or by email to *Garcia.Stephanie@dol.gov.*

Authority: 44 U.S.C. 3506(c)(2)(A).

SUPPLEMENTARY INFORMATION: The DOL, as part of continuing efforts to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or continuing collections of information before submitting them to the OMB for final approval. This program helps to ensure requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed.

I. Background

The ETA–5130, Benefit Appeals Report, contains information on the number of unemployment insurance appeals and the resultant decisions classified by program, appeals level, cases filed and disposed of (workflow), and decisions by level, appellant, and issue. The data on this report are used by the Department of Labor to monitor the benefit appeals process in the State Workforce Agencies (SWAs) and to develop any needed plans for remedial action. The data are also needed for workload forecasts and to determine administrative funding. If this information were not available, developing problems might not be discovered early enough to allow for timely solutions and avoidance of time consuming and costly corrective action.

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 it is approved by the OMB under the PRA 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 Control Number. See 5 CFR 1320.5(a) and 1320.6.

Interested parties are encouraged to provide comments to the contact shown in the **ADDRESSES** section. Comments must be written to receive consideration, and they will be summarized and included in the request for OMB approval of the final ICR. In order to help ensure appropriate consideration, comments should mention OMB 1205–0172.

Submitted comments will also be a matter of public record for this ICR and posted on the Internet, without redaction. The DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive statements/information in any comments.

The DOL is particularly interested in comments that:

* 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;

* 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 automated collection techniques or other forms of information technology.

Type of Review: Extension with revision.
Agency: Employment and Training Administration.
Title of Collection: Benefit Appeals Report.
Agency Form Number: ETA 5130.
OMB Control Number: 1205–0172.
Affected Public: State Workforce Agencies.
Estimated Number of Respondents: 53.
Frequency: Monthly.
Total Responses: 53 respondents × 12 responses per year = 636 responses for the regular program, 53 respondents × 12 responses per year = 636 responses for the Federal-State extended benefit program for an estimated total of 1,272 responses.
Estimated Total Burden Hours: 1 hour.
Total Burden Cost (capital/startup): $0.
Total Burden Cost (operating/maintaining): $0.
Total Annual Estimated Burden Hours: 1,272 hours (636 hours for the ETA 5130 Regular report + 636 hours for the ETA 5130 Federal-State Extended Benefits report).

Portia Wu,

Assistant Secretary for Employment and Training Administration.

[FR Doc. 2016–18659 Filed 8–4–16; 8:45 am]

BILLING CODE 4510–FW–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2016–0002]

Federal Advisory Council on Occupational Safety and Health (FACOSH)

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for nominations to serve on FACOSH.

SUMMARY: The Assistant Secretary of Labor for Occupational Safety and Health invites interested individuals to submit nominations for membership on FACOSH.

DATES: You must submit (postmark, send, transmit, deliver) nominations by October 31, 2016.

ADDRESSES: You may submit nominations and supporting materials using one of the following methods:

Electronically: You may submit materials, including attachments, electronically at *http://www.regulations.gov,* the Federal eRulemaking Portal. Follow the online instructions for making submissions;

Facsimile (FAX): If your submission, including attachments, does not exceed 10 pages, you may FAX it to the OSHA Docket Office at (202) 693–1648; or

Mail, express delivery, hand delivery, or messenger/courier service: You may submit nominations and supporting materials to the OSHA Docket Office, Docket No. OSHA–2016–0002, Room N–2625, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–2350 (OSHA TTY (877) 889–5627). Deliveries (hand, express mail, messenger/courier service) are accepted during the Department's and the OSHA Docket Office's normal business hours, 8:15 a.m.–4:45 p.m., weekdays.

Instructions: Your nominations and supporting materials must include the agency/organization name and docket number for this **Federal Register** notice. Due to security-related procedures, receipt of submissions by regular mail may result in a significant delay. Please contact the OSHA Docket Office for information about security procedures

for submitting nominations and supporting materials by hand delivery, express delivery, and messenger/courier service. For additional information on submitting nominations and supporting materials, see Public Participation in the **SUPPLEMENTARY INFORMATION** section of this notice.

OSHA will post submissions, including any personal information provided, without change in the FACOSH docket and they may be available online at *http://www.regulations.gov.* Therefore, OSHA cautions individuals about submitting certain personal information, such as Social Security numbers and birthdates.

FOR FURTHER INFORMATION CONTACT: *For press inquiries:* Mr. Frank Meilinger, Director, OSHA Office of Communications, Room N–3647, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–1999; email *meilinger.francis2@dol.gov.*

For general information: Mr. Francis Yebesi, Director, OSHA Office of Federal Agency Programs, Room N–3622, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–2122; email *ofap@dol.gov.*

SUPPLEMENTARY INFORMATION:

The Assistant Secretary of OSHA invites interested individuals to submit nominations for membership on FACOSH.

Background: FACOSH is authorized to advise the Secretary of Labor (Secretary) on all matters relating to the occupational safety and health of federal employees (5 U.S.C. 7902; 29 U.S.C. 668, Executive Order 12196, as amended). This includes providing advice on how to reduce and keep to a minimum the number of injuries and illnesses in the federal workforce, and how to encourage the establishment and maintenance of effective occupational safety and health programs in each federal agency.

FACOSH membership: FACOSH is comprised of 16 members, 8 management representatives from federal agencies and 8 representatives from labor organizations that represent federal employees. The Secretary appoints FACOSH members to staggered terms of up to three years. The number of members the Secretary will appoint to three-year terms beginning January 1, 2017, are:

- Three labor representatives; and
- Three management representatives.

FACOSH members serve at the pleasure of the Secretary and may be appointed to successive terms. FACOSH meets at least twice a year.

The Department of Labor is committed to equal opportunity in the workplace and seeks broad-based and diverse FACOSH membership. Any federal agency, labor organization representing federal workers, or individual(s) may nominate one or more qualified persons for membership on FACOSH. Interested individuals also are invited and encouraged to submit statements in support of a nominee(s).

Nomination requirements: Submission of nominations must include the following information:

1. The nominee's name, contact information and current employment;
2. Category of membership (management or labor) that the nominee is qualified to represent;
3. The nominee's resume or curriculum vitae, including prior membership on FACOSH and other relevant organizations, associations and committees;
4. A summary of the nominee's background, experience and qualifications that address the nominee's suitability to serve on FACOSH;
5. Articles or other documents the nominee has authored, if any, that indicate the nominee's knowledge, experience and expertise in occupational safety and health, particularly as it pertains to the federal workforce; and
6. A statement that the nominee is aware of the nomination, is willing to regularly attend and participate in FACOSH meetings, and has no apparent conflicts of interest that would preclude membership on FACOSH.

Member selection: The Secretary appoints FACOSH members based upon criteria

that include the nominee's level of responsibility for occupational safety and health matters involving the federal workforce; experience and competence in occupational safety and health; and willingness and ability to regularly and fully participate in FACOSH meetings. Federal agency management nominees who serve as their agency's Designated Agency Safety and Health Official (DASHO), or have an equivalent level of responsibility within their respective federal agencies, are preferred as management members. Labor nominees who have responsibilities for federal employee occupational safety and health matters within their respective labor organizations are preferred as labor members.

Information received through the nomination process, along with other relevant sources of information, will assist the Secretary in making appointments to FACOSH. In selecting FACOSH members, the Secretary will consider individuals nominated in response to this **Federal Register** notice, as well as other qualified individuals. OSHA will publish a list of the new FACOSH members in the **Federal Register**.

OSHA will consider any nomination submitted in response to this notice for the vacancies that occur on January 1, 2017. In addition, OSHA will consider the nominations for any vacancy that may occur during 2017, provided the information the nominee submitted continues to remain current and accurate. OSHA believes that ''rolling over'' nominations for future consideration will make it easier for interested individuals to submit nominations and be considered for membership on FACOSH. This process also will provide OSHA with a broad base of nominations for ensuring that FACOSH membership is fairly balanced, which the Federal Advisory Committee Act requires (5 U.S.C. App.2, Section (5)(b)(2); 41 CFR 102–3.30(c)). OSHA will continue to request nominations as vacancies occur, but nominees whose information is current and accurate will not need to resubmit a nomination.

Public Participation, Submissions, and Access to Public Record

Instructions for submitting nominations: Interested individuals may submit nominations and supplemental materials using one of the methods listed in the **ADDRESSES** section. All nominations, attachments and other materials must identify the agency name and the docket number for this **Federal Register** notice (Docket No. OSHA–2016–0002). You may supplement electronic nominations by uploading materials electronically. If, instead, you wish to submit hard copies of materials to supplement an electronic submission, you must submit them to the OSHA Docket Office (see **ADDRESSES** section). The additional material must clearly identify your electronic submission by name and docket number so that the materials can be attached to your nomination.

Because of security-related procedures, the use of regular mail may cause a significant delay in the receipt of nominations. For information about security procedures concerning the submission of materials by mail, hand, express delivery, messenger or courier service, please contact the OSHA Docket Office (see **ADDRESSES** section).

All submissions in response to this **Federal Register** notice are posted without change in the FACOSH docket and may be made available online at *http://www.regulations.gov.* Therefore,

OSHA cautions interested parties about submitting personal information, such as Social Security numbers and birthdates. Information on submitting nominations and supporting materials in response to this **Federal Register** notice is available at *http://www.regulations.gov* and from the OSHA Docket Office.

Access to docket and other materials: To read or download nominations and additional materials submitted in response to this **Federal Register** notice, go to Docket No. OSHA–2016–0002 at: *http://www.regulations.gov.* All submissions are listed in the docket index; however, some documents (*e.g.,* copyrighted materials) are not publicly available to read or download through that Web page. All submissions, including copyrighted materials, are available at the OSHA Docket Office. Contact the OSHA Docket Office for information about materials not available through *http://www.regulations.gov,* and for assistance using the internet to locate submissions.

Electronic copies of this **Federal Register** notice are available at: *http://www.regulations.gov.* This document, as well as news releases and other relevant information, also is available at OSHA's Web page at: *http://www.osha.gov.*

Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice pursuant to 5 U.S.C. 7902; 5 U.S.C. App. 2; 29 U.S.C. 668; Executive Order 12196 (45 FR 12629 (2/27/1980)), as amended; 41 CFR part 102–3; and Secretary of Labor's Order No. 1–2012 (77 FR 3912).

Signed at Washington, DC, on August 1, 2016.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2016–18622 Filed 8–4–16; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL CREDIT UNION ADMINISTRATION

Submission for OMB Review; Comment Request

Correction

In notice document 2016–18135, appearing on pages 50564–50565 in the Issue of Monday, August 1, 2016, make the following correction:

On page 50564, in the third column, under the heading **DATES:**, the entry ''August 31, 2016'' should read ''September 30, 2016''.

[FR Doc. C1–2016–18135 Filed 8–4–16; 8:45 am]

BILLING CODE 1505–01–D

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts

Arts Advisory Panel Meetings

AGENCY: National Endowment for the Arts, National Foundation on the Arts and Humanities.

ACTION: Notice of meetings.

SUMMARY: Pursuant to the Federal Advisory Committee Act, as amended, notice is hereby given that two meetings of the Arts Advisory Panel to the National Council on the Arts will be held by teleconference.

DATES: All meetings are Eastern time and ending times are approximate:

Research (review of applications): This meeting replaces the meeting previously scheduled for August 1, 2016, and will be closed.

Date and time: August 29, 2016; 2:00 p.m. to 4:00 p.m.

Literature (review of applications): This meeting will be closed.

Date and time: September 14, 2016; 2:30 p.m. to 5:00 p.m.

ADDRESSES: National Endowment for the Arts, Constitution Center, 400 7th St. SW., Washington, DC 20506.

FOR FURTHER INFORMATION CONTACT: Further information with reference to these meetings can be obtained from Ms. Kathy Plowitz-Worden, Office of Guidelines & Panel Operations, National Endowment for the Arts, Washington, DC 20506; *plowitzk@arts.gov,* or call 202/682–5691.

SUPPLEMENTARY INFORMATION: The closed portions of meetings are for the purpose of Panel review, discussion, evaluation, and recommendations on financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency. In accordance with the determination of the Chairman of July 5, 2016, these sessions will be closed to the public pursuant to subsection (c)(6) of section 552b of title 5, United States Code.

Dated: August 2, 2016.

Kathy Plowitz-Worden,

Panel Coordinator, National Endowment for the Arts.

[FR Doc. 2016–18591 Filed 8–4–16; 8:45 am]

BILLING CODE 7537–01–P

NATIONAL SCIENCE FOUNDATION

Proposal Review Panel for Materials Research; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub., L. 92–463, as amended), the National Science Foundation announces the following meeting:

Name: Proposal Review Panel for Materials Research—Site visit review of the National High Magnetic Field Laboratory (NHMFL) at Florida State University, Tallahassee, FL (#1203).

Dates & Times: August 29, 2016; 6:00 p.m.–9:00 p.m.; August 30, 2016; 7:30 a.m.–8:30 p.m.; August 31, 2016; 7:30 a.m.–2:30 p.m.

Place: Florida State University, Tallahassee, FL.

Type of Meeting: Part-Open.

Contact Person: Dr. Leonard Spinu, Program Director, Division of Materials Research, Room 1065, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230, Telephone (703) 292–2665.

Purpose of Meeting: Site visit to provide advice and recommendations concerning the support for the renewal proposal of the NHMFL.

Agenda

Monday, August 29, 2016

6:00 p.m.–9:00 p.m.: Closed—Briefing of panel

Tuesday, August 30, 2016

7:30 a.m.–10:00 a.m.: Open—Review of the NHMFL

10:20 a.m.–10:50 a.m.: Closed—Executive Session

10:50 a.m.–4:20 p.m.: Open—Review of NHMFL

4:20 p.m.–4:50 p.m.: Closed—Executive Session

4:50 p.m.–7:10 p.m.: Open—Review of NHMFL

7:10 p.m.–8:10 p.m.: Closed—Dinner—Executive Session

Wednesday, August 31, 2016

7:30 a.m.–8:10 a.m.: Open—Review of the NHMFL

8:10 a.m.–2:30 p.m.: Closed—Executive Session, Draft and Review Report

Reason for Closing: The work 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.

Dated: August 1, 2016.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2016–18543 Filed 8–4–16; 8:45 am]

BILLING CODE 7555–01–P

DEPARTMENT OF ENERGY

Excess Uranium Management: Effects of DOE Transfers of Excess Uranium on Domestic Uranium Mining, Conversion, and Enrichment Industries; Request for Information

AGENCY: Office of Nuclear Energy, Department of Energy.

ACTION: Extension of comment period.

SUMMARY: On July 19, 2016, the U.S. Department of Energy (DOE) published a request for information (RFI) seeking comment on certain issues related to DOE's preparation for a potential new Secretarial Determination covering continued transfers of uranium for cleanup services at the Portsmouth Gaseous Diffusion Plant and for down-blending of highly-enriched uranium to low-enriched uranium. The RFI established an August 18, 2016 deadline for the submission of written comments. DOE is extending the comment period to September 19, 2016.

DATES: DOE will accept comments, data, and information responding to this RFI submitted on or before September 19, 2016.

ADDRESSES: Interested persons may submit comments by any of the following methods.

1. *Email: RFI-UraniumTransfers@hq.doe.gov.* Submit electronic comments in Microsoft Word or PDF and avoid the use of special characters or any form of encryption.

2. *Postal Mail:* Ms. Cheryl Moss Herman, U.S. Department of Energy, Office of Nuclear Energy, Mailstop NE–52, 19901 Germantown Rd., Germantown, MD 20874–1290. If possible, please submit all items on a compact disk (CD), in which case it is not necessary to include printed copies.

3. *Hand Delivery/Courier:* Ms. Cheryl Moss Herman, U.S. Department of Energy, Office of Nuclear Energy, Mailstop NE–52, B–409, 19901 Germantown Rd., Germantown, MD 20874–1290. Phone: (301) 903–1788. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

Instructions: All submissions received must include the agency name for this request for information. No facsimiles (faxes) will be accepted.

FOR FURTHER INFORMATION CONTACT: Ms. Cheryl Moss Herman, U.S. Department of Energy, Office of Nuclear Energy, Mailstop NE–52, B–409, 19901 Germantown Rd., Germantown, MD 20874–1290. Phone: (301) 903–1788. Email: *Cheryl.Moss_Herman@Nuclear.Energy.Gov.*

SUPPLEMENTARY INFORMATION: On July 19, 2016, the U.S. Department of Energy (DOE) published a request for information (RFI) in the **Federal Register** (81 FR 46917). DOE noted that it is preparing for a potential new Secretarial Determination covering continued transfers of uranium for cleanup services at the Portsmouth Gaseous Diffusion Plant and for down-blending of highly-enriched uranium to low-enriched uranium. The RFI solicited information about the uranium markets and domestic uranium industries, potential effects of the proposed transfers in the uranium markets and possible consequences for the domestic uranium mining, conversion, and enrichment industries. The RFI established an August 18, 2016, deadline for the submission of written comments. DOE has received requests from the public for extension of the public comment period. In response to those requests and other considerations, DOE is extending the comment period to September 19, 2016 to provide the public additional time for comment.

Issued in Washington, DC, on August 1, 2016.

Raymond Furstenau,

Associate Principal Deputy Assistant Secretary for Nuclear Energy, Office of Nuclear Energy.

[FR Doc. 2016–18657 Filed 8–4–16; 8:45 am]

BILLING CODE 6450–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2016–0144]

Request for a License To Export High-Enriched Uranium; Correction

AGENCY: Nuclear Regulatory Commission.

ACTION: Export license application; correction.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is correcting a notice that was published in the **Federal Register** (FR) on July 13, 2016, regarding a request from Edlow International Company as Agent for SCK–CEN for a license application (XSNM3771) to export high-enriched uranium to SCK–CEN in Belgium for fuel reload at the BR–2 Research Reactor. This action is necessary to correct the date of the license application and to correct the date the license application was received.

DATES: The correction is effective August 5, 2016.

ADDRESSES: Please refer to Docket ID NRC–2016–0144 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0144. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''ADAMS Public Documents'' and then 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.*

- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Andrea Ferkile, Office of International Programs, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001; telephone: 301–415–8058, email: *Andrea.Ferkile@nrc.gov.*

SUPPLEMENTARY INFORMATION: In the FR on July 13, 2016, in FR Doc. 2016–16557, on page 45311, in the first column, second row, of the table entitled, ''NRC Export License Application—Description of Material,'' correct ''May 18, 2016'' to read ''July 07, 2016'' and correct ''June 03, 2016'' to read ''July 11, 2016.''

Dated at Rockville, Maryland, this 29th day of July, 2016.

For the Nuclear Regulatory Commission.

Mugeh Afshar-Tous,

Acting Deputy Director, Office of International Programs.

[FR Doc. 2016–18634 Filed 8–4–16; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78451; File No. SR–NASDAQ–2016–105]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to the Listing and Trading of the Shares of the Eaton Vance Floating-Rate & High Income NextShares of the Eaton Vance NextShares Trust II

August 1, 2016.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 27, 2016 The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in in Items I and II below, which Items have been prepared by Nasdaq. 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

Nasdaq proposes a proposed rule change with respect to the Eaton Vance Floating-Rate & High Income NextShares (the ''Fund''), a series of Eaton Vance NextShares Trust II (the ''Trust'').

The proposed rule change is being filed to reflect a proposed revision to the Fund's name and modify its proposed investments (which are set forth in an order previously granted by the Commission).[3] All capitalized terms referenced but not defined herein have the same meaning as in the Prior Release.

The text of the proposed rule change is available at *http://nasdaq.cchwallstreet.com/,* at Nasdaq's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The shares of the Fund will be offered by the Trust. The Trust is registered with the Commission as an open-end investment company and has filed a registration statement on Form N–1A (''Registration Statement'') with the Commission.[4] The Fund is a series of the Trust.

The Commission previously approved the listing and trading on the Exchange of the shares of the Fund under Nasdaq Rule 5745, which governs the listing and trading of NextShares™ on the Exchange.[5] The shares of the Fund have not commenced trading on the Exchange.

In this proposed rule change, the Exchange proposes to change the Fund's name and modify its proposed investments.[6] As stated in the Prior Release, the Fund is named Eaton Vance Floating-Rate & High Income NextShares and it normally will invest primarily in a combination of income-producing floating rate loans and other floating rate debt securities and high-yield corporate bonds. As proposed, the Fund will be renamed Eaton Vance Floating-Rate NextShares and it normally will invest primarily in income-producing floating rate loans and other floating rate debt securities.

Beyond the changes described above, there are no changes to any other information included in the Prior Release, except as made in the Amended Release; and all other facts presented and representations made in the Prior Release remain true and in effect. The Trust confirms that the Fund will continue to comply with all initial listing requirements under Nasdaq Rule 5745.

2. Statutory Basis

The Exchange believes that the proposal is consistent with section 6(b) of the Act, in general, and section 6(b)(5) of the Act, in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and in general, to protect investors and the public interest. The Fund will continue to comply with all the initial and continued listing requirements under Nasdaq Rule 5735.

The Exchange believes that the proposed rule change to change the Fund's name and to modify its proposed investments does not alter any of the arguments contained in the Prior Release in support of the original approval order that permitted the listing and trading of shares of the Fund and all other representations made in the Prior Release remain unchanged. The Exchange believes this proposed rule change is consistent with the Exchange's efforts to protect investors and the public interest through the disclosure of updated and correct information regarding the Fund.

For the above reasons, Nasdaq believes the proposed rule change is consistent with the requirements of section 6(b)(5) of the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. In fact, the Exchange believes that the introduction of the Fund will promote competition by making available to investors an actively managed investment strategy in a structure that offers the cost and tax efficiencies and shareholder protections of ETFs, while removing the requirement for daily portfolio holdings disclosure to ensure a tight relationship between market trading prices and NAV.

Moreover, the Exchange believes that the proposed method of trading in

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 74797 (April 23, 2015), 80 FR 23831 (April 29, 2015) (SR–NASDAQ–2015–036) (the ''Prior Notice''); *see also* Securities Exchange Act Release No. 75499 (July 21, 2015), 80 FR 44406 (July 27, 2015) (SR–NASDAQ–2015–036) (the ''Prior Order,'' and, together with the Prior Notice, the ''Prior Release''). Except for the changes discussed herein, all other facts presented and representations made in the Prior Release with respect to the Fund remain unchanged and in full effect.

[4] *See* Registration Statement on Form N–1A for the Eaton Vance NextShares Trust II dated December 10, 2015 (File Nos. 333–197734 and 811–22983).

[5] The Commission approved Nasdaq Rule 5745 in Securities Exchange Act Release No. 73562 (November 7, 2014), 79 FR 68309 (November 14, 2014) (SR–NASDAQ–2014–020).

[6] The changes described herein will be reflected in a revised prospectus and statement of additional information for the Fund to be filed with the Commission. The changes described herein will not be implemented until such proposed rule change is declared operative.

NextShares will provide investors with transparency of trading costs, and the ability to control trading costs using limit orders, that is not available for conventionally traded ETFs.

These developments could significantly enhance competition to the benefit of the markets and investors.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, the proposed rule change has become effective pursuant to section 19(b)(3)(A) of the Act[7] and Rule 19b–4(f)(6) thereunder.[8] The Exchange believes that this proposed rule change is properly designated as non-controversial because it enhances clarity and operational transparency without modifying members' rights or obligations.

The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange argues that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest because the proposed changes to the Fund are consistent with the Exchange arguments and Commission findings made in the Prior Release for the listing and trading of NextShares on the Exchange. In the context of the unique pricing and trading mechanisms of NextShares, the Commission believes that waiver of the 30-day operative delay with respect to these proposed changes to the Fund is consistent with the protection of investors and the public interest and hereby waives the 30-day operative delay and designates the proposed rule change to be operative upon filing.[9]

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: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NASDAQ–2016–105 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2016–105. 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 Web site (*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 Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2016–105 and should be submitted on or before August 26, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–18569 Filed 8–4–16; 8:45 am]

BILLING CODE 8011–01–P

[7] 15 U.S.C. 78s(b)(3)(A).

[8] 17 CFR 240.19b–4(f)(6).

[9] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[10] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78449; File No. SR–BOX–2016–26]

Self-Regulatory Organizations; BOX Options Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the BOX Rules Regarding Participants and Associated Persons Who Are or Become Subject to a Statutory Disqualification

August 1, 2016.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 25, 2016, BOX Options Exchange LLC (the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the BOX Rules regarding Participants and associated persons who are or become subject to a statutory disqualification. The text of the proposed rule change is available from the principal office of the Exchange, at the Commission's Public Reference Room and also on the Exchange's Internet Web site at *http://boxexchange.com.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

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 self-regulatory organization has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend Rule 2040 (Restrictions) to add language which provides the Exchange with the discretion to determine whether to permit a person to become an Options Participant or an associated person of a Participant or continue as a Participant or in association with a Participant on the Exchange.

Currently, Rule 2040 restricts any persons from becoming an Options Participant or continuing as an Options Participant where (1) such person is other than a natural person and is not a registered broker or dealer, (2) such person is a natural person who is not either a registered broker or dealer or associated with a registered broker or dealer, (3) such person is subject to a statutory disqualification,[3] except that a person may become a Participant or continue as a Participant where, pursuant to Rules 19d–1, 19d–2, 19d–3 and 19h–1 of the Act, the Commission has issued an order providing relief from such a disqualification and permitting such a person to become a Participant, or (4) such person is not a member of another registered national securities exchange or association.

The Exchange notes that the proposed rule changes below are substantially similar to the Rules of the International Securities Exchange (''ISE'').[4] The Exchange first proposes to amend the language of Rule 2040 to give itself the discretion to determine if a restriction on a Participant becoming or continuing on as an Options Participant is appropriate.

The Exchange then proposes to amend BOX Rule 2040(a)(3). Specifically, the Exchange proposes to add a reference to Section 3(a)(39) of the Exchange Act for the definition of statutory disqualification within BOX Rule 2040(a)(3). The Exchange also proposes to delete the language that allows a person to become a Participant or continue as a Participant where, pursuant to Rules 19d–1, 19d–2, 19d–3 and 19h–1 of the Act, the Commission has issued an order providing relief from such a disqualification and permitting such a person to become a Participant. The Exchange believes that this language is obsolete.

The Exchange then proposes to add three more situations with regard to whether a person may become a Participant or continue as a Participant in any capacity on the Exchange. The additional restrictions are (1) when such person fails to meet any of the qualification requirements for becoming a Participant or associated with a Participant after approval thereof; (2) such person fails to meet any condition placed by the Exchange on such Participant or association with a Participant; and (3) such person violates any agreement with the Exchange. The Exchange proposes these additions in order to allow the Exchange more discretion in its determination as to whether a person may become or continue as a Participant or in association with a Participant.

The Exchange also proposes to add language with regard to a Participant or associated person that becomes subject to a statutory disqualification under the Exchange Act. The proposed rule would allow a Participant or associated person who becomes subject to a statutory disqualification and who wants to continue as a Participant of the Exchange or in association with a Participant, to submit a request to the Exchange seeking to continue as a Participant or in association with a Participant notwithstanding the statutory disqualification.[5]

The Exchange also proposes to add language which allows Participants and associated persons whose request to become a Participant is denied or conditioned, or any person whose association with a Participant is denied or conditioned pursuant to the restrictions codified in Rule 2040(a), and any Participant or person associated with a Participant who is not permitted to continue as a Participant or be an associate with a Participant or to which association is conditioned to appeal the Exchange's decision under Rule 1300 (Review of Certain Exchange Actions) of the Rules.

Lastly, the Exchange proposes to add Interpretive Material which allows the Exchange to waive the provisions of Rule 2040 when a proceeding is pending before another self-regulatory organization (''SRO'') or similar association to determine whether to permit a Participant or associated person to become or continue being Participant or associated person notwithstanding a statutory disqualification. The Exchange notes that this proposed rule change is substantially similar to the comparable Rules of the Chicago Board Options Exchange (''CBOE'').[6] Further, in the event the Exchange determines to waive the provisions of this Rule with respect to a Participant or associated person, the Exchange shall determine whether the Exchange will concur in any Exchange Act Rule 19h–1 filing made by another SRO or similar association with respect to the Participant or associated person.

2. Statutory Basis

The Exchange believes that the proposal is consistent with the requirements of section 6(b) of the Act,[7] in general, and section 6(b)(5) of the Act,[8] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

The Exchange believes that the proposed rule changes are consistent with the requirements above. Specifically, the Exchange believes the proposed changes will better enable the Exchange to use its discretion in determining whether a person may become or continue as a Participant or associated person. Because of the discretionary language and additional restrictions, the Exchange may consider additional circumstances when determining whether a person may become or continue as a Participant or associated person on the Exchange.

The Exchange believes that Proposed Rule 2040(c) regarding any person or Participant's ability to appeal a denied

[3] The Exchange uses the Securities Exchange Act of 1934 definition of statutory disqualification. *See* 15 U.S.C. 78c(a)(39).

[4] *See* Securities Exchange Release No. 42455, 65 FR 11401 (March 2, 2000) (Order Granting Registration as a National Securities Exchange).

[5] The Participant or person associated with a Participant must submit the request within thirty (30) days of becoming subject to a statutory disqualification.

[6] *See* Securities Exchange Release No. 43056, 65 FR 46524 (July 28, 2000) (Order Approving Proposed Rule Change and Notice of Filing and Order Granting Accelerated Approval to Amendment No. 3 to the Proposed Rule Change by the Chicago Board Options Exchange, Inc. Relating to Membership Rules) (SR–CBOE–99–15).

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

or conditioned request to become or continue as a Participant or to associate with a Participant is reasonable because it provides a fair procedure for the Participants and persons associated with Participants pursuant to Rule 11000 (Summary Suspension).

The Exchange also believes the proposed rule change regarding the waiver of the provisions of Rule 2040 will better enable the Exchange to focus Exchange resources on other matters while another SRO or similar association is determining whether to permit a Participant or associated person to become or continue being a Participant or associated person on the exchange.

Lastly, the Exchange believes that amending the language in BOX Rule 2040(a)(3) is appropriate, as the added language which defers to the Exchange Act for a particular definition, will add clarity to the rules. Further, the Exchange believes is it reasonable to remove obsolete language in BOX Rule 2040(a)(3) because the Exchange is eliminating any potential for confusion by simplifying the Exchange Rules, ensuring that Participants, regulators, and the public can more easily navigate the Exchange's Rulebook.

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.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

(a) This proposed rule change is filed pursuant to paragraph (A) of section 19(b)(3) of the Exchange Act [9] and Rule 19b–4(f)(6) thereunder.[10]

(b) This proposed rule change does not significantly affect the protection of investors or the public interest, does not impose any significant burden on competition, and, by its terms, does not become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6) thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–BOX–2016–26 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–BOX–2016–26. 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 Web site (*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 Web site viewing and printing in the Commission's Public Reference Room, on official business days between the hours of 10:00 a.m. and 3:00 p.m., located at 100 F Street NE., Washington, DC 20549. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File Number SR–BOX–2016–26 and should be submitted on or before August 26, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–18567 Filed 8–4–16; 8:45 am]

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[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(6).

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78405; File No. SR–BX–2016–044]

Self-Regulatory Organizations; NASDAQ BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Update Public Disclosure of Exchange Usage of Market Data

July 25, 2016.

Correction

In notice document 2016–17908 appearing on pages 50041–50042 in the issue of July 29, 2016, make the following correction:

On page 50041, in the first column, the File No. in the heading is corrected to read as set forth above.

[FR Doc. C1–2016–17908 Filed 8–4–16; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78450; File No. SR–CBOE–2016–051)

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to the Series 9/10 Examination Program

August 1, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 27, 2016, Chicago Board Options Exchange, Incorporated (the ''Exchange'' or ''CBOE'') filed with the Securities and

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the CBOE. CBOE has designated the proposed rule change as ''constituting a stated policy, practice, or interpretation with respect to the meaning, administration, or enforcement of an existing rule'' under Section 19(b)(3)(A)(i) of the Act [3] and Rule 19b–4(f)(1) thereunder,[4] which renders the proposal effective upon receipt of this filing by the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

CBOE is filing a proposal to adopt revisions to the content outline and selection specifications for the General Securities Sales Supervisor (Series 9/10) examination program.[5] The revisions update the material to reflect changes to the laws, rules and regulations covered by the examination and to incorporate the functions and associated tasks currently performed by a General Securities Sales Supervisor. In addition, CBOE is proposing to adopt changes to the format of the content outline. CBOE is not proposing any textual changes to the By-Laws, Schedules to the By-Laws or Rules of CBOE. CBOE is proposing these revisions to adopt the revised Series 9/10 examination program of the Financial Industry Regulatory Authority, Inc. (''FINRA''). FINRA currently administers Series 9/10 examinations on behalf of CBOE (and other self-regulatory organizations).

The revised content outline is attached.[6] The Series 9/10 selection specifications were submitted to the Commission under separate cover by FINRA. FINRA submitted the Series 9/10 selection specifications in connection with a FINRA filing to revise its Series 9/10 Examination Program.[7] CBOE is in agreement with the selection specifications submitted by FINRA.

The text of the proposed rule change is available on the Exchange's Web site (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Section 6(c)(3) of the Act [8] authorizes CBOE to prescribe standards of training, experience, and competence for persons associated with CBOE Trading Permit Holders (''TPH''). In accordance with that provision, CBOE, in consultation with a committee of industry representatives, has advised FINRA in developing examinations that are designed to establish that persons associated with CBOE TPHs have attained specified levels of competence and knowledge, consistent with applicable registration requirements under CBOE rules. CBOE, in consultation with a committee of industry representatives, periodically reviews the content of the examinations to determine whether revisions are necessary or appropriate in view of changes pertaining to the subject matter covered by the examinations.

CBOE Rule 9.2, in relevant part, states, ''No TPH organization shall be approved to transact options business with the public until those persons associated with it who are designated as Options Principals have been approved by and registered with the Exchange. Persons engaged in the supervision of options sales practices or a person to whom the designated general partner or executive officer (pursuant to Rule 9.8) or another Registered Options Principal delegates the authority to supervise options sales practices shall be designated as Options Principals.'' [9]

CBOE Rule 9.2, Interpretation and Policy .01 further states: ''Individuals engaged in the supervision of options sales practices and designated as Options Principals are required to qualify as an Options Principal by passing the Registered Options Principals Examination (Series 4) or the Sales Supervision Examination (Series 9/10).'' [10] The Exchange notes that, with the Series 9/10 examination, an individual is only qualified to supervise sales activities. The scope of responsibility associated with the Series 4 is broader. In that regard, CBOE Rule 9.2, Interpretation and Policy .02 states: ''Individuals who are delegated responsibility pursuant to Rule 9.8 for reviewing the acceptance of discretionary accounts, for approving exceptions to a TPH organization's criteria or standards for uncovered options accounts, and for approval of communications, shall be designated as Options Principals and are required to qualify as an Options Principal by passing the Registered Options Principal Examination (Series 4).'' [11]

In consultation with a committee of industry representatives, including representatives from CBOE, FINRA recently undertook a review of the Series 9/10 examination program. As a result of this review, FINRA filed revisions to the content outline to reflect changes to the laws, rules and regulations covered by the examination and to incorporate the functions and associated tasks currently performed by a General Securities Sales Supervisor. FINRA also made changes to the format of the content outline.[12] CBOE is filing this rule change to reflect CBOE's adoption of the revisions to the Series 9/10 examination program that were filed by FINRA.

CBOE is proposing to adopt the revised Series 9/10 content outline, as revised by FINRA. FINRA revised the content outline to reflect changes to the laws, rules and regulations covered by the examination. The revised content outline is now divided into two parts with eight major job functions that are performed by a General Securities Sales Supervisor. The functions and

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[3] 15 U.S.C. 78s(b)(3)(A)(i).

[4] 17 CFR 240.19b–4(f)(1).

[5] CBOE is also proposing corresponding revisions made by FINRA to the Series 9/10 question bank. CBOE is submitting this filing for immediate effectiveness pursuant to Section 19(b)(3)(A) of the act [sic] and Rule 19b–4(f)(1) thereunder.

[6] The Commission notes that the revised content outline is attached to the filing, not to this Notice. The content outline is available as part of the filing on CBOE's Web site.

[7] *See* Securities Exchange Act Release No. 76812 (December 31, 2015), 81 FR 834 (January 7, 2016) (SR–FINRA–2015–058).

[8] 15 U.S.C. 78f(c)(3).

[9] *See* CBOE Rule 9.2.

[10] *See* CBOE Rule 9.2 Interpretation and Policy .01.

[11] *See* CBOE Rule 9.2 Interpretation and Policy .02. CBOE Rule 9.8 pertains to the supervision of accounts and includes provisions on the duty to supervise, maintenance of customer records, internal controls, annual branch office inspections, risk-based surveillance and branch office identification, criteria for inspection programs, written reports, and reports to control persons.

[12] *See* SR–FINRA–2015–058, note 4 [sic], *supra.*

associated tasks, which appear in the revised content outline, reflect the day-to-day activities of a General Securities Sales Supervisor. CBOE is also proposing to adopt the changes made by FINRA to the format of the content outline, including the preface, sample questions and reference materials.

FINRA also adjusted the number of examination questions assigned to each major job function to ensure that the overall examination better reflects the key tasks performed by a General Securities Sales Supervisor. The questions on the revised Series 9/10 examination will place greater emphasis on key tasks such as supervision of registered persons, sales practices and compliance. CBOE is proposing to adopt these revisions related to the Series 9/10 examination questions.

Finally, CBOE is proposing to adopt the changes made by FINRA to the Series 9/10 selection specifications and question bank.

Availability of Content Outline

The revised Series 9/10 content outline is available on FINRA's Web site, at *www.finra.org/brokerqualifications/exams*.

CBOE is filing the proposed rule change for immediate effectiveness. CBOE will announce the proposed rule change in a *Regulatory Circular*.

2. Statutory Basis

CBOE believes that the proposed revisions to the Series 9/10 examination program are consistent with the provisions of Section 6(b)(5) of the Act,[13] which requires, among other things, that CBOE rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest, and Section 6(c)(3) of the Act,[14] which authorizes CBOE to prescribe standards of training, experience, and competence for persons associated with CBOE TPHs. CBOE believes that the proposed revisions will further these purposes by updating the examination program to reflect changes to the laws, rules and regulations covered by the examination and to incorporate the functions and associated tasks currently performed by a General Securities Sales Supervisor.

B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The updated examination aligns with the functions and associated tasks currently performed by a General Securities Sales Supervisor and tests knowledge of the most current laws, rules, regulations and skills relevant to those functions and associated tasks. As such, the proposed revisions would make the examination more efficient and effective.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [15] and paragraph (f)(1) of Rule 19b–4 thereunder.[16] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–CBOE–2016–051 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2016–051. 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 Web site (*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 Web site 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; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2016–051 and should be submitted on or before August 26, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–18568 Filed 8–4–16; 8:45 am]

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[13] 15 U.S.C. 78f(b)(5).

[14] 15 U.S.C. 78f(c)(3).

[15] 15 U.S.C. 78s(b)(3)(A).

[16] 17 CFR 240.19b–4(f)(1).

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78452; File No. SR–BatsEDGX–2016–33]

Self-Regulatory Organizations; Bats EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Adopt an Options Regulatory Fee

August 1, 2016.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 20, 2016, Bats EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange has designated the proposed rule change as one establishing or changing a member due, fee, or other charge imposed by the Exchange under section 19(b)(3)(A)(ii) of the Act [3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposed rule change effective upon filing with the Commission. 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 filed a proposal to amend the fee schedule applicable to Members [5] and non-members of the Exchange pursuant to EDGX Rules 15.1(a) and (c).

The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to modify the fee schedule applicable to the Exchange's options platform (''EDGX Options'') to adopt an ORF in the amount of $0.0002 per contract side. The per-contract ORF will be assessed by the Exchange to each Member and non-Member for all options transactions cleared by OCC in the ''customer'' range, regardless of the exchange on which the transaction occurs. The ORF will be collected indirectly from Members and non-Members through their clearing firms by OCC on behalf of the Exchange. The ORF will be collected indirectly from Members and non-Members through their clearing firms by OCC on behalf of EDGX Options.

The Exchange believes it is appropriate to charge the ORF to transactions by Members and non-Members that clear as customer at the OCC, irrespective of where the transactions takes place. Many of the Exchange's surveillance programs for customer trading activity require the Exchange to look at activity across all options markets, such as surveillances for position limit violations, manipulation, insider trading, front-running and contrary exercise advice violations/expiring exercise declarations. Accordingly, there is a strong nexus between the ORF and the Exchange's regulatory activities with respect to its Members', as well as non-Members', customer trading activity. These activities span across multiple exchanges.

In addition to its own surveillance programs, the Exchange works with other SROs and exchanges on intermarket surveillance related issues. Through its participation in the Intermarket Surveillance Group (''ISG''),[6] the Exchange shares information and coordinates inquiries and investigations with other exchanges designed to address potential intermarket manipulation and trading abuses. Also, the Exchange and the other options exchanges are required to populate a consolidated options audit trail (''COATS'') [7] system in order to surveil trading activities across markets.

The Exchange proposes to assess ORF monthly based on information received from the OCC regarding transactions that cleared in the customer range. Notably, the Exchange believes that this will help to alleviate confusion or even potential double-billing of customer transactions. In particular, by billing all customer transactions on a monthly basis the Exchange will be able to capture transactions that may have been executed on the Exchange that were submitted for clearing by a Member but then ''flipped'' to the account of a non-Member. Thus, the Exchange believes that charging the ORF to Members and non-Members across all markets will avoid having non-Members clear their trades through non-Members in order to avoid the fee and to thereby avoid paying for their fair share for regulation. If the ORF did not apply to activity across markets then a Member or non-Member would send their orders to the least cost, least regulated exchange. In addition, applying the fee to all Members' and non-Members' activity across all market will avoid options participants from terminating their membership status on or not becoming a Members of certain exchanges simply to avoid being assessed ORF.

As discussed above, the ORF is designed to recover a material portion of the costs to the Exchange of the supervision and regulation of Members' and non-Member's customer options business, including performing routine surveillances and investigations, as well as policy, rulemaking, interpretive and enforcement activities. The Exchange believes that revenue generated from the ORF, when combined with all of the Exchange's other regulatory fees and fines, will cover a material portion, but not all, of the Exchange's regulatory costs.[8]

The Exchange will monitor the amount of revenue collected from the ORF to ensure that it, in combination with its other regulatory fees and fines, does not exceed the Exchange's total regulatory costs. The Exchange expects to monitor its regulatory costs and revenues at a minimum on a semi-annual basis. If the Exchange determines regulatory revenues exceed or are insufficient to cover a material portion of its regulatory costs, the Exchange will adjust the ORF by submitting a fee change filing to the Commission. The Exchange will notify Members and non-Members of adjustments to the ORF at least 30 calendar days prior to the effective date of the change.[9]

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[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

[5] The term ''Member'' is defined as ''any registered broker or dealer that has been admitted to membership in the Exchange.'' *See* Exchange Rule 1.5(n).

[6] ISG is an industry organization formed in 1983 to coordinate intermarket surveillance among the SROs by co-operatively sharing regulatory information pursuant to a written agreement between the parties. The goal of the ISG's information sharing is to coordinate regulatory efforts to address potential intermarket trading abuses and manipulations.

[7] COATS effectively enhances intermarket options surveillance by enabling the options exchanges to reconstruct the market promptly to effectively surveil certain rules.

[8] The Exchange notes that its regulatory responsibilities with respect to compliance with options sales practice rules has been allocated to the Financial Industry Regulatory Authority, Inc. (''FINRA'') under a 17d–2 Agreement. The ORF is not designed to cover the cost of options sales practice regulation.

[9] The Exchange announced its intent to charge an ORF on June 30, 2016. *See* Bats Options Exchange Regulatory Fee Schedule Update Effective August 1, 2016 *available at: http://cdn.batstrading.com/resources/fee_schedule/2016/Bats-Options-Exchange-Regulatory-Fee-Schedule-Update-Effective-August-1-2016.pdf.* The semi-annual review and notice provisions are similar to those adopted by NYSE Arca, Inc. (''NYSE Arca''). *See* Securities Exchange Act Release No. 70500

The Exchange notes that there is established precedent for an SRO charging a fee across markets, namely, FINRAs Trading Activity Fee [10] and the BZX, MIAX, NYSE Amex, NYSE Arca, CBOE, PHLX, ISE and BOX ORFs. While the Exchange does not have all of the same regulatory responsibilities as FINRA, the Exchange believes that, like other exchanges that have adopted an ORF, its broad regulatory responsibilities with respect to a Member's and non-Members' activities, irrespective of where their transactions take place, support a regulatory fee applicable to transactions on other markets. Unlike FINRA's Trading Activity Fee, the ORF would apply only to a Member's and non-Member's customer options transactions.

Implementation Date

The Exchange proposes to implement the ORF on August 1, 2016.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of section 6 of the Act.[11] Specifically, the Exchange believes that the proposed rule change is consistent with section 6(b)(4) of the Act,[12] in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and other persons using any facility or system which the Exchange operates or controls. The Exchange notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues or providers of routing services if they deem fee levels to be excessive.

The Exchange believes the ORF is equitable and not unfairly discriminatory because it would be objectively allocated to Members and non-Members in that it would be charged to all Members and non-Members on all their transactions that clear as customer transactions at the OCC. Moreover, the Exchange believes the ORF ensures fairness by assessing fees to those Members and non-Members that are directly based on the amount of customer options business they conduct. Regulating customer trading activity is much more labor intensive and requires greater expenditure of human and technical resources than regulating non-customer trading activity, which tends to be more automated and less labor-intensive. As a result, the costs associated with administering the customer component of the Exchange's overall regulatory program are materially higher than the costs associated with administering the non-customer component (*e.g.,* Member proprietary transactions) of its regulatory program. In addition, the Exchange believes the amount of the ORF is reasonable as it is significantly lower than ORFs charged by other exchanges. By way of comparison, MIAX charges an ORF of $0.0045 per contract side,[13] and both NYSE Arca and NYSE Amex charge an ORF of $0.0055 per contract side.[14] The CBOE charges an ORF of $0.0081 per contract.[15]

The Exchange believes applying the ORF to transactions executed or cleared by non-Members is equitable and not unfairly discriminatory because it should avoid having transactions cleared through non-Members in order to avoid the fee and to thereby avoid paying for their fair share for regulation.[16] If the ORF did not apply to activity across markets then a non-Member would send their orders to the least cost, least regulated exchange. In addition, applying the fee to all Members' and non-Members' activity across all market will avoid options participants from terminating their membership status on or not becoming a Members of certain exchanges simply to avoid being assessed ORF. Moreover, the Exchange believes the ORF ensures fairness by assessing fees to those Members and non-Members that are directly based on the amount of customer options business they conduct.

The Exchange also believes it is reasonable and appropriate for the Exchange to charge the ORF for options transactions by a non-Member regardless of the exchange on which the transactions occur. The Exchange has a statutory obligation to enforce compliance by Members and their associated persons under the Act and the rules of the Exchange and cannot effectively surveil for manipulative conduct by market participants (including non-Members) trading on the Exchange without looking at and evaluating activity across all options markets. Many of the Exchange's market surveillance programs require the Exchange to look at and evaluate activity across all options markets, such as surveillance for position limit violations, manipulation, front-running and contrary exercise advice violations/expiring exercise declarations.

The ORF is designed to recover a material portion of the costs of supervising and regulating Members' and non-Members' customer options business including performing routine surveillances, investigations, examinations, financial monitoring, and policy, rulemaking, interpretive, and enforcement activities. The Exchange will monitor, on at least a semi-annual basis the amount of revenue collected from the ORF to ensure that it, in combination with its other regulatory fees and fines, does not exceed the Exchange's total regulatory costs. If the Exchange determines regulatory revenues exceed or are insufficient to cover a material portion of its regulatory costs, the Exchange will adjust the ORF by submitting a fee change filing to the Commission. The Exchange will notify Members and non-Members of adjustments to the ORF via regulatory circular.

The Exchange has designed the ORF to generate revenues that, when combined with all of the Exchange's other regulatory fees, will be less than or equal to the Exchange's regulatory costs, which is consistent with the Commission's view that regulatory fees be used for regulatory purposes and not to support the Exchange's business side. In this regard, the Exchange believes that the initial level of the fee is reasonable.

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 ORF is not intended to have any impact on competition. Rather, it is designed to

(September 25, 2013), 78 FR 60361 (October 1, 2013) (SR–NYSEArca–2013–91).

[10] *See* Securities Exchange Act Release No. 47946 (May 30, 2003), 68 FR 3402 (June 6, 2003).

[11] 15 U.S.C. 78f.

[12] 15 U.S.C. 78f(b)(4).

[13] *See* MIAX fee schedule *available at http://www.miaxoptions.com/sites/default/files/MIAX_Options_Fee_Schedule_06012016.pdf* (date May 1, 2016).

[14] *See* NYSE Arca Options fee schedule *available at https://www.nyse.com/publicdocs/nyse/markets/arca-options/NYSE_Arca_Options_Fee_Schedule.pdf* (dated June 6, 2016); *and* NYSE Amex fee schedule *available at https://www.nyse.com/publicdocs/nyse/markets/amex-options/NYSE_Amex_Options_Fee_Schedule.pdf* (dated June 9, 2016).

[15] *See* CBOE fee schedule *available at http://www.cboe.com/framed/pdfframed.aspx?content=/publish/feeschedule/CBOEFeeSchedule.pdf&section=SEC_RESOURCES&title=CBOE%20Fee%20Schedule* (dated May 16, 2016).

[16] Despite rule text to the contrary, the Exchange believes based on conversations with market participants that other options exchanges currently charge an ORF on all options transactions cleared by the OCC in the customer range regardless of whether they are executed or cleared by their member.

enable the Exchange to recover a material portion of the Exchange's cost related to its regulatory activities. The proposed ORF is also comparable to, and in most instances less than, ORF fees charged by other options exchanges. Further, the expansion of ORF to non-Members is also not designed to have an impact on competition as the Exchange believes based on conversations from market participants that it is consistent with the practice by other exchanges in applying ORF to non-Member transactions, despite rule text to the contrary.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any written comments from members or other interested parties.

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 [17] and paragraph (f) of Rule 19b–4 thereunder.[18] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

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 No. SR–BatsEDGX–2016–33 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 No. SR–BatsEDGX–2016–33. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*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 Web site 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; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–BatsEDGX–2016–33, and should be submitted on or before August 26, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–18570 Filed 8–4–16; 8:45 am]

BILLING CODE 8011–01–P

[17] 15 U.S.C. 78s(b)(3)(A).

[18] 17 CFR 240.19b–4(f).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78453; File No. SR–BatsBZX–2016–42]

Self-Regulatory Organizations; Bats BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Options Regulatory Fee

August 1, 2016.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 20, 2016, Bats BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange has designated the proposed rule change as one establishing or changing a member due, fee, or other charge imposed by the Exchange under section 19(b)(3)(A)(ii) of the Act [3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposed rule change effective upon filing with the Commission. 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 filed a proposal to amend the fee schedule applicable to Members [5] and non-members of the Exchange pursuant to BZX Rules 15.1(a) and (c).

The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to modify the fee schedule applicable to the Exchange's options platform (''BZX Options'') to amend the rate of its ORF as well as to expand its application to non-Members. Currently, the Exchange

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

[5] The term ''Member'' is defined as ''any registered broker or dealer that has been admitted to membership in the Exchange.'' *See* Exchange Rule 1.5(n).

charges an ORF in the amount of $0.0010 per contract side. The Exchange proposes to decrease the amount of ORF to $0.0008 per contract side.

Currently, the per-contract ORF is assessed by the Exchange to each Member for all options transactions executed and cleared, or simply cleared, by the Member, that are cleared by OCC in the ''customer'' range, regardless of the exchange on which the transaction occurs. The ORF is collected indirectly from Members through their clearing firms by OCC on behalf of the Exchange. The ORF is also charged for transactions that are not executed by a Member but are ultimately cleared by a Member. Thus, in the case where a non-Member executes a transaction and a Member clears the transaction, the ORF is assessed to the Member who clears the transaction. Similarly, in the case where a Member executes a transaction and another Member clears the transaction, the ORF is assessed to the Member who clears the transaction.

The Exchange now proposes to expand the application of ORF to options transactions executed or cleared by non-Members in the ''customer'' range. As proposed, the ORF will be assessed by BZX Options to each Member *and non-Member* for all options transactions cleared by OCC in the ''customer'' range, regardless of the exchange on which the transaction occurs. Like for Members, the ORF will be collected indirectly from non-Members through their clearing firms by OCC on behalf of BZX Options.

The Exchange believes it is appropriate to charge the ORF to transactions by non-Members that clear as customer at the OCC, irrespective of where the transactions takes place. Many of the Exchange's surveillance programs for customer trading activity require the Exchange to look at activity across all options markets, such as surveillances for position limit violations, manipulation, insider trading, front-running and contrary exercise advice violations/expiring exercise declarations. Accordingly, there is a strong nexus between the ORF and the Exchange's regulatory activities with respect to its Members', as well as non-Members', customer trading activity. These activities span across multiple exchanges.

In addition to its own surveillance programs, the Exchange works with other SROs and exchanges on intermarket surveillance related issues. Through its participation in the Intermarket Surveillance Group (''ISG''),[6] the Exchange shares information and coordinates inquiries and investigations with other exchanges designed to address potential intermarket manipulation and trading abuses. Also, the Exchange and the other options exchanges are required to populate a consolidated options audit trail (''COATS'')[7] system in order to surveil trading activities across markets.

The Exchange proposes to assess ORF monthly based on information received from the OCC regarding transactions that cleared in the customer range. Notably, the Exchange believes that this will help to alleviate confusion or even potential double-billing of customer transactions. In particular, by billing all customer transactions on a monthly basis the Exchange will be able to capture transactions that may have been executed on the Exchange that were submitted for clearing by a Member but then ''flipped'' to the account of a non-Member. Thus, the Exchange believes that charging the ORF to Members and non-Members across all markets will avoid having non-Members clear their trades through non-Members in order to avoid the fee and to thereby avoid paying for their fair share for regulation. If the ORF did not apply to activity across markets then a non-Member would send their orders to the least cost, least regulated exchange. In addition, applying the fee to all Members' and non-Members' activity across all market will avoid options participants from terminating their membership status on or not becoming a Members of certain exchanges simply to avoid being assessed ORF.

As discussed above, the ORF is designed to recover a material portion of the costs to the Exchange of the supervision and regulation of Members' and non-Member's customer options business, including performing routine surveillances and investigations, as well as policy, rulemaking, interpretive and enforcement activities. The Exchange believes that revenue generated from the ORF, when combined with all of the Exchange's other regulatory fees and fines, will continue to cover a material portion, but not all, of the Exchange's regulatory costs.[8]

The Exchange will continue to monitor the amount of revenue collected from the ORF to ensure that it, in combination with its other regulatory fees and fines, does not exceed the Exchange's total regulatory costs. The Exchange expects to monitor its regulatory costs and revenues at a minimum on a semi-annual basis. If the Exchange determines regulatory revenues exceed or are insufficient to cover a material portion of its regulatory costs, the Exchange will adjust the ORF by submitting a fee change filing to the Commission. The Exchange will continue to notify Members and non-Members of adjustments to the ORF at least 30 calendar days prior to the effective date of the change.[9]

Implementation Date

The Exchange proposes to implement changes to the ORF on August 1, 2016.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of section 6 of the Act.[10] Specifically, the Exchange believes that the proposed rule change is consistent with section 6(b)(4) of the Act,[11] in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and other persons using any facility or system which the Exchange operates or controls. The Exchange notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues or providers of routing services if they deem fee levels to be excessive.

The Exchange believes the decreased ORF is equitable and not unfairly discriminatory because it would be objectively allocated to Members and non-Members in that it would be charged to all Members and non-Members on all their transactions that

[6] ISG is an industry organization formed in 1983 to coordinate intermarket surveillance among the SROs by co-operatively sharing regulatory information pursuant to a written agreement between the parties. The goal of the ISG's information sharing is to coordinate regulatory efforts to address potential intermarket trading abuses and manipulations.

[7] COATS effectively enhances intermarket options surveillance by enabling the options exchanges to reconstruct the market promptly to effectively surveil certain rules.

[8] The Exchange notes that its regulatory responsibilities with respect to compliance with options sales practice rules has been allocated to the Financial Industry Regulatory Authority, Inc. (''FINRA'') under a 17d–2 Agreement. The ORF is not designed to cover the cost of options sales practice regulation.

[9] The Exchange announced its intent to charge an ORF on June 30, 2016. *See* Bats Options Exchange Regulatory Fee Schedule Update Effective August 1, 2016 *available at: http://cdn.batstrading.com/resources/fee_schedule/2016/Bats-Options-Exchange-Regulatory-Fee-Schedule-Update-Effective-August-1-2016.pdf.*

[10] 15 U.S.C. 78f.

[11] 15 U.S.C. 78f(b)(4).

clear as customer transactions at the OCC. In addition, the Exchange believes the amount of the ORF is reasonable as it is significantly lower than ORFs charged by other exchanges. By way of comparison, MIAX charges an ORF of $0.0045 per contract side,[12] and both NYSE Arca and NYSE Amex charge an ORF of $0.0055 per contract side.[13] The CBOE charges an ORF of $0.0081 per contract.[14]

The Exchange believes the expanding the decreased ORF to transactions executed or cleared by non-Members is equitable and not unfairly discriminatory because it should avoid having transactions cleared through non-Members in order to avoid the fee and to thereby avoid paying for their fair share for regulation.[15] If the ORF did not apply to activity across markets then a non-Member would send their orders to the least cost, least regulated exchange. In addition, applying the fee to all Members' and non-Members' activity across all market will avoid options participants from terminating their membership status on or not becoming a Members of certain exchanges simply to avoid being assessed ORF. Moreover, the Exchange believes the ORF ensures fairness by assessing fees to those Members and non-Members that are directly based on the amount of customer options business they conduct.

The Exchange also believes it is reasonable and appropriate for the Exchange to charge the ORF for options transactions by a non-Member regardless of the exchange on which the transactions occur. The Exchange has a statutory obligation to enforce compliance by Members and their associated persons under the Act and the rules of the Exchange and cannot effectively surveil for manipulative conduct by market participants (including non-Members) trading on the Exchange without looking at and evaluating activity across all options markets. Many of the Exchange's market surveillance programs require the Exchange to look at and evaluate activity across all options markets, such as surveillance for position limit violations, manipulation, front-running and contrary exercise advice violations/expiring exercise declarations.

The Exchange has designed the ORF to generate revenues that, when combined with all of the Exchange's other regulatory fees, will be less than or equal to the Exchange's regulatory costs, which is consistent with the Commission's view that regulatory fees be used for regulatory purposes and not to support the Exchange's business side. In this regard, the Exchange believes that the decreased level of the fee and its expansion to non-Members is reasonable and appropriate.

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 ORF is not intended to have any impact on competition. Rather, it is designed to enable the Exchange to recover a material portion of the Exchange's cost related to its regulatory activities. The decreased ORF is also comparable to, and in most instances less than, ORF fees charged by other options exchanges. The expansion of ORF to non-Members is also not designed to have an impact on competition as the Exchange believes based on conversations from market participants that it is consistent with the practice by other exchanges in applying ORF to non-Member transactions, despite rule text to the contrary.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any written comments from members or other interested parties.

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 [16] and paragraph (f) of Rule 19b–4 thereunder.[17] 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 No. SR–BatsBZX–2016–42 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 No. SR–BatsBZX–2016–42. 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 Web site (*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 Web site 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; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make

[12] *See* MIAX fee schedule *available at http://www.miaxoptions.com/sites/default/files/MIAX_Options_Fee_Schedule_06012016.pdf* (dated May 1, 2016).

[13] *See* NYSE Arca Options fee schedule *available at https://www.nyse.com/publicdocs/nyse/markets/arca-options/NYSE_Arca_Options_Fee_Schedule.pdf* (dated June 6, 2016); *and* NYSE Amex fee schedule *available at https://www.nyse.com/publicdocs/nyse/markets/amex-options/NYSE_Amex_Options_Fee_Schedule.pdf* (dated June 9, 2016).

[14] *See* CBOE fee schedule *available at http://www.cboe.com/framed/pdfframed.aspx?content=/publish/feeschedule/CBOEFeeSchedule.pdf&section=SEC_RESOURCES&title=CBOE%20Fee%20Schedule* (dated May 16, 2016).

[15] Despite rule text to the contrary, the Exchange believes based on conversations with market participants that other options exchanges currently charge an ORF on all options transactions cleared by the OCC in the customer range regardless of whether they are executed or cleared by their member.

[16] 15 U.S.C. 78s(b)(3)(A).

[17] 17 CFR 240.19b–4(f).

available publicly. All submissions should refer to File No. SR–BatsBZX–2016–42, and should be submitted on or before August 26, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–18571 Filed 8–4–16; 8:45 am]

BILLING CODE 8011–01–P

SOCIAL SECURITY ADMINISTRATION

[Docket No: SSA–2016–0035]

Agency Information Collection Activities: Proposed Request and Comment Request

The Social Security Administration (SSA) publishes a list of information collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law 104–13, the Paperwork Reduction Act of 1995, effective October 1, 1995. This notice includes revisions of OMB-approved information collections.

SSA is soliciting comments on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. Mail, email, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses or fax numbers.

(OMB), Office of Management and Budget, Attn: Desk Officer for SSA, Fax: 202–395–6974, Email address: *OIRA_Submission@omb.eop.gov.*

(SSA), Social Security Administration, OLCA, Attn: Reports Clearance Director, 3100 West High Rise, 6401 Security Blvd., Baltimore, MD 21235, Fax: 410–966–2830, Email address: *OR.Reports.Clearance@ssa.gov.*

Or you may submit your comments online through *www.regulations.gov,* referencing Docket ID Number [SSA–2016–0035].

I. The information collections below are pending at SSA. SSA will submit them to OMB within 60 days from the date of this notice. To be sure we consider your comments, we must receive them no later than October 4, 2016. Individuals can obtain copies of the collection instruments by writing to the above email address.

1. Application for Child's Insurance Benefits—20 CFR 404.350–404.368, 404.603, & 416.350—0960–0010. Title II of the Social Security Act (Act) provides for the payment of monthly benefits to children of an insured retired, disabled, or deceased worker. Section 202(d) of the Act discloses the conditions and requirements the applicant must meet when filing an application. SSA uses the information on Form SSA–4–BK to determine entitlement for children of living and deceased workers to monthly Social Security payments. Respondents are guardians completing the form on behalf of the children of living or deceased workers, or the children of living or deceased workers.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
Life Claims (paper)	15,207	1	12	3,041
Life Claims (Modernized Claim System (MCS)/Signature Proxy)	465,428	1	11	85,328
Death Claims (paper)	6,290	1	12	1,258
Death Claims (MCS/Signature Proxy)	193,131	1	11	35,407
Totals	680,056			125,034

2. Private Printing and Modification of Prescribed Application and Other Forms—20 CFR 422.527—0960–0663. 20 CFR 422.527 of the Code of Federal Regulations requires a person, institution, or organization (third-party entities) to obtain approval from SSA prior to reproducing, duplicating, or privately printing any application or other form the agency owns. To obtain SSA's approval, entities must make their requests in writing using their company letterhead, providing the required information set forth in the regulation. SSA uses the information to: (1) Ensure requests comply with the law and regulations, and (2) process requests from third-party entities who want to reproduce, duplicate, or privately print any SSA application or other SSA form. SSA employees review the requests and provide approval via email or mail to the third-party entities. The respondents are third-party entities who submit a request to SSA to reproduce, duplicate, or privately print an SSA-owned form.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
20 CFR 422.527	10	15	10	25

3. Protection and Advocacy for Beneficiaries of Social Security (PABSS)—20 CFR 435.51–435.52—0960–0768. The PABSS projects are part of Social Security's strategy to increase the number of Social Security Disability Insurance (SSDI) or Supplemental Security Income (SSI) recipients who return to work and achieve financial independence and self-sufficiency as the result of receiving support, representation, advocacy, or other services. PABSS provides information and advice about obtaining vocational rehabilitation and employment services,

[18] 17 CFR 200.30–3(a)(12).

and to provide advocacy or other services a beneficiary with a disability may need to secure, maintain, or regain gainful employment. The PABSS Annual Program Performance Report collects statistical information from each of the PABSS projects in an effort to manage and capture program performance and quantitative data. Social Security uses the information to evaluate the efficacy of the program, and to ensure beneficiaries are receiving quality services. The project data is valuable to Social Security in its analysis of and future planning for the SSDI and SSI programs. The respondents are the 57 PABSS project sites, and recipients of SSDI and SSI programs.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
PABSS Program Grantees	57	1	60	57
Beneficiaries	8,284	1	30	4,142
Totals	8,341			4,199

II. SSA submitted the information collection below to OMB for clearance. Your comments regarding the information collection would be most useful if OMB and SSA receive them 30 days from the date of this publication. To be sure we consider your comments, we must receive them no later than September 6, 2016. Individuals can obtain copies of the OMB clearance package by writing to *OR.Reports.Clearance@ssa.gov.*

Application for Supplemental Security Income—20 CFR 416.207 and 416.305–416.335, Subpart C—0960–0229. The SSI program provides aged, blind, and disabled individuals who have little or no income, with funds for food, clothing, and shelter. Individuals complete Form SSA–8000–BK to apply for SSI. SSA uses the information from Form SSA–8000–BK and its electronic intranet counterpart, Modernized Supplemental Security Income Claims System (MSSICS), to determine: (1) Whether SSI claimants meet all statutory and regulatory eligibility requirements; and (2) SSI payment amounts. The respondents are applicants for SSI or their representative payees.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–8000–BK (Paper Version)	17,541	1	41	11,986
MSSICS/Signature Proxy	1,373,401	1	35	801,151
Totals	1,390,942			813,137

Dated: August 2, 2016.

Naomi R. Sipple,

Reports Clearance Officer, Social Security Administration.

[FR Doc. 2016–18588 Filed 8–4–16; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF STATE

[Public Notice: 9664]

Executive Order 13224 Designation of Jamaat-ul-Ahrar, aka JuA, aka Jamaatul Ahrar, aka Jamaatul-Ahrar, aka Jamat-ul-Ahrar, aka Aafia Siddique Brigade, aka Jamaat-e-Ahrar, aka Jamatul Ahrar, aka Tehreek-i-Taliban Jamaat-Ul-Ahrar, aka Tehrik-e-Taliban Pakistan Jamaat-e-Ahrar, aka Jamaat-ul-Ahrar TTP, aka TTP-JA, aka TTP-JuA as a Specially Designated Global Terrorist

Acting under the authority of and in accordance with section 1(b) of Executive Order 13224 of September 23, 2001, as amended by Executive Order 13268 of July 2, 2002, and Executive Order 13284 of January 23, 2003, I hereby determine that the individual known as Jamaat-ul-Ahrar, also known as JuA, also known as Jamaatul Ahrar, also known as Jamaatul-Ahrar, also known as Jamat-ul-Ahrar, also known as Aafia Siddique Brigade, also known as Jamaat-e-Ahrar, also known as Jamatul Ahrar, also known as Tehreek-i-Taliban Jamaat-Ul-Ahrar, also known as Tehrik-e-Taliban Pakistan Jamaat-e-Ahrar, also known as Jamaat-ul-Ahrar TTP, also known as TTP-JA, also known as TTP-JuA committed, or poses a significant risk of committing, acts of terrorism that threaten the security of U.S. nationals or the national security, foreign policy, or economy of the United States.

Consistent with the determination in section 10 of Executive Order 13224 that prior notice to persons determined to be subject to the Order who might have a constitutional presence in the United States would render ineffectual the blocking and other measures authorized in the Order because of the ability to transfer funds instantaneously, I determine that no prior notice needs to be provided to any person subject to this determination who might have a constitutional presence in the United States, because to do so would render ineffectual the measures authorized in the Order.

This notice shall be published in the **Federal Register**.

Dated: July 14, 2016.

John F. Kerry,

Secretary of State.

[FR Doc. 2016–18678 Filed 8–4–16; 8:45 am]

BILLING CODE 4710–AD–P

DEPARTMENT OF STATE

[Public Notice: 9665]

Review of the Designation as a Foreign Terrorist Organization of Harakat ul-Jihad-i-Islami (and Other Aliases)

Based upon a review of the Administrative Record assembled pursuant to Section 219(a)(4)(C) of the

Immigration and Nationality Act, as amended (8 U.S.C. 1189(a)(4)(C)) (''INA''), and in consultation with the Attorney General and the Secretary of the Treasury, I conclude that the circumstances that were the basis for the designation of the aforementioned organization as a Foreign Terrorist Organization have not changed in such a manner as to warrant revocation of the designation and that the national security of the United States does not warrant a revocation of the designation. Therefore, I hereby determine that the designation of the aforementioned organization as a Foreign Terrorist Organization, pursuant to Section 219 of the INA (8 U.S.C. 1189), shall be maintained.

This determination shall be published in the **Federal Register**.

Dated: July 20, 2016.

John F. Kerry,

Secretary of State.

[FR Doc. 2016–18671 Filed 8–4–16; 8:45 am]

BILLING CODE 4710–AD–P

DEPARTMENT OF STATE

[Public Notice: 9663]

Executive Order 13224 Designation of Mohamed Abrini, aka Mohammed Abrini, aka Mohammad Abrini as a Specially Designated Global Terrorist

Acting under the authority of and in accordance with section 1(b) of Executive Order 13224 of September 23, 2001, as amended by Executive Order 13268 of July 2, 2002, and Executive Order 13284 of January 23, 2003, I hereby determine that the individual known as Mohamed Abrini, also known as Mohammed Abrini, also known as Mohammad Abrini committed, or poses a significant risk of committing, acts of terrorism that threaten the security of U.S. nationals or the national security, foreign policy, or economy of the United States.

Consistent with the determination in section 10 of Executive Order 13224 that prior notice to persons determined to be subject to the Order who might have a constitutional presence in the United States would render ineffectual the blocking and other measures authorized in the Order because of the ability to transfer funds instantaneously, I determine that no prior notice needs to be provided to any person subject to this determination who might have a constitutional presence in the United States, because to do so would render ineffectual the measures authorized in the Order.

This notice shall be published in the **Federal Register**.

Dated: July 12, 2016.

John F. Kerry,

Secretary of State.

[FR Doc. 2016–18668 Filed 8–4–16; 8:45 am]

BILLING CODE 4710–AD–P

DEPARTMENT OF STATE

[Public Notice: 9659]

Notice of Public Meeting

The Department of State will conduct an open meeting at 9:00 a.m. on Monday, August 22, 2016, in room 7P15–01 of the Douglas A. Munro Coast Guard Headquarters Building at St. Elizabeth's, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593. The primary purpose of the meeting is to prepare for the third session of the International Maritime Organization's (IMO) Sub-Committee on Carriage of Cargoes and Containers (CCC 3) to be held at the IMO Headquarters, United Kingdom, on September 5–9, 2016.

The agenda items to be considered include:

—Decisions of other IMO bodies
—Amendments to the IGF Code and development of guidelines for low-flashpoint fuels
—Safety requirements for carriage of liquefied hydrogen in bulk
—Amendments to the IMSBC Code and supplements
—Amendments to the IMDG Code and supplements
—Amendments to SOLAS regulations II–2/20.2 and II–2/20–1 to clarify the fire safety requirements for cargo spaces containing vehicles with fuel in their tanks for their own propulsion
—Suitability of high manganese austenitic steel for cryogenic service and development of any necessary amendments to the IGC Code and IGF Code
—Mandatory requirements for classification and declaration of solid bulk cargoes as harmful to the marine environment
—Unified interpretation of provisions of IMO safety, security and environment-related conventions
—Consideration of reports of incidents involving dangerous goods or marine pollutants in packaged form on board ships or in port areas

Members of the public may attend this meeting up to the seating capacity of the room. Upon request to the meeting coordinator, members of the public may also participate via teleconference. To facilitate the building security process, and to request reasonable accommodation, those who plan to attend should contact the meeting coordinator, Ms. Amy Parker, by email at *Amy.M.Parker@uscg.mil*, by phone at (202) 372–1423, or in writing at 2703 Martin Luther King Jr. Ave. SE., Stop 7509, Washington, DC 20593–7509, not later than August 15, 2016. Requests made after August 15, 2016 might not be able to be accommodated. The building is accessible by taxi, public transportation, and privately owned conveyance (upon request). Please note that due to security considerations, two valid, government issued photo identifications must be presented to gain entrance to the Coast Guard Headquarters building. It is recommended that attendees arrive no later than 30 minutes ahead of the scheduled meeting for the security screening process.

Additional information regarding this and other IMO public meetings may be found at: *www.uscg.mil/imo.*

Dated: July 26, 2016.

Jonathan W. Burby,

Coast Guard Liaison Officer, Office of Ocean and Polar Affairs, Department of State.

[FR Doc. 2016–18379 Filed 8–4–16; 8:45 am]

BILLING CODE 4710–09–P

SURFACE TRANSPORTATION BOARD

30-Day Notice of Intent To Seek Extension of Approval: Recordations (Rail and Water Carrier Liens), Water Carrier Tariffs, and Agricultural Contract Summaries

AGENCY: Surface Transportation Board.

ACTION: Notice and Request for Comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995, (PRA), the Surface Transportation Board (STB or Board) gives notice that it is requesting from the Office of Management and Budget (OMB) approval of an extension for the information collections required under rail or water carrier equipment liens (recordations), under water carrier tariffs, and under rail agricultural contract summaries. The information collections are described in more detail below. The Board previously published a notice about this collection in the **Federal Register**. 81 FR 26,302 (May 2, 2016). That notice allowed for a 60-day public review and comment period. No comments were received.

DATES: Comments on this information collection should be submitted by September 6, 2016.

ADDRESSES: Written comments should be identified as ''Paperwork Reduction Act Comments, Surface Transportation Board: Recordations, Water Carrier Tariffs, and Agricultural Contract Summaries.'' These comments should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Chandana L. Achanta, Surface Transportation Board Desk Officer, by email at *OIRA_SUBMISSION@OMB.EOP.GOV;* by fax at (202) 395–6974; or by mail to Room 10235, 725 17th Street NW., Washington, DC 20503. Please also direct comments to Chris Oehrle, Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001, or to *PRA@stb.dot.gov.*

FOR FURTHER INFORMATION CONTACT: For further information regarding this collection, contact Michael Higgins, Deputy Director, Office of Public Assistance, Governmental Affairs, and Compliance at (202) 245–0284 or at *higginsm@stb.dot.gov.* [Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1–800–877–8339.]

SUPPLEMENTARY INFORMATION: Comments are requested concerning: (1) The accuracy of the Board's burden estimates; (2) ways to enhance the quality, utility, and clarity of the information collected; (3) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology when appropriate; and (4) whether the collection of information is necessary for the proper performance of the functions of the Board, including whether the collection has practical utility. Submitted comments will be summarized and included in the Board's request for OMB approval.

Description of Collections

Collection Number 1

Title: Agricultural Contract Summaries.

OMB Control Number: 2140–0024.

STB Form Number: None.

Type of Review: Extension with change.

Number of Respondents: Approximately 10 (seven Class I railroads and a limited number of other railroads).

Frequency: On occasion. (Over the last three years, respondents have filed an average of 161 agricultural contract summaries per year. The same number of filings is expected during each of the next 3 years).

Total Burden Hours (annually including all respondents): 40.25 hours (161 submissions × .25 hours estimated per submission).

Total Annual ''Non-hour Burden'' Cost (such as start-up and mailing costs): There are no non-hourly burden costs for this collection. The collection is filed electronically.

Needs and Uses: Under 49 U.S.C. 10709(d), railroads are required to file a summary of the nonconfidential terms of any contract for the transportation of agricultural products.

Collection Number 2

Title: Recordations (Rail and Water Carrier Liens).

OMB Control Number: 2140–0025.

STB Form Number: None.

Type of Review: Extension with change.

Respondents: Parties holding liens on rail equipment or water carrier vessels, and carriers filing proof that a lien has been removed.

Number of Respondents: Approximately 50 respondents.

Frequency: On occasion. (Over the last three years, respondents have filed an average of 1,831 responses per year. The same number of filings is expected during each of the next 3 years).

Total Burden Hours (annually including all respondents): 457.75 hours (1,831 submissions × .25 hours estimated per response).

Total ''Non-hour Burden'' Cost (such as start-up and mailing costs): There are no non-hourly burden costs for this collection. The collection may be filed electronically.

Needs and Uses: Under 49 U.S.C. 11301 and 49 CFR 1177, liens on rail equipment must be filed with the STB in order to perfect a security interest in the equipment. Subsequent amendments, assignments of rights, or release of obligations under such instruments must also be filed with the agency. This information is maintained by the Board for public inspection. Recordation at the STB obviates the need for recording the liens in individual States.

Collection Number 3

Title: Water Carrier Tariffs.

OMB Control Number: 2140–0026.

STB Form Number: None.

Type of Review: Extension with change.

Respondents: Water carriers that provide freight transportation in noncontiguous domestic trade.

Number of Respondents: Approximately 29.

Frequency: On occasion. (Over the last three years, respondents have filed an average of 885 responses per year.[1] The same number of filings is expected during each of the next 3 years).

Total Burden Hours (annually including all respondents): 663.75 hours (885 filings × .75 hour estimated time per filing).

Total ''Non-hour Burden'' Cost (such as start-up costs and mailing costs): There are no non-hourly burden costs for this collection. The collection may be filed electronically.

Needs and Uses: Under 49 U.S.C. 13702(b) and 49 CFR 1312, water carriers that provide freight transportation in noncontiguous domestic trade (*i.e.,* domestic, as opposed to international) shipments moving to or from Alaska, Hawaii, or the U.S. territories or possessions (Puerto Rico, Guam, the U.S. Virgin Islands, American Samoa, and the Northern Mariana Islands)) must file tariffs, providing a list of prices and fees that the water carrier charges to the shipping public.

Under the PRA, a Federal agency conducting or sponsoring a collection of information must display a currently valid OMB control number. A collection of information, which is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c), includes agency requirements that persons submit reports, keep records, or provide information to the agency, third parties, or the public. Section 3507(b) of the PRA requires, concurrent with an agency's submitting a collection to OMB for approval, a 30-day notice and comment period through publication in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information.

Dated: August 2, 2016.

Brendetta S. Jones,

Clearance Clerk.

[FR Doc. 2016–18637 Filed 8–4–16; 8:45 am]

BILLING CODE 4915–01–P

TENNESSEE VALLEY AUTHORITY

Ash Impoundment Closure Final Environmental Impact Statement Part I Programmatic Review and Part II Site-Specific Review of 10 Ash Impoundments

AGENCY: Tennessee Valley Authority.

ACTION: Record of Decision.

SUMMARY: This notice is provided in accordance with the Council on

[1] In its 60-day notice, the Board inadvertently used an estimate of an average of 228 water carrier tariffs filed with the Board each year. The average number of tariffs filed is corrected here, as are the burden hours.

Environmental Quality's regulations (40 CFR parts 1500 to 1508) and Tennessee Valley Authority's (TVA's) procedures for implementing the National Environmental Policy Act (NEPA). TVA's Final Ash Impoundment Closure Environmental Impact Statement (EIS) Part I—Programmatic NEPA Review analyzed methods for closing impoundments that hold coal combustion residuals (CCRs) on a programmatic basis. Part II of this EIS addressed closing 10 impoundments or other wet-CCR facilities (collectively, ''impoundments'') at six of TVA's plants on a site-specific basis.

TVA has decided that the environmental and other factors identified in part I for screening and evaluating closure alternatives on a site-specific basis are appropriate for use in its future decision-making processes involving the proposed closure of CCR impoundments. It also has decided to implement the preferred closure alternatives identified for each of the site-specific evaluations in part II. The Notice of Availability (NOA) of the Final Ash Impoundment Closure EIS, Part I Programmatic NEPA Review and Part II Site Specific NEPA Reviews was published in the **Federal Register** on June 10, 2016.

FOR FURTHER INFORMATION CONTACT: Ashley Farless, 1101 Market Street BR 4A, Chattanooga, TN 37402, 423.751.2361, *CCR@TVA.gov.* The Final EIS, this Record of Decision (ROD) and other project documents are available on TVA's Web site *https://www.tva.gov/nepa*.

SUPPLEMENTARY INFORMATION: TVA is a corporate agency of the United States that provides electricity for business customers and local power distributors serving more than 9 million people in parts of seven southeastern states. TVA receives no taxpayer funding, deriving virtually all of its revenues from sales of electricity. In addition to operating and investing its revenues in its power system, TVA provides flood control, navigation and land management for the Tennessee River system and assists local power companies and state and local governments with economic development and job creation.

TVA has coal-fired plants and CCR impoundments in Alabama, Kentucky, and Tennessee. CCRs are byproducts produced from burning coal and include fly ash, bottom ash, boiler slag and flue gas desulfurization materials. CCRs are not hazardous, but they contain small amounts of chemical substances such as arsenic, chromium and cobalt. TVA has monitored ecological conditions adjacent to its plants and conducted toxicity testing of CCR wastewater from its plants for years. None of the data show adverse impacts to human health or the environment from CCR-related contamination.

During 2015, TVA produced nearly 4 million tons of CCR with approximately 2.1 million tons being synthetic gypsum,1.1 million tons being fly ash, 0.4 million tons of bottom ash and 0.3 million tons of boiler slag. Approximately 34 percent of CCRs produced was used or marketed, and the remaining CCRs are currently stored in landfills and impoundments at or near coal-fired plant sites. TVA CCR impoundments vary in size from less than 10 acres to nearly 400 acres. All of TVA's CCR facilities operate under permits issued by the States in which they are located.

TVA has committed to closing its wet CCR impoundments and converting wet CCR management processes to dry processes. These actions are undertaken on a project-by-project basis, subject to technical feasibility, availability of resources and environmental review.

In April 2015, the U.S. Environmental Protection Agency (EPA) established national criteria and schedules for the management and closure of CCR facilities. EPA purposefully structured its CCR Rule to encourage utilities to accelerate the closure of CCR impoundments because of the decrease in groundwater contamination risk and increased structural stability that results from eliminating the hydraulic pressure of ponded water.

On April 18, 2016, after release of the Draft EIS, EPA asked the D.C. Circuit Court of Appeals to remand and vacate the accelerated closure incentive in a partial settlement of litigation challenging the CCR Rule. This does not affect EPA's technical determination that accelerated closure will significantly reduce structural failure and groundwater contamination risks. Because of this pending regulatory change, TVA decided not to use the April 2018 incentive closure date as a significant factor in its consideration of the reasonableness of a closure alternative. Instead, TVA took into account the 5-year timeframe that EPA set for completing impoundment closures [40 Code of Federal Regulations (CFR) 257.102(f)]. However, early closure is environmentally preferable to closure later and this still remains an important consideration in TVA's analyses.

The purpose of this action is to support the implementation of TVA's goal of eliminating all wet CCR storage at its coal plants by closing CCR impoundments across the TVA system in a safe and effective manner, and to assist TVA in complying with EPA's CCR Rule.

Alternatives Considered

The EIS addressed closure alternatives that have reasonable prospects of providing a solution to the disposal of CCR. EPA's rule establishes two primary closure methods: (1) Closure-in-Place and (2) Closure-by-Removal. EPA observed that most facilities would be closed in place because of the difficulty and cost of Closure-by-Removal. It determined that either closure method would be equally protective of human health and the environment if completed properly. Accordingly, TVA developed three alternatives to the proposed action:

- Alternative A—No Action
- Alternative B—Closure-in-Place
- Alternative C—Closure-by-Removal

The EIS analyzes, to the extent practicable, the impacts resulting from each of these closure alternatives and the effectiveness of best management practices and mitigation measures in reducing potential impacts.

Alternative A—No Action

Under the No Action Alternative, TVA would not close any of the CCR impoundments at its coal-fired power plants. This alternative is included because applicable regulations require consideration of a No Action Alternative in order to provide a baseline for potential changes to environmental resources. However, the No Action Alternative is inconsistent with TVA's goal to convert all of its wet CCR systems to dry systems, the general direction of EPA's CCR Rule and other actions required by state regulatory programs related to CCR management.

Alternative B—Closure-in-Place

Closure-in-Place involves dewatering the impoundment, stabilizing the CCR in place and installing a cover system. The cover system over the compacted CCR prevents precipitation and storm water runoff from reaching the CCR. Doing this reduces hydraulic pressure and thereby reduces risks of structural instability and groundwater contamination. TVA concluded that it would take less than five years to close an impoundment in place, depending on its size, the distance to the cover system borrow area, and the condition of the road network between the borrow location and impoundment being closed.

Alternative C—Closure-by-Removal

Closure-by-Removal involves dewatering the impoundment and

excavating CCR, transporting it to a lined, permitted landfill, reshaping the site and filling it with borrow material. The duration of Closure-by-Removal projects would depend on a number of factors including, primarily, the amount of CCR to be removed from the impoundment, logistics associated with drying out the CCR and loading it into trucks or rail cars, and the amount of borrow material that must be transported to the site to fill in the excavated hole.

Environmentally Preferred Alternative

Part I: Programmatic NEPA Review

The EIS includes baseline information for understanding the potential environmental and socioeconomic impacts associated with the closure alternatives considered by TVA. TVA carefully considered 21 resource areas related to the human and natural environments and the impacts on these resources associated with each closure alternative.

Both CCR impoundment closure alternatives involve several common actions that are anticipated to result in environmental impacts. These include temporary construction-related impacts (*e.g.,* dewatering of impoundments, noise and fugitive dust generated from construction) and those associated with the transport of borrow material needed to close the CCR impoundment.

For Closure-in-Place, TVA's analyses confirm EPA's determination that dewatering and capping impoundments would reduce the potential risks of groundwater contamination and structural instability because the hydraulic pressure would be reduced. Compared to Closure-by-Removal, this alternative would have significantly less risks to workforce health and safety and those risks related to off-site transportation of CCR (crashes, derailments, road damage and other transportation-related effects). It also is less costly than Closure-by-Removal.

Closure-by-Removal would result in a greater reduction in potential groundwater contamination risk than Closure-in-Place over the long term because CCR material would be excavated and moved to a permitted landfill. However, this alternative would result in notably greater impacts associated with other environmental factors and would increase the potential for impacts on worker-related and transportation-related health and safety. In addition, Closure-by-Removal can raise environmental justice concerns associated with the transportation and disposal of CCR material in off-site locations.

Under both closure alternatives, actions to avoid, minimize or mitigate losses of resources, values or associated uses would be included.

Recognizing the potential pathways for risk exposure related to existing CCR impoundments, TVA identified a number of factors that are important in the screening and evaluation of project alternatives. These include: The volume of CCR materials, schedule/duration of closure activities, mode and duration of transportation movements, the potential for health and environmental risks, effects on wetlands, effects on adjacent environmental resources and cost.

At a programmatic level, TVA determined that Closure-in-Place would have fewer overall adverse environmental impacts than Closure-by-Removal and generally would be environmentally preferable.

Part II: Site-Specific NEPA Review

TVA identified 10 CCR impoundments at six of its plants that could quickly initiate and complete the closure process within the five-year time period identified in the CCR Rule. These are impoundments at its Allen, Bull Run, Kingston and John Sevier plants in Tennessee and at its Widows Creek and Colbert plants in Alabama. TVA conducted a site-specific NEPA review for each of these facilities that tiers off of the programmatic level review in part I of the Final EIS.

TVA used the screening and evaluation factors discussed above to determine which closure alternatives should be considered in greater detail in its site-specific analyses. Based on these factors, Alternative B was retained for analysis at all sites. Alternative C was retained for the closures proposed at the Allen Fossil Plant and John Sevier Fossil Plant. Alternative C was determined not to be reasonable at the other locations.

TVA has identified Alternative B, Closure-in-Place, as the environmentally preferred alternative in each site-specific review. It would achieve the purpose and need of the project to close the impoundments in a reasonable period while enhancing the protection of human health and the environment and avoid the adverse environmental impacts associated with Alternative C.

Decision

TVA has decided to use the screening and evaluation factors identified in Part I of the EIS to help frame its evaluation of future proposals to close other CCR impoundments at its coal-fired power plants. Conclusions reached from the programmatic analysis of each closure alternative should be applicable to any CCR impoundment within the TVA system regardless of the location. The evaluation of future closure activities at a specific location would tier from the analysis presented in the programmatic EIS and therefore implementation of part I will facilitate the closure of CCR impoundments in an environmentally appropriate manner. Using measures to avoid, minimize and mitigate the potential impacts associated with individual CCR impoundment closures will further help to protect human health and the environment.

In addition, TVA chose the preferred closure method—Alternative B—identified in the site-specific analyses in part II of the EIS for the proposed closure of the 10 impoundments. The impact analyses for each impoundment concluded that Closure-in-Place would meet the purpose for closing impoundments and enhance the protection of human health and environment. Compared to Closure-by-Removal, Closure-in-Place would have significantly fewer environmental and social impacts, could be completed more quickly, and would be substantially less costly.

In its June 21, 2016 letter summarizing its review of the FEIS, EPA rated the FEIS ''LO'' (lack of objection) and said: ''Overall, EPA concurs with the TVA's preferred alternative to close identified facilities in place according to the CCR Rule.''

Public Involvement

On August 27, 2015, TVA published a Notice of Intent (NOI) in the **Federal Register** announcing that it planned to prepare a programmatic EIS to address the closure of CCR impoundments at its coal-fired power plants. The NOI initiated a 30-day public scoping period, which concluded on September 30, 2015. In addition to the NOI in the **Federal Register**, TVA published notices regarding this effort in regional and local newspapers; issued a news release to more than 400 media outlets; and posted the news release on the TVA Web site to solicit public input.

The Draft Environmental Impact Statement (Draft EIS) was released to the public on December 30, 2015, and a Notice of Availability (NOA) of the Draft EIS was published in the **Federal Register** on January 8, 2016 (81 FR 936). Again more than 400 media outlets received notice of the Draft EIS availability. Publication in the **Federal Register** initiated the formal public comment period that was originally scheduled to close on February 14, 2016, but was extended until March 9, 2016 in response to several requests.

TVA accepted comments submitted through an electronic comment form on the EIS Web site, by post and email. During the comment period, TVA held 10 public meetings to discuss the Draft EIS and proposed site-specific closures with interested members of the public and to accept comments on it. TVA published notices of the public meetings in local and/or regional newspapers as well as provided information on TVA's Web site.

Additionally, TVA briefed customers, business leaders and local, state and federal officials on the EIS in one-on-one meetings, a webinar and conference calls. TVA created a five minute video that was shown at meetings and posted on the web.

TVA received approximately 70 comment submissions which included letters, emails, petition-style submissions, comment forms, and submissions through the project Web site. The comment submissions were signed by more than 650 individuals.

Approximately 583 individuals and groups submitted comments as part of organized campaigns. These comments were received as part of emails, form letters and submissions consisting of the text and a list of names and addresses of those who supported the comments. TVA provided responses to these comments.

Two organized commenting campaigns were submitted by:

- Sierra Club (411 individuals signed a form letter)
- Southern Alliance for Clean Energy (164 individuals signed a petition)

In addition, the Southern Environmental Law Center (SELC) and nine other environmental advocacy groups submitted an 89-page letter with hundreds of pages of attachments commenting on the Draft EIS. This letter was also carefully reviewed and responded to by TVA.

The most frequently mentioned topics included the public involvement process, the action purpose and need, range of closure alternatives, identification of the preferred alternative, need to comply with other federal and state requirements, need for full public disclosure, beneficial use of CCR and a range of environmental resource issues such as, potential impacts on groundwater, surface water, transportation, wildlife, floodplains, wetlands, air quality, socioeconomics and environmental justice, land use, safety and waste management.

TVA also provided information about the Draft EIS and its preliminary conclusions to a formal session of its Regional Energy Resource Council on January 20–21, 2016. This council is chartered under the Federal Advisory Committee Act and provides advice to TVA on energy resource activities. Council members represent a diverse group of stakeholders, including TVA customers, state governments, environmental advocacy groups and educational institutions. After discussion of the Draft EIS and TVA's analyses, the only additional action that the Council recommended that TVA take was to conduct a robust monitoring program at its CCR facilities.

The NOA for the Final EIS was published in the **Federal Register** on June 10, 2016. Although not required, TVA solicited comments on the Final EIS during the mandatory 30-day waiting period after a final EIS is released.

Only 11 commenters responded. Most of the comments consisted of brief statements. Four commenters had concerns about impacts from CCRs. TVA responded to similar concerns from commenters on the draft EIS. One commenter simply informed us that it was permitted to construct a municipal solid waste landfill in Tennessee near a rail line that would be able to accept coal ash, but construction had not yet commenced. Another commenter endorsed Closure-in-Place. The Commonwealth of Kentucky and the U.S. Army Corps of Engineers observed that their approvals may be needed for some closure activities in the future. The Department of the Interior supports TVA's plans to transition to dry ash storage and concluded that TVA had responded to all of its comments in the final EIS.

The two remaining commenters were the SELC with a coalition of other environmental advocacy groups and the EPA. SELC's comments largely repeated its earlier comments. They continue to argue that TVA needs to conduct additional studies before making closure decisions. Notably, no other federal, state, or local agency or government criticized the FEIS or objected to the identification of Closure-in-Place as TVA's preferred approach to closing the 10 CCR facilities that are evaluated in part II of the FEIS. As discussed above, EPA rated the FEIS ''LO'' and concurred with TVA's identification of Closure-in-Place as its preferred alternative in the site-specific reviews in part II.

Mitigation Measures

The reduction of environmental impacts was an important goal in TVA's process for identifying CCR impoundment closure methods. Mitigation measures, actions taken to reduce adverse impacts associated with proposed actions, include:

- Implementation of fugitive dust control systems;
- Erosion and sediment best management practices (BMPs) (*e.g.,* silt fences and/or or truck washes) to reduce the risk of impacts to surface waters from construction impacts;
- Other construction BMPs to minimize and restore areas disturbed during construction such as revegetation with native species;
- Implementation of supplemental groundwater mitigative measures that could include monitoring, assessment, or corrective action programs as required by the CCR Rule and state requirements.

Additional measures identified in Part II, the Site Specific NEPA review include:

- Evaluate the use of a temporary traffic signal to minimize traffic impacts during the transport of borrow material to the Bull Run Fossil Plant.

Dated: July 28, 2016.

Robert M. Deacy, Sr.,

Senior Vice President, Generation Construction, Projects & Services, Tennessee Valley Authority.

[FR Doc. 2016–18600 Filed 8–4–16; 8:45 am]

BILLING CODE 8120–08–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Passenger Facility Charge (PFC) Program; Draft FAA Order 5500.1B

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: This notice announces a request for comments on the draft FAA Order 5500.1B, Passenger Facility Charge. When finalized, this Order will replace Order 5500.1, Passenger Facility Charge, issued on August 9, 2001. This revised Order clarifies and updates statutory and regulatory requirements, including those affected by changes to the PFC statute from multiple FAA reauthorizations.

DATES: Comments must be received on or before September 30, 2016.

ADDRESSES: An electronic copy of draft FAA Order 5500.1B, and comment form, is available after August 4, 2016, through the Internet at the FAA Airports Web site at *http://www.faa.gov/airports/.* You may submit comments using the Draft PFC Order 5500.1B Comment Form available at the same

web address, using any of the following methods:

- *Email: 9-faa-arp-pfc-order-55001b@faa.gov.*
- *Facsimile:* (202) 267–5302.
- *Mail:* FAA Office of Airports, Office of Airport Planning and Programming, Financial Analysis and PFC Branch (APP–510), Room 619E, 800 Independence Avenue SW., Washington, DC 20591.

For more information on the notice and comment process, see the **SUPPLEMENTARY INFORMATION** section of this document. Privacy:

FOR FURTHER INFORMATION CONTACT: Joe Hebert, Manager, Financial Analysis and Passenger Facility Charge Branch, APP–510, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591, telephone (202) 267–8375; facsimile (202) 267–5302, email *joe.hebert@faa.gov.*

SUPPLEMENTARY INFORMATION:

Availability of Documents

You can get an electronic copy of this notice and the Draft PFC Order 5500.1B by visiting the FAA's Airports Web page at *http://www.faa.gov/airports/* after August 1, 2016.

Background

The Passenger Facility Charge Program (PFC) is an airport capital funding program, established by the Airport Safety and Capacity Expansion Act of 1990 as amended, 49 U.S.C. 40117 *et seq.* Order 5500.1, Passenger Facility Charge, issued August 9, 2001, provides instructions and sets forth policy and procedures used in the administration of PFC Program. The PFC Program allows the collection and use of fees up to $4.50 per enplaned passenger at commercial airports controlled by public agencies.

The primary audience for this order is all FAA employees with Passenger Facility Charge (PFC) responsibilities. The secondary audience includes Public Agencies and Air Carriers involved with collecting, using, and reporting PFC revenues. This Order, once finalized, is intended to replace the above referenced 2001 PFC Order with updated information that reflects current legislation, regulation, and policy. The Office of Airports reorganized and revised this Order to clarify what is required by law and policy and to incorporate PFC Updates 35–02 (dated October 5, 2001) though 69–12 (dated September 14, 2012).

Since 2001, there have been substantial changes to the laws, regulation, and policies relating to PFCs.

To incorporate these changes and provide the most useful and current program guidance to agency employees, the Office of Airport Planning and Programming, Financial Assistance Division has drafted an updated version to revise the Order to maximize its clarity. This update is a fundamental rewrite of FAA Order 5500.1, the current version of the PFC Order. The update clarifies the different responsibilities of the FAA Office of Airports staff and those of public agencies applying to collect and use PFCs. The update also clarifies the responsibilities of air carriers collecting, handling, and remitting PFCs to public agencies. This updated version of the Order includes the requirements for all PFC funded projects and can be used as a ready-reference for project-specific requirements.

Invitation for Public Comment

While the FAA generally does not request public comment on internal orders, the agency is offering this opportunity for public comment in recognition of the interest of multiple stakeholders of the aviation industry in PFCs. The agency will consider all comments received by the closing date of the comment period in finalizing this Order. Comments received after that date may be considered if consideration will not delay agency action on the Order.

Comments should be submitted on the Draft PFC Order 5500.1B Comment Form, which is available for downloading at *http://www.faa.gov/airports/.* Comments that are not submitted on the Draft PFC Order 5500.1B Comment Form may be considered only if consideration will not delay agency action on the Order.

Issued in Washington, DC, on July 29, 2016.

Elliott Black,

Director, Office of Airport Planning and Programming.

[FR Doc. 2016–18670 Filed 8–4–16; 8:45 am]

BILLING CODE 4910–13–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 Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning TD 8770, Certain Transfers of Stock or Securities by U.S. Persons to Foreign Corporations and Related Reporting Requirements; and TD 8662, Stock Transfer Rules.

DATES: Written comments should be received on or before October 4, 2016 to be assured of consideration.

ADDRESSES: Direct all written comments to Tuawana Pinkston, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulations should be directed to Martha R. Brinson, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the Internet at *Martha.R.Brinson@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: TD 8770, Certain Transfers of Stock or Securities by U.S. Persons to Foreign Corporations and Related Reporting Requirements; and TD 8862, Stock Transfer Rules.

OMB Number: 1545–1271.

Regulation Project Number: TD 8770 and TD 8662.

Abstract: A United States entity must generally file a gain recognition agreement with the IRS in order to defer gain on a Code section 367(a) transfer of stock to a foreign corporation, and must file a notice with the IRS if it realizes any income in a Code section 367(b) exchange. These regulations provide guidance and reporting requirements related to these transactions to ensure compliance with the respective Code sections.

Current Actions: There are no changes to these existing regulations.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 580.

Estimated Time per Respondent: 4 hours, 7 minutes.

Estimated Total Annual Burden Hours: 2,390.

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. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: July 28, 2016.

Tuawana Pinkston,

IRS Reports Clearance Officer.

[FR Doc. 2016–18617 Filed 8–4–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Special Projects Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Special Projects Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Tuesday, September 6, 2016.

FOR FURTHER INFORMATION CONTACT: Kim Vinci at 1–888–912–1227 or 916–974–5086.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that a meeting of the Taxpayer Advocacy Panel Special Projects Committee will be held Tuesday, September 6, 2016, at 1:00 p.m. Eastern Time via teleconference. The public is invited to make oral comments or submit written statements for consideration. Due to limited conference lines, notification of intent to participate must be made with Kim Vinci. For more information please contact: Kim Vinci at 1–888–912–1227 or 916–974–5086, TAP Office, 4330 Watt Ave, Sacramento, CA 95821, or contact us at the Web site: *http://www.improveirs.org.*

The agenda will include a discussion on various special topics with IRS processes.

Dated: August 1, 2016.

Shawn Collins,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2016–18618 Filed 8–4–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Taxpayer Communications Project Committee

AGENCY: Internal Revenue Service (IRS) Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Taxpayer Communications Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Thursday, September 15, 2016.

FOR FURTHER INFORMATION CONTACT: Antoinette Ross at 1–888–912–1227 or (202) 317–4110.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Taxpayer Communications Project Committee will be held Thursday, September 15, 2016, at 2:00 p.m. Eastern Time via teleconference. The public is invited to make oral comments or submit written statements for consideration. Due to limited conference lines, notification of intent to participate must be made with Antoinette Ross. For more information please contact: Antoinette Ross at 1–888–912–1227 or (202) 317–4110, or write TAP Office, 1111 Constitution Avenue NW., Room 1509—National Office, Washington, DC 20224, or contact us at the Web site: *http://www.improveirs.org.*

The committee will be discussing various issues related to Taxpayer Communications and public input is welcome.

Dated: August 1, 2016.

Shawn Collins,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2016–18623 Filed 8–4–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Toll-Free Phone Line Project Committee; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting; correction.

SUMMARY: In the **Federal Register** notice that was originally published on July 8, 2016, (Volume 81, Number 131, Page 44686) the date was August 17, 2016 at 2:30 p.m., Eastern Time. The new meeting date is: Wednesday, August 24, 2016, at 2:30 p.m., Eastern Time.

DATES: The meeting will be held Wednesday, August 24, 2016.

FOR FURTHER INFORMATION CONTACT: Linda Rivera at 1–888–912–1227 or (202) 317–3337.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Toll Free Project Committee will be held Wednesday, August 24, 2016, at 2:30 p.m. Eastern Time via teleconference. The public is invited to make oral comments or submit written statements for consideration. Due to limited conference lines, notification of intent to participate must be made with Linda Rivera. For more information please contact: Ms. Rivera at 1–888–912–1227 or (202) 317–3337, or write TAP Office, 1111 Constitution Avenue NW., Room 1509—National Office, Washington, DC 20224, or contact us at the Web site: *http://www.improveirs.org.*

The committee will be discussing Toll-free issues and public input is welcomed.

Dated: July 27, 2016.

Shawn Collins,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2016–18625 Filed 8–4–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Joint Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Joint Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Wednesday, September 28, 2016.

FOR FURTHER INFORMATION CONTACT: Kim Vinci at 1–888–912–1227 or 916–974–5086.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Joint Committee will be held Wednesday, September 28, 2016, at 1:00 p.m. Eastern Time via teleconference. The public is invited to make oral comments or submit written statements for consideration. For more information please contact: Kim Vinci at 1–888–912–1227 or 916–974–5086, TAP Office, 4330 Watt Ave, Sacramento, CA 95821, or contact us at the Web site: *http://www.improveirs.org.*

The agenda will include various committee issues for submission to the IRS and other TAP related topics. Public input is welcomed.

Dated: August 1, 2016.

Shawn Collins,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2016–18633 Filed 8–4–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Tax Forms and Publications Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Tax Forms and Publications Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Thursday, September 8, 2016.

FOR FURTHER INFORMATION CONTACT: Donna Powers at 1–888–912–1227 or (954) 423–7977.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Tax Forms and Publications Project Committee will be held Thursday, September 8, 2016, at 1:00 p.m.. Eastern Time via teleconference. The public is invited to make oral comments or submit written statements for consideration. Due to limited conference lines, notification of intent to participate must be made with Donna Powers. For more information please contact: Donna Powers at 1–888–912–1227 or (954) 423–7977 or write: TAP Office, 1000 S. Pine Island Road, Plantation, FL 33324 or contact us at the Web site: *http://www.improveirs.org.* The committee will be discussing various issues related to Tax Forms and Publications and public input is welcomed.

Dated: August 1, 2016.

Shawn Collins,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2016–18627 Filed 8–4–16; 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 Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Amortization of Reforestation Expenditures.

DATES: Written comments should be received on or before October 4, 2016 to be assured of consideration.

ADDRESSES: Direct all written comments to Joseph Durbala, 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 Kerry Dennis at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW., Washington, DC 20224, or through the internet at *Kerry.Dennis@irs.gov*.

SUPPLEMENTARY INFORMATION:

Title: Amortization of Reforestation Expenditures.

OMB Number: 1545–0735.

Regulation Project Number: TD 7927.

Abstract: Internal Revenue Code section 194 allows taxpayers to elect to amortize certain reforestation expenditures over a 7-year period if the expenditures meet certain requirements. The regulations implement this election provision and allow the IRS to determine if the election is proper and allowable.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households, business, or other for-profit organizations, and farms.

Estimated Number of Respondents: 12,000.

Estimated Time per Respondent: 30 minutes.

Estimated Total Annual Burden Hours: 6,001.

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. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the

agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: July 27, 2016.

Joseph Durbala,

IRS Reports Clearance Officer.

[FR Doc. 2016–18624 Filed 8–4–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Taxpayer Assistance Center Improvements Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: The Taxpayer Advocacy Panel Taxpayer Assistance Center Improvements Project Committee will conduct an open meeting and will solicit public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Wednesday, September 14, 2016.

FOR FURTHER INFORMATION CONTACT: Otis Simpson at 1–888–912–1227 or 202–317–3332.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that a meeting of the Taxpayer Advocacy Panel Taxpayer Assistance Center Improvements Project Committee will be held Wednesday, September 14, 2016, at 2:00 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited conference lines, notification of intent to participate must be made with Otis Simpson. For more information please contact: Otis Simpson at 1–888–912–1227 or 202–317–3332, TAP Office, 1111 Constitution Avenue NW., Room 1509—National Office, Washington, DC 20224, or contact us at the Web site: *http://www.improveirs.org.*

The committee will be discussing various issues related to the Taxpayer Assistance Centers and public input is welcomed.

Dated: August 1, 2016.

Shawn Collins,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2016–18631 Filed 8–4–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Toll-Free Phone Line Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Toll-Free Phone Line Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Wednesday, September 14, 2016.

FOR FURTHER INFORMATION CONTACT: Linda Rivera at 1–888–912–1227 or (202) 317–3337.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Toll-Free Phone Line Project Committee will be held Wednesday, September 14, 2016, at 2:30 p.m. Eastern Time via teleconference. The public is invited to make oral comments or submit written statements for consideration. Due to limited conference lines, notification of intent to participate must be made with Linda Rivera. For more information please contact: Ms. Rivera at 1–888–912–1227 or (202) 317–3337, or write TAP Office, 1111 Constitution Avenue NW., Room 1509—National Office, Washington, DC 20224, or contact us at the Web site: *http://www.improveirs.org.*

The committee will be discussing Toll-free issues and public input is welcomed.

Dated: August 1, 2016.

Shawn Collins,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2016–18626 Filed 8–4–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Notices and Correspondence Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Notices and Correspondence Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Wednesday, September 28, 2016.

FOR FURTHER INFORMATION CONTACT: Theresa Singleton at 1–888–912–1227 or 202–317–3329.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that a meeting of the Taxpayer Advocacy Panel Notices and Correspondence Project Committee will be held Wednesday, September 28, 2016, at 12:00 p.m. Eastern Time via teleconference. The public is invited to make oral comments or submit written statements for consideration. Due to limited conference lines, notification of intent to participate must be made with Theresa Singleton. For more information please contact: Theresa Singleton at 1–888–912–1227 or 202–317–3329, TAP Office, 1111 Constitution Avenue NW., Room 1509—National Office, Washington, DC 20224, or contact us at the Web site: *http://www.improveirs.org.*

The agenda will include a discussion on various letters, and other issues related to written communications

Dated: August 1, 2016.

Shawn Collins,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2016–18629 Filed 8–4–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Office Of The Secretary

List of Countries Requiring Cooperation With an International Boycott

In accordance with section 999(a)(3) of the Internal Revenue Code of 1986, the Department of the Treasury is publishing a current list of countries

which require or may require participation in, or cooperation with, an international boycott (within the meaning of section 999(b)(3) of the Internal Revenue Code of 1986).

On the basis of the best information currently available to the Department of the Treasury, the following countries require or may require participation in, or cooperation with, an international boycott (within the meaning of section 999(b)(3) of the Internal Revenue Code of 1986).

Iraq
Kuwait
Lebanon
Libya
Qatar
Saudi Arabia
Syria
United Arab Emirates
Yemen

Dated: July 26, 2016.

Danielle Rolfes,

International Tax Counsel, (Tax Policy).

[FR Doc. 2016–18619 Filed 8–4–16; 8:45 am]

BILLING CODE 4810–25–P

FEDERAL REGISTER

Vol. 81 Friday,
No. 151 August 5, 2016

Part II

Department of Health and Human Services

Centers for Medicare and Medicaid Services

42 CFR Part 413

Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2017, SNF Value-Based Purchasing Program, SNF Quality Reporting Program, and SNF Payment Models Research; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 413

[CMS–1645–F]

RIN 0938–AS75

Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2017, SNF Value-Based Purchasing Program, SNF Quality Reporting Program, and SNF Payment Models Research

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule updates the payment rates used under the prospective payment system (PPS) for skilled nursing facilities (SNFs) for fiscal year (FY) 2017. In addition, it specifies a potentially preventable readmission measure for the Skilled Nursing Facility Value-Based Purchasing Program (SNF VBP), and implements requirements for that program, including performance standards, a scoring methodology, and a review and correction process for performance information to be made public, aimed at implementing value-based purchasing for SNFs. Additionally, this final rule includes additional polices and measures in the Skilled Nursing Facility Quality Reporting Program (SNF QRP). This final rule also responds to comments on the SNF Payment Models Research (PMR) project.

DATES: These regulations are effective on October 1, 2016.

FOR FURTHER INFORMATION CONTACT:

Penny Gershman, (410) 786–6643, for information related to SNF PPS clinical issues.

John Kane, (410) 786–0557, for information related to the development of the payment rates and case-mix indexes.

Kia Sidbury, (410) 786–7816, for information related to the wage index.

Bill Ullman, (410) 786–5667, for information related to level of care determinations, consolidated billing, and general information.

Stephanie Frilling, (410) 786–4507, for information related to skilled nursing facility value-based purchasing.

Charlayne Van, (410) 786–8659, for information related to skilled nursing facility quality reporting.

SUPPLEMENTARY INFORMATION:

Availability of Certain Tables Exclusively Through the Internet on the CMS Web Site

As discussed in the FY 2017 SNF PPS proposed rule (81 FR 24230), tables setting forth the Wage Index for Urban Areas Based on CBSA Labor Market Areas and the Wage Index Based on CBSA Labor Market Areas for Rural Areas are no longer published in the **Federal Register**. Instead, these tables are available exclusively through the Internet on the CMS Web site. The wage index tables for this final rule can be accessed on the SNF PPS Wage Index home page, at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html.*

Readers who experience any problems accessing any of these online SNF PPS wage index tables should contact Kia Sidbury at (410) 786–7816.

To assist readers in referencing sections contained in this document, we are providing the following Table of Contents.

Table of Contents

Acronyms

In addition, because of the many terms to which we refer by acronym in this final rule, we are listing these abbreviations and their corresponding terms in alphabetical order below:

AIDS Acquired Immune Deficiency Syndrome
ARD Assessment reference date
BBA Balanced Budget Act of 1997, Pub. L. 105–33
BBRA Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, Pub. L. 106–113
BIPA Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. 106–554
CAH Critical access hospital
CASPER Certification and Survey Provider Enhanced Reporting
CBSA Core-based statistical area
CCN CMS Certification Number
CFR Code of Federal Regulations
CMI Case-mix index
CMS Centers for Medicare & Medicaid Services
FFS Fee-for-service
FR Federal Register
FY Fiscal year
HCPCS Healthcare Common Procedure Coding System
HIQR Hospital Inpatient Quality Reporting
HOQR Hospital Outpatient Quality Reporting
HRRP Hospital Readmissions Reduction Program
HVBP Hospital Value-Based Purchasing
IGI IHS (Information Handling Services) Global Insight, Inc.
IMPACT Improving Medicare Post-Acute Care Transformation Act of 2014, Pub. L. 113–185
IPPS Inpatient prospective payment system
IRF Inpatient Rehabilitation Facility
LTC Long-term care
LTCH Long-term care hospital
MAP Measures Application Partnership
MDS Minimum data set
MFP Multifactor productivity
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108–173
MSA Metropolitan statistical area
NF Nursing facility
NQF National Quality Forum
OMB Office of Management and Budget
PAC Post-acute care
PAMA Protecting Access to Medicare Act of 2014, Pub. L. 113–93
PBJ Payroll-Based Journal
PMR Payment Models Research
PPS Prospective Payment System
PQRS Physician Quality Reporting System
QIES Quality Improvement Evaluation System
QIES ASAP Quality Improvement and Evaluation System Assessment Submission and Processing
QRP Quality Reporting Program
RAI Resident assessment instrument
RAVEN Resident assessment validation entry
RFA Regulatory Flexibility Act, Pub. L. 96–354
RIA Regulatory impact analysis
RUG–III Resource Utilization Groups, Version 3
RUG–IV Resource Utilization Groups, Version 4
RUG–53 Refined 53-Group RUG–III Case-Mix Classification System
SCHIP State Children's Health Insurance Program
sDTI Suspected deep tissue injuries
SNF Skilled nursing facility

SNF QRP Skill nursing facility quality reporting program
SNFRM Skilled Nursing Facility 30-Day All-Cause Readmission Measure
STM Staff time measurement
STRIVE Staff time and resource intensity verification
TEP Technical expert panel
UMRA Unfunded Mandates Reform Act, Pub. L. 104–4
VBP Value-based purchasing

I. Executive Summary

A. Purpose

This final rule updates the SNF prospective payment rates for FY 2017 as required under section 1888(e)(4)(E) of the Social Security Act (the Act). It also responds to section 1888(e)(4)(H) of the Act, which requires the Secretary to provide for publication in the **Federal Register** before the August 1 that precedes the start of each fiscal year (FY) certain specified information relating to the payment update (see section II.C.). This final rule also includes an update on the SNF PMR project. In addition, it specifies a potentially preventable readmission measure for the Skilled Nursing Facility (SNF) Value-Based Purchasing (VBP) Program and finalizes other requirements related to that Program's implementation, including performance standards, a scoring methodology, and a review and correction process for performance information to be made public under the Program. We are also including four new quality and resource use measures for the SNF QRP and new SNF review and correction procedures for performance data that are to be publicly reported.

B. Summary of Major Provisions

In accordance with sections 1888(e)(4)(E)(ii)(IV) and 1888(e)(5) of the Act, the federal rates in this final rule reflect an update to the rates that we published in the SNF PPS final rule for FY 2016 (80 FR 46390), which reflects the SNF market basket index, as adjusted by the multifactor productivity (MFP) adjustment, for FY 2017. We are also finalizing various requirements for the SNF VBP Program, including a potentially preventable readmission measure, performance standards, and a scoring methodology, among other policies. In addition, we are adopting and implementing four new quality and resource use measures for the SNF QRP and new SNF review and correction procedures for performance data that are to be publicly reported as we continue to implement this program and meet the requirements of the IMPACT Act.

C. Summary of Cost and Benefits

Provision description	Total transfers
FY 2017 SNF PPS payment rate update	The overall economic impact of this final rule would be an estimated increase of $920 million in aggregate payments to SNFs during FY 2017.

II. Background on SNF PPS

A. Statutory Basis and Scope

As amended by section 4432 of the Balanced Budget Act of 1997 (BBA, Pub. L. 105–33, enacted on August 5, 1997), section 1888(e) of the Act provides for the implementation of a PPS for SNFs. This methodology uses prospective, case-mix adjusted per diem payment rates applicable to all covered SNF services defined in section 1888(e)(2)(A) of the Act. The SNF PPS is effective for cost reporting periods beginning on or after July 1, 1998, and covers all costs of furnishing covered SNF services (routine, ancillary, and capital-related costs) other than costs associated with approved educational activities and bad debts. Under section 1888(e)(2)(A)(i) of the Act, covered SNF services include post-hospital extended care services for which benefits are provided under Part A, as well as those items and services (other than a small number of excluded services, such as physician services) for which payment may otherwise be made under Part B and which are furnished to Medicare beneficiaries who are residents in a SNF during a covered Part A stay. A comprehensive discussion of these provisions appears in the May 12, 1998 interim final rule (63 FR 26252). In addition, a detailed discussion of the legislative history of the SNF PPS is available online at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/Legislative_History_07302013.pdf.*

Section 215(a) of PAMA added section 1888(g) to the Act requiring the Secretary to specify an all-cause all-condition hospital readmission measure and a resource use measure, an all-condition risk-adjusted potentially preventable hospital readmission measure, for the SNF setting. Additionally, section 215(b) of PAMA added section 1888(h) to the Act requiring the Secretary to implement a VBP program for SNFs. Finally, section 2(a) of the IMPACT Act added section 1899B to the Act that, among other things, requires SNFs to report standardized data for measures in specified quality and resource use domains. In addition, the IMPACT Act added section 1888(e)(6) to the Act, which requires the Secretary to implement a quality reporting program for SNFs, which includes a requirement that SNFs report certain data to receive their full payment under the SNF PPS.

B. Initial Transition for the SNF PPS

Under sections 1888(e)(1)(A) and 1888(e)(11) of the Act, the SNF PPS included an initial, three-phase transition that blended a facility-specific rate (reflecting the individual facility's historical cost experience) with the federal case-mix adjusted rate. The transition extended through the facility's first 3 cost reporting periods under the PPS, up to and including the one that began in FY 2001. Thus, the SNF PPS is no longer operating under the transition, as all facilities have been paid at the full federal rate effective with cost reporting periods beginning in FY 2002. As we now base payments for SNFs entirely on the adjusted federal per diem rates, we no longer include adjustment factors under the transition related to facility-specific rates for the upcoming FY.

C. Required Annual Rate Updates

Section 1888(e)(4)(E) of the Act requires the SNF PPS payment rates to be updated annually. The most recent annual update occurred in a final rule that set forth updates to the SNF PPS payment rates for FY 2016 (80 FR 46390, August 4, 2015).

Section 1888(e)(4)(H) of the Act specifies that we provide for publication annually in the **Federal Register** of the following:

- The unadjusted federal per diem rates to be applied to days of covered SNF services furnished during the upcoming FY.
- The case-mix classification system to be applied for these services during the upcoming FY.
- The factors to be applied in making the area wage adjustment for these services.

Along with other revisions discussed later in this preamble, this final rule would provide the required annual updates to the per diem payment rates for SNFs for FY 2017.

III. Analysis of and Responses to Public Comments on the FY 2017 SNF PPS Proposed Rule

In response to the publication of the FY 2017 SNF PPS proposed rule, we received 95 public comments from individuals, providers, corporations, government agencies, private citizens, trade associations, and major organizations. The following are brief summaries of each proposed provision, a summary of the public comments that we received related to that proposal, and our responses to the comments.

A. General Comments on the FY 2017 SNF PPS Proposed Rule

In addition to the comments we received on specific proposals contained within the proposed rule (which we address later in this final rule), commenters also submitted the following, more general, observations on the SNF PPS and SNF care generally. A discussion of these comments, along with our responses, appears below.

Comment: One commenter stated that there is a significant amount of fraud and abuse in the SNF PPS. The commenter further stated that, often times, non-licensed professionals will dictate the type of care beneficiaries receive, specifically referring to the number of therapy minutes a beneficiary receives. This commenter also stated that if a health care professional tries to speak about these issues, his or her job may be in jeopardy.

Response: We appreciate this commenter raising these concerns. While outside the scope of this rule, we will pass these concerns along to our colleagues in the Center for Program Integrity, who are responsible for identifying and addressing instances of fraud, waste and abuse in the Medicare program. Additionally, information on areas of potential waste, fraud or abuse may be reported to the Office of the Inspector General Hotline by calling 1–800–HHS–TIPS (1–800–447–8477).

Comment: A number of commenters raised concerns regarding the cost of care for the beneficiary. One commenter discussed how the individual beneficiary cost for living in a nursing home seemed to greatly exceed the cost of living in the community. A few commenters referenced the pace and breadth of potential changes to conditions of participation for long-term care facilities, notably those contained in rulemaking such as the 2015 proposed rule entitled ''Medicare and Medicaid Programs: Reform of Requirements for Long-Term Care Facilities'' (80 FR 42168), as well as noted that the cost of implementing these provisions is not covered by Medicaid or Medicare.

Response: While we appreciate the commenters raising these concerns, these comments and the provisions of the proposed rule referenced by commenters are outside the scope of this final rule. That being said, we will share these comments with the appropriate team within CMS responsible for these provisions.

Comment: A few commenters raised concerns regarding decisions made by Medicare Administrative Contractors. One commenter requested that we instruct these contractors to refrain from denying coverage and payment for SNF Part B claims in which physician visits occur more frequently than the minimum standards set by the conditions of participation at § 483.40. Another commenter requested that we examine potential instances in which contractors might unnecessarily target speech-language pathology services by making revisions to Medicare manuals which might affect coverage of these services.

Response: With regard to our instructing the contractors to refrain from denying coverage or payment for SNF Part B claims in which physician visits occur more frequently than the minimum standard set by the conditions of participation, this comment is outside the scope of this final rule. However, we will forward these comments to the appropriate division within CMS for consideration. With regard to contractors targeting speech-language pathology services, we are not aware of such targeting. We will continue to educate the contractors to ensure compliance with all federal guidance and regulations.

B. SNF PPS Rate Setting Methodology and FY 2017 Update

1. Federal Base Rates

Under section 1888(e)(4) of the Act, the SNF PPS uses per diem federal payment rates based on mean SNF costs in a base year (FY 1995) updated for inflation to the first effective period of the PPS. We developed the federal payment rates using allowable costs from hospital-based and freestanding SNF cost reports for reporting periods beginning in FY 1995. The data used in developing the federal rates also incorporated a Part B add-on, which is an estimate of the amounts that, prior to the SNF PPS, would have been payable under Part B for covered SNF services furnished to individuals during the course of a covered Part A stay in a SNF.

In developing the rates for the initial period, we updated costs to the first effective year of the PPS (the 15-month period beginning July 1, 1998) using a SNF market basket index, and then standardized for geographic variations in wages and for the costs of facility differences in case mix. In compiling the database used to compute the federal payment rates, we excluded those providers that received new provider exemptions from the routine cost limits, as well as costs related to payments for exceptions to the routine cost limits. Using the formula that the BBA prescribed, we set the federal rates at a level equal to the weighted mean of freestanding costs plus 50 percent of the difference between the freestanding mean and weighted mean of all SNF costs (hospital-based and freestanding) combined. We computed and applied separately the payment rates for facilities located in urban and rural areas, and adjusted the portion of the federal rate attributable to wage-related costs by a wage index to reflect geographic variations in wages.

2. SNF Market Basket Update

a. SNF Market Basket Index

Section 1888(e)(5)(A) of the Act requires us to establish a SNF market basket index that reflects changes over time in the prices of an appropriate mix of goods and services included in covered SNF services. Accordingly, we have developed a SNF market basket index that encompasses the most commonly used cost categories for SNF routine services, ancillary services, and capital-related expenses. We use the SNF market basket index, adjusted in the manner described below, to update the federal rates on an annual basis. In the SNF PPS final rule for FY 2014 (78 FR 47939 through 47946), we revised and rebased the market basket, which included updating the base year from FY 2004 to FY 2010.

For the FY 2017 proposed rule, the FY 2010-based SNF market basket growth rate was estimated to be 2.6 percent, which was based on the IHS Global Insight Inc. (IGI) first quarter 2016 forecast, with historical data through fourth quarter 2015. However, as discussed in the FY 2017 SNF PPS proposed rule (81 FR 24234), we proposed that if more recent data become available (for example, a more recent estimate of the FY 2010 based SNF market basket and/or MFP adjustment), we would use such data, if appropriate, to determine the FY 2017 SNF market basket percentage change, labor-related share relative importance, forecast error adjustment, and MFP adjustment in this final rule. Since that time, we have received an updated FY

2017 market basket percentage increase, which is based on the second quarter 2016 IGI forecast of the FY 2010-based SNF market basket. The revised market basket growth rate is 2.7 percent. In section III.B.2.e. of this final rule, we discuss the specific application of this adjustment to the forthcoming annual update of the SNF PPS payment rates.

b. Use of the SNF Market Basket Percentage

Section 1888(e)(5)(B) of the Act defines the SNF market basket percentage as the percentage change in the SNF market basket index from the midpoint of the previous FY to the midpoint of the current FY. For the federal rates set forth in this final rule, we use the percentage change in the SNF market basket index to compute the update factor for FY 2017. This is based on the IGI second quarter 2016 forecast (with historical data through the first quarter 2016) of the FY 2017 percentage increase in the FY 2010-based SNF market basket index for routine, ancillary, and capital-related expenses, which is used to compute the update factor in this final rule. As discussed in sections III.B.2.c. and III.B.2.d. of this final rule, this market basket percentage change is reduced by the applicable forecast error correction (as described in § 413.337(d)(2)) and by the MFP adjustment as required by section 1888(e)(5)(B)(ii) of the Act. Finally, as discussed in section II.B. of this final rule, we no longer compute update factors to adjust a facility-specific portion of the SNF PPS rates, because the initial three-phase transition period from facility-specific to full federal rates that started with cost reporting periods beginning in July 1998 has expired.

c. Forecast Error Adjustment

As discussed in the June 10, 2003 supplemental proposed rule (68 FR 34768) and finalized in the August 4, 2003, final rule (68 FR 46057 through 46059), § 413.337(d)(2) provides for an adjustment to account for market basket forecast error. The initial adjustment for market basket forecast error applied to the update of the FY 2003 rate for FY 2004, and took into account the cumulative forecast error for the period from FY 2000 through FY 2002, resulting in an increase of 3.26 percent to the FY 2004 update. Subsequent adjustments in succeeding FYs take into account the forecast error from the most recently available FY for which there are final data, and apply the difference between the forecasted and actual change in the market basket when the difference exceeds a specified threshold. We originally used a 0.25 percentage point threshold for this purpose; however, for the reasons specified in the FY 2008 SNF PPS final rule (72 FR 43425, August 3, 2007), we adopted a 0.5 percentage point threshold effective for FY 2008 and subsequent FYs. As we stated in the final rule for FY 2004 that first issued the market basket forecast error adjustment (68 FR 46058, August 4, 2003), the adjustment will reflect both upward and downward adjustments, as appropriate.

For FY 2015 (the most recently available FY for which there is final data), the estimated increase in the market basket index was 2.5 percentage points, while the actual increase for FY 2015 was 2.3 percentage points, resulting in the actual increase being 0.2 percentage point lower than the estimated increase. Accordingly, as the difference between the estimated and actual amount of change in the market basket index does not exceed the 0.5 percentage point threshold, the FY 2017 market basket percentage change of 2.7 percent will be not adjusted to account for the forecast error. Table 1 shows the forecasted and actual market basket amounts for FY 2015.

TABLE 1—DIFFERENCE BETWEEN THE FORECASTED AND ACTUAL MARKET BASKET INCREASES FOR FY 2015

Index	Forecasted FY 2015 increase *	Actual FY 2015 increase **	FY 2015 difference
SNF	2.5	2.3	0.2

* Published in **Federal Register**; based on second quarter 2014 IGI forecast (2010-based index).
** Based on second quarter 2016 IGI forecast, with historical data through the first quarter 2016 (2010-based index).

d. Multifactor Productivity Adjustment

Section 3401(b) of the Affordable Care Act requires that, in FY 2012 (and in subsequent FYs), the market basket percentage under the SNF payment system as described in section 1888(e)(5)(B)(i) of the Act is to be reduced annually by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act, added by section 3401(a) of the Affordable Care Act, sets forth the definition of this productivity adjustment. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost-reporting period, or other annual period) (the MFP adjustment). The Bureau of Labor Statistics (BLS) is the agency that publishes the official measure of private nonfarm business MFP. We refer readers to the BLS Web site at *http://www.bls.gov/mfp* for the BLS historical published MFP data.

MFP is derived by subtracting the contribution of labor and capital inputs growth from output growth. The projections of the components of MFP are currently produced by IGI, a nationally recognized economic forecasting firm with which CMS contracts to forecast the components of the market baskets and MFP. To generate a forecast of MFP, IGI replicates the MFP measure calculated by the BLS, using a series of proxy variables derived from IGI's U.S. macroeconomic models. For a discussion of the MFP projection methodology, we refer readers to the FY 2012 SNF PPS final rule (76 FR 48527 through 48529) and the FY 2016 SNF PPS final rule (80 FR 46395). A complete description of the MFP projection methodology is available on our Web site at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html*.

(i) Incorporating the MFP Adjustment Into the Market Basket Update

Per section 1888(e)(5)(A) of the Act, the Secretary shall establish a SNF market basket index that reflects changes over time in the prices of an appropriate mix of goods and services included in covered SNF services. Section 1888(e)(5)(B)(ii) of the Act, added by section 3401(b) of the Affordable Care Act, requires that for FY 2012 and each subsequent FY, after determining the market basket percentage described in section 1888(e)(5)(B)(i) of the Act, the Secretary shall reduce such percentage by the

productivity adjustment described in section 1886(b)(3)(B)(xi)(II) (which we refer to as the MFP adjustment). Section 1888(e)(5)(B)(ii) of the Act further states that the reduction of the market basket percentage by the MFP adjustment may result in the market basket percentage being less than zero for a FY, and may result in payment rates under section 1888(e) of the Act for a FY being less than such payment rates for the preceding FY. Thus, if the application of the MFP adjustment to the market basket percentage calculated under section 1888(e)(5)(B)(i) of the Act results in an MFP-adjusted market basket percentage that is less than zero, then the annual update to the unadjusted federal per diem rates under section 1888(e)(4)(E)(ii) of the Act would be negative, and such rates would decrease relative to the prior FY.

For the FY 2017 update, the MFP adjustment is calculated as the 10-year moving average of changes in MFP for the period ending September 30, 2017. In the FY 2017 SNF PPS proposed rule, this adjustment was calculated to be 0.5 percent. However, as discussed in the FY 2017 SNF PPS proposed rule (81 FR 24234), we proposed that if more recent data become available (for example, a more recent estimate of the FY 2010-based SNF market basket and/or MFP adjustment), we would use such data, if appropriate, to determine, among other things, the FY 2017 SNF market basket percentage change and the MFP adjustment in this final rule. Therefore, based on IGI's most recent second quarter 2016 forecast (with historical data through first quarter 2016), the MFP adjustment for FY 2017 is 0.3 percent. Consistent with section 1888(e)(5)(B)(i) of the Act and § 413.337(d)(2) of the regulations, the market basket percentage for FY 2017 for the SNF PPS is based on IGI's second quarter 2016 forecast of the SNF market basket update, which is estimated to be 2.7 percent, as adjusted by any applicable forecast error adjustment (as discussed above, in this final rule, we are not applying a forecast error adjustment to the SNF market basket update). In accordance with section 1888(e)(5)(B)(ii) of the Act (as added by section 3401(b) of the Affordable Care Act) and § 413.337(d)(3), this market basket percentage is then reduced by the MFP adjustment (the 10-year moving average of changes in MFP for the period ending September 30, 2017) of 0.3 percent, which is calculated as described above and based on IGI's second quarter 2016 forecast. The resulting MFP-adjusted SNF market basket update is equal to 2.4 percent, or 2.7 percent less 0.3 percentage point.

e. Market Basket Update Factor for FY 2017

Sections 1888(e)(4)(E)(ii)(IV) and 1888(e)(5)(i) of the Act require that the update factor used to establish the FY 2017 unadjusted federal rates be at a level equal to the market basket index percentage change. Accordingly, we determined the total growth from the average market basket level for the period of October 1, 2015 through September 30, 2016 to the average market basket level for the period of October 1, 2016 through September 30, 2017. This process yields a percentage change in the market basket of 2.7 percent.

As further explained in section III.B.2.c. of this final rule, as applicable, we adjust the market basket percentage change by the forecast error from the most recently available FY for which there is final data and apply this adjustment whenever the difference between the forecasted and actual percentage change in the market basket exceeds a 0.5 percentage point threshold. Since the difference between the forecasted FY 2015 SNF market basket percentage change and the actual FY 2015 SNF market basket percentage change (FY 2015 is the most recently available FY for which there is historical data) did not exceed the 0.5 percentage point threshold, the FY 2017 market basket percentage change of 2.7 percent will not be adjusted by the forecast error correction.

For FY 2017, section 1888(e)(5)(B)(ii) of the Act requires us to reduce the market basket percentage change by the MFP adjustment (the 10-year moving average of changes in MFP for the period ending September 30, 2017) of 0.3 percent, as described in section III.B.2.d. of this final rule. The resulting net SNF market basket update would equal 2.4 percent, or 2.7 percent less the 0.3 percentage point MFP adjustment. A discussion of the general comments that we received on the market basket update factor for FY 2017, and our responses to those comments, appears below.

Comment: We received a number of comments in relation to applying the FY 2017 market basket update factor in the determination of the FY 2017 unadjusted federal per diem rates, with some commenters supporting its application in determining the FY 2017 unadjusted per diem rates, while others opposed its application. In their March 2016 report (available at *http://medpac.gov/documents/reports/chapter-7-skilled-nursing-facility-services-(march-2016-report).pdf?sfvrsn=0*) and in their comment on the FY 2017 SNF PPS proposed rule, MedPAC recommended that we eliminate the market basket update for SNFs altogether and implement revisions to the SNF PPS.

Response: We appreciate all of the comments received on the proposed market basket update for FY 2017. In response to those comments opposing the application of the FY 2017 market basket update factor in determining the FY 2017 unadjusted federal per diem rates, specifically MedPAC's proposal to eliminate the market basket update for SNFs, under section 1888(e)(4)(E)(ii)(IV) and (e)(5)(B) of the Act, we are required to update the unadjusted Federal per diem rates each fiscal year by the SNF market basket percentage change, as reduced by the MFP adjustment.

Comment: Several commenters recommended that the SNF market basket be reweighted more frequently. They stated that due to the rapidly changing long term care environment, SNFs have and will continue to make significant modifications to their operations, including the need to respond to alternative payment models, managed care, and emerging quality requirements. One specific recommendation was to update the SNF market basket cost weights in accordance with the hospital market basket update schedule in order to increase the accuracy of the SNF market basket—particularly if the SNF wage index continues to be directly linked to the hospital wage index.

Response: We appreciate the commenter's suggestion for a more frequent rebasing of the SNF market basket. In the past, we have rebased the SNF market basket roughly every 5 to 7 years. In accordance with section 404 of Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA, Pub. L. 108–173), we determined that the frequency for rebasing the hospital market basket would be every 4 years. The SNF market basket was last rebased and revised 3 years ago in the FY 2014 SNF PPS final rule (reflecting 2010 base year expenditures), and was effective beginning in FY 2014. We will continue to review the most recent SNF Medicare cost report data and resulting market basket cost weights for any notable changes, and determine if we need to rebase the SNF market basket more frequently than roughly every 5 to 7 years. Should we determine that the SNF market basket would be improved by updating the base year, such an update would be proposed in

rulemaking and be subject to public comment.

Comment: One commenter requested that we engage in an ongoing dialogue with the commenter's association on their market basket research. The goal of such discussions would be to inform us and support any analogous CMS reform efforts.

Response: We appreciate the commenter's review of the market basket and continued dialogue regarding their research. Additionally, the commenter is encouraged to submit any research to *CMSDNHS@cms.hhs.gov*.

Comment: One commenter identified a potential error in our calculation of the proposed FY 2017 unadjusted federal per diem rates. Specifically, the commenter stated that the FY 2017 unadjusted federal per diem rates published in the FY 2017 SNF PPS proposed rule (81 FR 24234) did not appear to reflect the full, proposed FY 2017 market basket update factor of 2.1 percent.

Response: We appreciate this comment and, after review of the calculations used to determine the FY 2017 unadjusted federal per diem rates, we have determined that there was an error in our calculation of the proposed FY 2017 unadjusted federal per diem rates. Specifically, when performing the calculation of the FY 2017 unadjusted federal per diem rates, we begin with the FY 2016 unadjusted federal per diem rates which are updated by the FY 2017 MFP-adjusted market basket update factor in accordance with section 1888(e)(4)(E)(ii)(IV) and (e)(5)(B) of the Act. However, in performing the calculation, we inadvertently made an error in transcribing the FY 2016 unadjusted federal per diem rates (though we applied the correct FY 2017 proposed market basket update factor of 2.1 percent). Specifically, for the FY 2017 SNF PPS proposed rule, we inadvertently used the following rates as the FY 2016 unadjusted urban federal per diem rates in the calculation of the proposed FY 2017 urban unadjusted federal per diem rates: $171.12 (nursing case-mix), $128.90 (therapy case-mix), $16.97 (therapy non-case-mix), and $87.33 (non-case-mix). We inadvertently used the following rates as the FY 2016 unadjusted rural federal per diem rates in the calculation of the proposed FY 2017 unadjusted rural federal per diem rates: $163.48 (nursing case-mix), $148.62 (therapy case-mix), $18.14 (therapy non-case-mix), and $88.95 (non-case-mix). The correct FY 2016 urban and rural unadjusted federal per diem rates which should have been used in this calculation, and which have been used in the calculation of the final FY 2017 urban and rural unadjusted federal per diem rates provided in Tables 2 and 3 below, are those in Tables 2 and 3 of the FY 2016 SNF PPS final rule (80 FR 46397).

Additionally, as further discussed in section III.B.4., we also discovered an error in the calculation of the proposed FY 2017 wage index budget neutrality factor, which also impacted the calculation of the proposed FY 2017 unadjusted federal per diem rates set forth in the proposed rule (81 FR 24234) (as well as the impact analysis provided in Table 19 of the FY 2017 SNF PPS proposed rule (81 FR 24278), as further discussed in section VI.A.4. of this final rule).

We appreciate the commenter bringing this error to our attention. The corrected final FY 2017 SNF PPS unadjusted federal per diem rates are set forth below in Tables 2 and 3. We further note that, as described previously in this section, the FY 2017 market basket update factor and MFP adjustment were both updated in advance of the final rule. As such, the FY 2017 unadjusted federal per diem rates provided in Tables 2 and 3 reflect the updated FY 2017 market basket increase factor and MFP adjustment, as well as the corrected FY 2016 unadjusted federal per diem rates and corrected wage index budget neutrality factor which serve as the foundation for calculating the FY 2017 unadjusted federal per diem rates.

Accordingly, for the reasons specified in this final rule and in the FY 2017 SNF PPS proposed rule (81 FR 24230), we are applying the FY 2017 market basket factor, as adjusted by the MFP adjustment as described above, in our determination of the FY 2017 unadjusted federal per diem rates. We used the SNF market basket, adjusted as described previously, to adjust each per diem component of the federal rates forward to reflect the change in the average prices for FY 2017 from average prices for FY 2016. We further adjusted the rates by a wage index budget neutrality factor, described later in this section. Tables 2 and 3 reflect the updated components of the unadjusted federal rates for FY 2017, prior to adjustment for case-mix. As discussed previously in this section, the unadjusted federal per diem rates provided below reflect the updated FY 2017 market basket update factor, as adjusted by the updated MFP adjustment, and the corrections to the FY 2016 unadjusted federal per diem rates and the FY 2017 wage index budget neutrality factor described previously.

TABLE 2—FY 2017 UNADJUSTED FEDERAL RATE PER DIEM URBAN

Rate component	Nursing—case-mix	Therapy—case-mix	Therapy—non-case-mix	Non-case-mix
Per Diem Amount	$175.28	$132.03	$17.39	$89.46

TABLE 3—FY 2017 UNADJUSTED FEDERAL RATE PER DIEM RURAL

Rate component	Nursing—case-mix	Therapy—case-mix	Therapy—non-case-mix	Non-case-mix
Per Diem Amount	$167.45	$152.24	$18.58	$91.11

3. Case-Mix Adjustment

Under section 1888(e)(4)(G)(i) of the Act, the federal rate also incorporates an adjustment to account for facility case-mix, using a classification system that accounts for the relative resource utilization of different patient types. The statute specifies that the adjustment is to reflect both a resident classification system that the Secretary establishes to account for the relative resource use of different patient types, as well as resident assessment data and other data that the Secretary considers appropriate. In the interim final rule with comment period that initially implemented the SNF PPS (63 FR 26252, May 12, 1998), we developed the RUG–III case-mix classification system, which tied the amount of payment to resident resource

use in combination with resident characteristic information. Staff time measurement (STM) studies conducted in 1990, 1995, and 1997 provided information on resource use (time spent by staff members on residents) and resident characteristics that enabled us not only to establish RUG–III, but also to create case-mix indexes (CMIs). The original RUG–III grouper logic was based on clinical data collected in 1990, 1995, and 1997. As discussed in the SNF PPS proposed rule for FY 2010 (74 FR 22208), we subsequently conducted a multi-year data collection and analysis under the Staff Time and Resource Intensity Verification (STRIVE) project to update the case-mix classification system for FY 2011. The resulting Resource Utilization Groups, Version 4 (RUG–IV) case-mix classification system reflected the data collected in 2006–2007 during the STRIVE project, and was finalized in the FY 2010 SNF PPS final rule (74 FR 40288) to take effect in FY 2011 concurrently with an updated new resident assessment instrument, version 3.0 of the Minimum Data Set (MDS 3.0), which collects the clinical data used for case-mix classification under RUG–IV.

We note that case-mix classification is based, in part, on the beneficiary's need for skilled nursing care and therapy services. The case-mix classification system uses clinical data from the MDS to assign a case-mix group to each patient that is then used to calculate a per diem payment under the SNF PPS. As discussed in section IV.A. of the FY 2017 SNF PPS proposed rule (81 FR 24241 through 24242), the clinical orientation of the case-mix classification system supports the SNF PPS's use of an administrative presumption that considers a beneficiary's initial case-mix classification to assist in making certain SNF level of care determinations. Further, because the MDS is used as a basis for payment, as well as a clinical assessment, we have provided extensive training on proper coding and the time frames for MDS completion in our Resident Assessment Instrument (RAI) Manual. For an MDS to be considered valid for use in determining payment, the MDS assessment must be completed in compliance with the instructions in the RAI Manual in effect at the time the assessment is completed. For payment and quality monitoring purposes, the RAI Manual consists of both the Manual instructions and the interpretive guidance and policy clarifications posted on the appropriate MDS Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/MDS30RAIManual.html*.

In addition, we note that section 511 of the MMA, amended section 1888(e)(12) of the Act, to provide for a temporary increase of 128 percent in the PPS per diem payment for any SNF residents with Acquired Immune Deficiency Syndrome (AIDS), effective with services furnished on or after October 1, 2004. This special add-on for SNF residents with AIDS was to remain in effect until the Secretary certifies that there is an appropriate adjustment in the case mix to compensate for the increased costs associated with such residents. The add-on for SNF residents with AIDS is also discussed in Program Transmittal #160 (Change Request #3291), issued on April 30, 2004, which is available online at *www.cms.gov/transmittals/downloads/r160cp.pdf*. In the SNF PPS final rule for FY 2010 (74 FR 40288), we did not address this certification in that final rule's implementation of the case-mix refinements for RUG–IV, thus allowing the add-on payment required by section 511 of the MMA to remain in effect. For the limited number of SNF residents that qualify for this add-on, there is a significant increase in payments. For example, using FY 2014 data (which still used ICD–9–CM coding), we identified fewer than 4,800 SNF residents with a diagnosis code of 042 (Human Immunodeficiency Virus (HIV) Infection). As explained in the FY 2016 SNF PPS final rule (80 FR 46397 through 46398), on October 1, 2015 (consistent with section 212 of PAMA), we converted to using ICD–10–CM code B20 to identify those residents for whom it is appropriate to apply the AIDS add-on established by section 511 of the MMA. For FY 2017, an urban facility with a resident with AIDS in RUG–IV group ''HC2'' would have a case-mix adjusted per diem payment of $438.13 (see Table 4) before the application of the MMA adjustment. After an increase of 128 percent, this urban facility would receive a case-mix adjusted per diem payment of approximately $998.94.

Under section 1888(e)(4)(H) of the Act, each update of the payment rates must include the case-mix classification methodology applicable for the upcoming FY. The payment rates set forth in this final rule reflect the use of the RUG–IV case-mix classification system from October 1, 2016, through September 30, 2017. We list the case-mix adjusted RUG–IV payment rates, provided separately for urban and rural SNFs, in Tables 4 and 5 with corresponding case-mix values. We use the revised OMB delineations adopted in the FY 2015 SNF PPS final rule (79 FR 45632, 45634) to identify a facility's urban or rural status for the purpose of determining which set of rate tables would apply to the facility. Tables 4 and 5 do not reflect the add-on for SNF residents with AIDS enacted by section 511 of the MMA, which we apply only after making all other adjustments (such as wage index and case-mix). We would note that the case mix adjusted rates provided below are based on the FY 2017 unadjusted federal per diem rates provided in Tables 2 and 3 of this section, which reflect the updated FY 2017 SNF market basket update factor and updated MFP adjustment, as well as corrections to the errors associated with the unadjusted federal per diem rates published in the FY 2017 SNF PPS proposed rule (81 FR 24234) described previously in this section.

TABLE 4—RUG–IV CASE-MIX ADJUSTED FEDERAL RATES AND ASSOCIATED INDEXES—URBAN

RUG–IV Category	Nursing index	Therapy index	Nursing component	Therapy component	Non-case-mix therapy comp	Non-case-mix component	Total rate
RUX	2.67	1.87	$468.00	$246.90		$89.46	$804.36
RUL	2.57	1.87	450.47	246.90		89.46	786.83
RVX	2.61	1.28	457.48	169.00		89.46	715.94
RVL	2.19	1.28	383.86	169.00		89.46	642.32
RHX	2.55	0.85	446.96	112.23		89.46	648.65
RHL	2.15	0.85	376.85	112.23		89.46	578.54
RMX	2.47	0.55	432.94	72.62		89.46	595.02
RML	2.19	0.55	383.86	72.62		89.46	545.94
RLX	2.26	0.28	396.13	36.97		89.46	522.56
RUC	1.56	1.87	273.44	246.90		89.46	609.80
RUB	1.56	1.87	273.44	246.90		89.46	609.80

TABLE 4—RUG–IV CASE-MIX ADJUSTED FEDERAL RATES AND ASSOCIATED INDEXES—URBAN—Continued

RUG–IV Category	Nursing index	Therapy index	Nursing component	Therapy component	Non-case-mix therapy comp	Non-case-mix component	Total rate
RUA	0.99	1.87	173.53	246.90	.....	89.46	509.89
RVC	1.51	1.28	264.67	169.00	.....	89.46	523.13
RVB	1.11	1.28	194.56	169.00	.....	89.46	453.02
RVA	1.10	1.28	192.81	169.00	.....	89.46	451.27
RHC	1.45	0.85	254.16	112.23	.....	89.46	455.85
RHB	1.19	0.85	208.58	112.23	.....	89.46	410.27
RHA	0.91	0.85	159.50	112.23	.....	89.46	361.19
RMC	1.36	0.55	238.38	72.62	.....	89.46	400.46
RMB	1.22	0.55	213.84	72.62	.....	89.46	375.92
RMA	0.84	0.55	147.24	72.62	.....	89.46	309.32
RLB	1.50	0.28	262.92	36.97	.....	89.46	389.35
RLA	0.71	0.28	124.45	36.97	.....	89.46	250.88
ES3	3.58	.....	627.50	.....	$17.39	89.46	734.35
ES2	2.67	.....	468.00	.....	17.39	89.46	574.85
ES1	2.32	.....	406.65	.....	17.39	89.46	513.50
HE2	2.22	.....	389.12	.....	17.39	89.46	495.97
HE1	1.74	.....	304.99	.....	17.39	89.46	411.84
HD2	2.04	.....	357.57	.....	17.39	89.46	464.42
HD1	1.60	.....	280.45	.....	17.39	89.46	387.30
HC2	1.89	.....	331.28	.....	17.39	89.46	438.13
HC1	1.48	.....	259.41	.....	17.39	89.46	366.26
HB2	1.86	.....	326.02	.....	17.39	89.46	432.87
HB1	1.46	.....	255.91	.....	17.39	89.46	362.76
LE2	1.96	.....	343.55	.....	17.39	89.46	450.40
LE1	1.54	.....	269.93	.....	17.39	89.46	376.78
LD2	1.86	.....	326.02	.....	17.39	89.46	432.87
LD1	1.46	.....	255.91	.....	17.39	89.46	362.76
LC2	1.56	.....	273.44	.....	17.39	89.46	380.29
LC1	1.22	.....	213.84	.....	17.39	89.46	320.69
LB2	1.45	.....	254.16	.....	17.39	89.46	361.01
LB1	1.14	.....	199.82	.....	17.39	89.46	306.67
CE2	1.68	.....	294.47	.....	17.39	89.46	401.32
CE1	1.50	.....	262.92	.....	17.39	89.46	369.77
CD2	1.56	.....	273.44	.....	17.39	89.46	380.29
CD1	1.38	.....	241.89	.....	17.39	89.46	348.74
CC2	1.29	.....	226.11	.....	17.39	89.46	332.96
CC1	1.15	.....	201.57	.....	17.39	89.46	308.42
CB2	1.15	.....	201.57	.....	17.39	89.46	308.42
CB1	1.02	.....	178.79	.....	17.39	89.46	285.64
CA2	0.88	.....	154.25	.....	17.39	89.46	261.10
CA1	0.78	.....	136.72	.....	17.39	89.46	243.57
BB2	0.97	.....	170.02	.....	17.39	89.46	276.87
BB1	0.90	.....	157.75	.....	17.39	89.46	264.60
BA2	0.70	.....	122.70	.....	17.39	89.46	229.55
BA1	0.64	.....	112.18	.....	17.39	89.46	219.03
PE2	1.50	.....	262.92	.....	17.39	89.46	369.77
PE1	1.40	.....	245.39	.....	17.39	89.46	352.24
PD2	1.38	.....	241.89	.....	17.39	89.46	348.74
PD1	1.28	.....	224.36	.....	17.39	89.46	331.21
PC2	1.10	.....	192.81	.....	17.39	89.46	299.66
PC1	1.02	.....	178.79	.....	17.39	89.46	285.64
PB2	0.84	.....	147.24	.....	17.39	89.46	254.09
PB1	0.78	.....	136.72	.....	17.39	89.46	243.57
PA2	0.59	.....	103.42	.....	17.39	89.46	210.27
PA1	0.54	.....	94.65	.....	17.39	89.46	201.50

TABLE 5—RUG–IV CASE-MIX ADJUSTED FEDERAL RATES AND ASSOCIATED INDEXES—RURAL

RUG–IV Category	Nursing index	Therapy index	Nursing component	Therapy component	Non-case-mix therapy comp	Non-case-mix component	Total rate
RUX	2.67	1.87	$447.09	$284.69	.....	$91.11	$822.89
RUL	2.57	1.87	430.35	284.69	.....	91.11	806.15
RVX	2.61	1.28	437.04	194.87	.....	91.11	723.02
RVL	2.19	1.28	366.72	194.87	.....	91.11	652.70
RHX	2.55	0.85	427.00	129.40	.....	91.11	647.51
RHL	2.15	0.85	360.02	129.40	.....	91.11	580.53
RMX	2.47	0.55	413.60	83.73	.....	91.11	588.44
RML	2.19	0.55	366.72	83.73	.....	91.11	541.56
RLX	2.26	0.28	378.44	42.63	.....	91.11	512.18

TABLE 5—RUG–IV CASE-MIX ADJUSTED FEDERAL RATES AND ASSOCIATED INDEXES—RURAL—Continued

RUG–IV Category	Nursing index	Therapy index	Nursing component	Therapy component	Non-case-mix therapy comp	Non-case-mix component	Total rate
RUC	1.56	1.87	261.22	284.69	.....	91.11	637.02
RUB	1.56	1.87	261.22	284.69	.....	91.11	637.02
RUA	0.99	1.87	165.78	284.69	.....	91.11	541.58
RVC	1.51	1.28	252.85	194.87	.....	91.11	538.83
RVB	1.11	1.28	185.87	194.87	.....	91.11	471.85
RVA	1.10	1.28	184.20	194.87	.....	91.11	470.18
RHC	1.45	0.85	242.80	129.40	.....	91.11	463.31
RHB	1.19	0.85	199.27	129.40	.....	91.11	419.78
RHA	0.91	0.85	152.38	129.40	.....	91.11	372.89
RMC	1.36	0.55	227.73	83.73	.....	91.11	402.57
RMB	1.22	0.55	204.29	83.73	.....	91.11	379.13
RMA	0.84	0.55	140.66	83.73	.....	91.11	315.50
RLB	1.50	0.28	251.18	42.63	.....	91.11	384.92
RLA	0.71	0.28	118.89	42.63	.....	91.11	252.63
ES3	3.58	.....	599.47	.....	$18.58	91.11	709.16
ES2	2.67	.....	447.09	.....	18.58	91.11	556.78
ES1	2.32	.....	388.48	.....	18.58	91.11	498.17
HE2	2.22	.....	371.74	.....	18.58	91.11	481.43
HE1	1.74	.....	291.36	.....	18.58	91.11	401.05
HD2	2.04	.....	341.60	.....	18.58	91.11	451.29
HD1	1.60	.....	267.92	.....	18.58	91.11	377.61
HC2	1.89	.....	316.48	.....	18.58	91.11	426.17
HC1	1.48	.....	247.83	.....	18.58	91.11	357.52
HB2	1.86	.....	311.46	.....	18.58	91.11	421.15
HB1	1.46	.....	244.48	.....	18.58	91.11	354.17
LE2	1.96	.....	328.20	.....	18.58	91.11	437.89
LE1	1.54	.....	257.87	.....	18.58	91.11	367.56
LD2	1.86	.....	311.46	.....	18.58	91.11	421.15
LD1	1.46	.....	244.48	.....	18.58	91.11	354.17
LC2	1.56	.....	261.22	.....	18.58	91.11	370.91
LC1	1.22	.....	204.29	.....	18.58	91.11	313.98
LB2	1.45	.....	242.80	.....	18.58	91.11	352.49
LB1	1.14	.....	190.89	.....	18.58	91.11	300.58
CE2	1.68	.....	281.32	.....	18.58	91.11	391.01
CE1	1.50	.....	251.18	.....	18.58	91.11	360.87
CD2	1.56	.....	261.22	.....	18.58	91.11	370.91
CD1	1.38	.....	231.08	.....	18.58	91.11	340.77
CC2	1.29	.....	216.01	.....	18.58	91.11	325.70
CC1	1.15	.....	192.57	.....	18.58	91.11	302.26
CB2	1.15	.....	192.57	.....	18.58	91.11	302.26
CB1	1.02	.....	170.80	.....	18.58	91.11	280.49
CA2	0.88	.....	147.36	.....	18.58	91.11	257.05
CA1	0.78	.....	130.61	.....	18.58	91.11	240.30
BB2	0.97	.....	162.43	.....	18.58	91.11	272.12
BB1	0.90	.....	150.71	.....	18.58	91.11	260.40
BA2	0.70	.....	117.22	.....	18.58	91.11	226.91
BA1	0.64	.....	107.17	.....	18.58	91.11	216.86
PE2	1.50	.....	251.18	.....	18.58	91.11	360.87
PE1	1.40	.....	234.43	.....	18.58	91.11	344.12
PD2	1.38	.....	231.08	.....	18.58	91.11	340.77
PD1	1.28	.....	214.34	.....	18.58	91.11	324.03
PC2	1.10	.....	184.20	.....	18.58	91.11	293.89
PC1	1.02	.....	170.80	.....	18.58	91.11	280.49
PB2	0.84	.....	140.66	.....	18.58	91.11	250.35
PB1	0.78	.....	130.61	.....	18.58	91.11	240.30
PA2	0.59	.....	98.80	.....	18.58	91.11	208.49
PA1	0.54	.....	90.42	.....	18.58	91.11	200.11

4. Wage Index Adjustment

Section 1888(e)(4)(G)(ii) of the Act requires that we adjust the federal rates to account for differences in area wage levels, using a wage index that the Secretary determines appropriate. Since the inception of the SNF PPS, we have used hospital inpatient wage data in developing a wage index to be applied to SNFs. We proposed to continue this practice for FY 2017, as we continue to believe that in the absence of SNF-specific wage data, using the hospital inpatient wage index data is appropriate and reasonable for the SNF PPS. As explained in the update notice for FY 2005 (69 FR 45786), the SNF PPS does not use the hospital area wage index's occupational mix adjustment, as this adjustment serves specifically to define the occupational categories more clearly in a hospital setting; moreover, the collection of the occupational wage data also excludes any wage data related to SNFs. Therefore, we believe that using the updated wage data exclusive of the occupational mix adjustment continues to be appropriate for SNF payments. For FY 2017, the updated wage data are for

hospital cost reporting periods beginning on or after October 1, 2012 and before October 1, 2013 (FY 2013 cost report data).

We note that section 315 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA, Pub. L. 106–554, enacted on December 21, 2000) authorized us to establish a geographic reclassification procedure that is specific to SNFs, but only after collecting the data necessary to establish a SNF wage index that is based on wage data from nursing homes. However, to date, this has proven to be unfeasible due to the volatility of existing SNF wage data and the significant amount of resources that would be required to improve the quality of that data.

In addition, we proposed to continue to use the same methodology discussed in the SNF PPS final rule for FY 2008 (72 FR 43423) to address those geographic areas in which there are no hospitals, and thus, no hospital wage index data on which to base the calculation of the FY 2017 SNF PPS wage index. For rural geographic areas that do not have hospitals, and therefore, lack hospital wage data on which to base an area wage adjustment, we would use the average wage index from all contiguous Core-Based Statistical Areas (CBSAs) as a reasonable proxy. For FY 2017, there are no rural geographic areas that do not have hospitals, and thus, this methodology would not be applied. For rural Puerto Rico, we would not apply this methodology due to the distinct economic circumstances that exist there (for example, due to the close proximity to one another of almost all of Puerto Rico's various urban and non-urban areas, this methodology would produce a wage index for rural Puerto Rico that is higher than that in half of its urban areas); instead, we would continue to use the most recent wage index previously available for that area. For urban areas without specific hospital wage index data, we would use the average wage indexes of all of the urban areas within the state to serve as a reasonable proxy for the wage index of that urban CBSA. For FY 2017, the only urban area without wage index data available is CBSA 25980, Hinesville-Fort Stewart, GA. The wage index applicable to FY 2017 is set forth in Tables A and B available on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html.*

Once calculated, we would apply the wage index adjustment to the labor-related portion of the federal rate. Each year, we calculate a revised labor-related share, based on the relative importance of labor-related cost categories (that is, those cost categories that are labor-intensive and vary with the local labor market) in the input price index. In the SNF PPS final rule for FY 2014 (78 FR 47944 through 47946), we finalized a proposal to revise the labor-related share to reflect the relative importance of the FY 2010-based SNF market basket cost weights for the following cost categories: Wages and salaries; employee benefits; the labor-related portion of nonmedical professional fees; administrative and facilities support services; all other: Labor-related services; and a proportion of capital-related expenses.

We calculate the labor-related relative importance from the SNF market basket, and it approximates the labor-related portion of the total costs, after taking into account historical and projected price changes between the base year and FY 2017. The price proxies that move the different cost categories in the market basket do not necessarily change at the same rate, and the relative importance captures these changes. Accordingly, the relative importance figure more closely reflects the cost share weights for FY 2017 than the base year weights from the SNF market basket.

We calculate the labor-related relative importance for FY 2017 in four steps. First, we compute the FY 2017 price index level for the total market basket and each cost category of the market basket. Second, we calculate a ratio for each cost category by dividing the FY 2017 price index level for that cost category by the total market basket price index level. Third, we determine the FY 2017 relative importance for each cost category by multiplying this ratio by the base year (FY 2010) weight. Finally, we add the FY 2017 relative importance for each of the labor-related cost categories (wages and salaries, employee benefits, the labor-related portion of non-medical professional fees, administrative and facilities support services, all other: Labor-related services, and a portion of capital-related expenses) to produce the FY 2017 labor-related relative importance. Table 6 summarizes the updated labor-related share for FY 2017, compared to the labor-related share that was used for the FY 2016 SNF PPS final rule. In the FY 2017 SNF PPS proposed rule, the labor-related share for FY 2017 was proposed to be 68.9 percent. However, as discussed in the FY 2017 SNF PPS proposed rule (81 FR 24234), we proposed that if more recent data become available, we would use such data, if appropriate, to determine, among other things, the FY 2017 SNF labor related share. Therefore, based on IGI's most recent second quarter 2016 forecast (with historical data through first quarter 2016), the labor-related share for FY 2017 is 68.8 percent.

We invited public comments on these proposals. A discussion of the comments we received on these proposals, as well as a discussion of the general comments we received on the wage index adjustment, and our responses to those comments, appears below.

Comment: One commenter is concerned with the significant drop in the wage index for Great Falls, Montana (CBSA 24500). The commenter mentioned that Montana is a frontier state as defined in the Affordable Care Act and that the Affordable Care Act, specifically section 10324 of the Affordable Care Act, establishes a wage index floor of 1.0 for frontier state hospitals. The commenter recommends that CMS use its authority to apply the ACA-mandated frontier floor for hospitals to SNFs.

Response: We appreciate the commenter's concern regarding the application of a floor on area wage indexes for SNFs in frontier states. Section 10324 of the Affordable Care Act requires that hospitals in frontier states cannot be assigned a wage index of less than 1.0000. We do not believe it would be prudent at this time to adopt such a policy under the SNF PPS. As we stated in the FY 2016 SNF PPS final rule (80 FR 46401), MedPAC has recommended eliminating the rural floor policy (which actually sets a floor for urban hospitals) from the calculation of the IPPS wage index (see, for example, Chapter 3 of MedPAC's March 2013 Report to Congress on Medicare Payment Policy, available at *http://medpac.gov/documents/reports/mar13_entirereport.pdf*, which notes on page 65 that in 2007, MedPAC had ''. . . recommended eliminating these special wage index adjustments and adopting a new wage index system to avoid geographic inequities that can occur due to current wage index policies (Medicare Payment Advisory Commission 2007b.'') We stated in the FY 2016 SNF PPS final rule that if we adopted the rural floor at that time under the SNF PPS, we believed that the SNF PPS wage index could become vulnerable to problems similar to those that MedPAC identified in its March 2013 Report to Congress. Similarly, we have concerns regarding adopting a frontier state floor at this time under the SNF PPS as we are concerned that the frontier state floor could produce vulnerabilities for the SNF PPS wage index similar to those discussed by

MedPAC in its report. As stated above, under section 1888(e)(4)(G)(ii) of the Act and § 413.337(a)(1)(ii) of the regulations, we adjust the SNF PPS rates to account for differences in area wage levels. We believe that applying a floor to those facilities located in frontier states would make the wage index for those areas less reflective of the area wage levels.

Comment: Several commenters recommend that we continue exploring potential approaches for collecting SNF-specific wage data to establish a SNF-specific wage index. These commenters stated that the hospital wage index does not provide a reasonable proxy for SNF wages and occupational mix and should be replaced by use of SNF-specific data as soon as is practicable. One commenter recommended that we consider collecting base-hourly wage data as part of the Payroll-Based Journal (PBJ) initiative, which may be used in developing a SNF-specific wage index.

Response: We appreciate the commenters raising these concerns regarding the use of the hospital wage index data under the SNF PPS, and the commenter's recommendation to continue exploring potential approaches for collecting SNF-specific wage data to establish a SNF-specific wage index. However, we note that, consistent with our previous responses to these recurring comments (most recently published in the FY 2016 SNF PPS final rule (80 FR 46401)), developing such a wage index would require a resource-intensive audit process similar to that used for IPPS hospital data, to improve the quality of the SNF cost report data, in order for it to be used as part of this analysis. We would further note that, as this audit process is quite extensive in the case of approximately 3,300 hospitals, it would be significantly more so in the case of approximately 15,000 SNFs. Therefore, while we continue to review all available data and contemplate the potential methodological approaches for a SNF-specific wage index in the future, we continue to believe that in the absence of the appropriate SNF-specific wage data, using the pre-reclassified hospital inpatient wage data (without the occupational mix adjustment) is appropriate and reasonable for the SNF PPS. With regard to the PBJ recommendation, we will pass this comment to our colleagues managing that initiative for further consideration.

Comment: A few commenters suggested that we modify the use of hospital wage data used to construct the SNF PPS wage index, specifically calling for us to remove certain labor categories and data that are specific to hospitals only. These commenters also suggested that this modified methodology could further be tailored to SNFs by weighting it by occupational mix data for SNFs published by the Bureau of Labor Statistics (BLS).

Response: We appreciate these commenters' suggestion that we modify the current hospital wage data used to construct the SNF PPS wage index to reflect the SNF environment more accurately. While we consider whether or not such an approach may constitute an interim step in the process of developing a SNF-specific wage index, we would note that other provider types also use the hospital wage index as the basis for their associated wage index. As such, we believe that such a recommendation should be part of a broader discussion of wage index reform across Medicare payment systems.

Comment: A few commenters raised concerns around evolving minimum wage standards across the country and recommended that we consider ways to incorporate increasing minimum wage standards into the SNF PPS wage index. One commenter recommended that we should modify the wage index adjustment in the future to identify ''living wages'' across the country and that wage index policies should ensure that facilities pay their staff such a living wage. This commenter also recommended that we reward facilities that invest in their workforce.

Response: With regard to rising minimum wage standards, we would note that such increases would likely be reflected in future data used to create the hospital wage index, to the extent these changes to state minimum wage standards are reflected in increased wages to hospital staff. Therefore, such standards would already be incorporated into the calculation of the SNF PPS wage index to the extent that these standards impact on facility wages. With regard to the comment that we should modify the wage index adjustment to identify and support facilities that pay a living wage to their staff, the purpose of the wage index adjustment is to reflect the actual wages being paid to staff, not to influence the wages being paid to staff. Therefore, we do not believe that we should make modifications to the wage index to reflect an ideal standard of wages that does not currently exist.

Accordingly, after considering the comments received and for the reasons discussed previously in this section and in the FY 2017 SNF PPS proposed rule (81 FR 24237 through 24241), we are finalizing the FY 2017 wage index adjustment and related policies as proposed in the FY 2017 SNF PPS proposed rule. For FY 2017, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2012 and before October 1, 2013 (FY 2013 cost report data). Table 6 summarizes the updated labor-related share for FY 2017, compared to the labor-related share that was used in the FY 2016 SNF PPS final rule.

TABLE 6—LABOR-RELATED RELATIVE IMPORTANCE, FY 2016 AND FY 2017

	Relative importance, labor-related, FY 2016 15:2 forecast [1]	Relative importance, labor-related, FY 2017 16:2 forecast [2]
Wages and salaries	48.8	48.8
Employee benefits	11.3	11.1
Nonmedical Professional fees: Labor-related	3.5	3.4
Administrative and facilities support services	0.5	0.5
All Other: Labor-related services	2.3	2.3
Capital-related (.391)	2.7	2.7
Total	69.1	68.8

[1] Published in the **Federal Register**; based on second quarter 2015 IGI forecast.
[2] Based on second quarter 2016 IGI forecast, with historical data through first quarter 2016.

Tables 7 and 8 show the RUG–IV case-mix adjusted federal rates by labor-related and non-labor-related components.

TABLE 7—RUG–IV CASE-MIX ADJUSTED FEDERAL RATES FOR URBAN SNFS BY LABOR AND NON-LABOR COMPONENT

RUG–IV category	Total rate	Labor portion	Non-labor portion
RUX	804.36	$553.40	$250.96
RUL	786.83	541.34	245.49
RVX	715.94	492.57	223.37
RVL	642.32	441.92	200.40
RHX	648.65	446.27	202.38
RHL	578.54	398.04	180.50
RMX	595.02	409.37	185.65
RML	545.94	375.61	170.33
RLX	522.56	359.52	163.04
RUC	609.80	419.54	190.26
RUB	609.80	419.54	190.26
RUA	509.89	350.80	159.09
RVC	523.13	359.91	163.22
RVB	453.02	311.68	141.34
RVA	451.27	310.47	140.80
RHC	455.85	313.62	142.23
RHB	410.27	282.27	128.00
RHA	361.19	248.50	112.69
RMC	400.46	275.52	124.94
RMB	375.92	258.63	117.29
RMA	309.32	212.81	96.51
RLB	389.35	267.87	121.48
RLA	250.88	172.61	78.27
ES3	734.35	505.23	229.12
ES2	574.85	395.50	179.35
ES1	513.50	353.29	160.21
HE2	495.97	341.23	154.74
HE1	411.84	283.35	128.49
HD2	464.42	319.52	144.90
HD1	387.30	266.46	120.84
HC2	438.13	301.43	136.70
HC1	366.26	251.99	114.27
HB2	432.87	297.81	135.06
HB1	362.76	249.58	113.18
LE2	450.40	309.88	140.52
LE1	376.78	259.22	117.56
LD2	432.87	297.81	135.06
LD1	362.76	249.58	113.18
LC2	380.29	261.64	118.65
LC1	320.69	220.63	100.06
LB2	361.01	248.37	112.64
LB1	306.67	210.99	95.68
CE2	401.32	276.11	125.21
CE1	369.77	254.40	115.37
CD2	380.29	261.64	118.65
CD1	348.74	239.93	108.81
CC2	332.96	229.08	103.88
CC1	308.42	212.19	96.23
CB2	308.42	212.19	96.23
CB1	285.64	196.52	89.12
CA2	261.10	179.64	81.46
CA1	243.57	167.58	75.99
BB2	276.87	190.49	86.38
BB1	264.60	182.04	82.56
BA2	229.55	157.93	71.62
BA1	219.03	150.69	68.34
PE2	369.77	254.40	115.37
PE1	352.24	242.34	109.90
PD2	348.74	239.93	108.81
PD1	331.21	227.87	103.34
PC2	299.66	206.17	93.49
PC1	285.64	196.52	89.12
PB2	254.09	174.81	79.28
PB1	243.57	167.58	75.99
PA2	210.27	144.67	65.60
PA1	201.50	138.63	62.87

TABLE 8—RUG–IV CASE-MIX ADJUSTED FEDERAL RATES FOR RURAL SNFS BY LABOR AND NON-LABOR COMPONENT

RUG–IV Category	Total rate	Labor portion	Non-labor portion
RUX	822.89	$566.15	$256.74
RUL	806.15	554.63	251.52
RVX	723.02	497.44	225.58
RVL	652.70	449.06	203.64
RHX	647.51	445.49	202.02
RHL	580.53	399.40	181.13
RMX	588.44	404.85	183.59
RML	541.56	372.59	168.97
RLX	512.18	352.38	159.80
RUC	637.02	438.27	198.75
RUB	637.02	438.27	198.75
RUA	541.58	372.61	168.97
RVC	538.83	370.72	168.11
RVB	471.85	324.63	147.22
RVA	470.18	323.48	146.70
RHC	463.31	318.76	144.55
RHB	419.78	288.81	130.97
RHA	372.89	256.55	116.34
RMC	402.57	276.97	125.60
RMB	379.13	260.84	118.29
RMA	315.50	217.06	98.44
RLB	384.92	264.82	120.10
RLA	252.63	173.81	78.82
ES3	709.16	487.90	221.26
ES2	556.78	383.06	173.72
ES1	498.17	342.74	155.43
HE2	481.43	331.22	150.21
HE1	401.05	275.92	125.13
HD2	451.29	310.49	140.80
HD1	377.61	259.80	117.81
HC2	426.17	293.20	132.97
HC1	357.52	245.97	111.55
HB2	421.15	289.75	131.40
HB1	354.17	243.67	110.50
LE2	437.89	301.27	136.62
LE1	367.56	252.88	114.68
LD2	421.15	289.75	131.40
LD1	354.17	243.67	110.50
LC2	370.91	255.19	115.72
LC1	313.98	216.02	97.96
LB2	352.49	242.51	109.98
LB1	300.58	206.80	93.78
CE2	391.01	269.01	122.00
CE1	360.87	248.28	112.59
CD2	370.91	255.19	115.72
CD1	340.77	234.45	106.32
CC2	325.70	224.08	101.62
CC1	302.26	207.95	94.31
CB2	302.26	207.95	94.31
CB1	280.49	192.98	87.51
CA2	257.05	176.85	80.20
CA1	240.30	165.33	74.97
BB2	272.12	187.22	84.90
BB1	260.40	179.16	81.24
BA2	226.91	156.11	70.80
BA1	216.86	149.20	67.66
PE2	360.87	248.28	112.59
PE1	344.12	236.75	107.37
PD2	340.77	234.45	106.32
PD1	324.03	222.93	101.10
PC2	293.89	202.20	91.69
PC1	280.49	192.98	87.51
PB2	250.35	172.24	78.11
PB1	240.30	165.33	74.97
PA2	208.49	143.44	65.05
PA1	200.11	137.68	62.43

Section 1888(e)(4)(G)(ii) of the Act also requires that we apply this wage index in a manner that does not result in aggregate payments under the SNF PPS that are greater or less than would otherwise be made if the wage adjustment had not been made. For FY 2017 (federal rates effective October 1, 2016), we will apply an adjustment to fulfill the budget neutrality requirement. We meet this requirement by multiplying each of the components of the unadjusted federal rates by a budget neutrality factor equal to the ratio of the weighted average wage adjustment factor for FY 2016 to the weighted average wage adjustment factor for FY 2017. For this calculation, we use the same FY 2015 claims utilization data for both the numerator and denominator of this ratio. We define the wage adjustment factor used in this calculation as the labor share of the rate component multiplied by the wage index plus the non-labor share of the rate component. The budget neutrality factor stated in the FY 2017 SNF PPS proposed rule was 1.0000. However, we discovered that in calculating the FY 2017 proposed wage index budget neutrality factor, we inadvertently failed to update the wage index data used in the calculation with the most recently available FY 2017 data. This resulted in a budget neutrality factor of 1.000, whereas, using the most recently available wage index data at the time of the proposed rule, the proposed factor should have been 0.9997. Moreover, because the wage index data used were incorrect and because the wage index is the primary source of variation in the impacts calculated in the regulatory impact analysis, the error which caused the incorrect calculation of the wage index budget neutrality factor in the proposed rule also affected the wage index impacts in Table 19 of the FY 2017 SNF PPS proposed rule (Projected Impact to the SNF PPS for FY 2017) (81 FR 24278). These impacts are discussed further in section V.A.4. of this final rule. We have recalculated the wage index budget neutrality factor for FY 2017 utilizing updated wage index data, and the final budget neutrality factor for FY 2017 is 1.0000.

In the SNF PPS final rule for FY 2006 (70 FR 45026, August 4, 2005), we adopted the changes discussed in the OMB Bulletin No. 03–04 (June 6, 2003), available online at *www.whitehouse.gov/omb/bulletins/b03–04.html,* which announced revised definitions for MSAs and the creation of micropolitan statistical areas and combined statistical areas.

In adopting the CBSA geographic designations, we provided for a 1-year transition in FY 2006 with a blended wage index for all providers. For FY 2006, the wage index for each provider consisted of a blend of 50 percent of the FY 2006 MSA-based wage index and 50 percent of the FY 2006 CBSA-based wage index (both using FY 2002 hospital data). We referred to the blended wage index as the FY 2006 SNF PPS transition wage index. As discussed in the SNF PPS final rule for FY 2006 (70 FR 45041), since the expiration of this 1-year transition on September 30, 2006, we have used the full CBSA-based wage index values.

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. In the FY 2015 SNF PPS final rule (79 FR 45644 through 45646), we finalized changes to the SNF PPS wage index based on the newest OMB delineations, as described in OMB Bulletin No. 13–01, beginning in FY 2015, including a 1-year transition with a blended wage index for FY 2015. OMB Bulletin No. 13–01 established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas in the United States and Puerto Rico based on the 2010 Census, and provided guidance on the use of the delineations of these statistical areas using standards published in the June 28, 2010 **Federal Register** (75 FR 37246 through 37252). In addition, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. On July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provides minor updates to and supersedes OMB Bulletin No. 13–01 that was issued on February 28, 2013. The attachment to OMB Bulletin No. 15–01 provides detailed information on the update to statistical areas since February 28, 2013. The updates provided in OMB Bulletin No. 15–01 are based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2012 and July 1, 2013. A copy of this bulletin may be obtained on the Web site at *https://www.whitehouse.gov/sites/default/files/omb/bulletins/2015/15–01.pdf.* As we previously stated in the FY 2008 SNF PPS proposed and final rules (72 FR 25538 through 25539, and 72 FR 43423), we again wish to clarify that this and all subsequent SNF PPS rules and notices are considered to incorporate any such updates and revisions set forth in the most recent OMB bulletin that applies to the hospital wage data used to determine the current SNF PPS wage index. As noted previously in this section, the wage index applicable to FY 2017 is set forth in Tables A and B available on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html.*

5. Adjusted Rate Computation Example

Using the hypothetical SNF XYZ described below, Table 9 shows the adjustments made to the federal per diem rates to compute the provider's actual per diem PPS payment. We derive the Labor and Non-labor columns from Table 7. The wage index used in this example is based on the final wage index, which may be found in Table A as referenced previously in this section. As illustrated in Table 9, SNF XYZ's total PPS payment would equal $46,861.86.

CHART 9—ADJUSTED RATE COMPUTATION EXAMPLE
SNF XYZ: LOCATED IN FREDERICK, MD (URBAN CBSA 43524)
WAGE INDEX: 0.9797
[See Wage Index in Table A] [1]

RUG–IV group	Labor	Wage index	Adjusted labor	Non-labor	Adjusted rate	Percent adjustment	Medicare days	Payment
RVX	$492.57	0.9797	$482.57	$223.37	$705.94	$705.94	14	$9,883.16
ES2	395.50	0.9797	387.47	179.35	566.82	566.82	30	17,004.60
RHA	248.50	0.9797	243.46	112.69	356.15	356.15	16	5,698.40
CC2 *	229.08	0.9797	224.43	103.88	328.31	748.55	10	7,485.50
BA2	157.93	0.9797	154.72	71.62	226.34	226.34	30	6,790.20

CHART 9—ADJUSTED RATE COMPUTATION EXAMPLE—Continued
SNF XYZ: LOCATED IN FREDERICK, MD (URBAN CBSA 43524)
WAGE INDEX: 0.9797
[See Wage Index in Table A] [1]

RUG–IV group	Labor	Wage index	Adjusted labor	Non-labor	Adjusted rate	Percent adjustment	Medicare days	Payment
							100	46,861.86

* Reflects a 128 percent adjustment from section 511 of the MMA.
[1] Available on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html*.

C. Additional Aspects of the SNF PPS

1. SNF Level of Care—Administrative Presumption

The establishment of the SNF PPS did not change Medicare's fundamental requirements for SNF coverage. However, because the case-mix classification is based, in part, on the beneficiary's need for skilled nursing care and therapy, we have attempted, where possible, to coordinate claims review procedures with the existing resident assessment process and case-mix classification system discussed in section III.B.3. of this final rule. This approach includes an administrative presumption that utilizes a beneficiary's initial classification in one of the upper 52 RUGs of the 66-group RUG–IV case-mix classification system to assist in making certain SNF level of care determinations.

In accordance with section 1888(e)(4)(H)(ii) of the Act and the regulations at § 413.345, we include in each update of the federal payment rates in the **Federal Register** the designation of those specific RUGs under the classification system that represent the required SNF level of care, as provided in § 409.30. As set forth in the FY 2011 SNF PPS update notice (75 FR 42910), this designation reflects an administrative presumption under the 66-group RUG–IV system that beneficiaries who are correctly assigned to one of the upper 52 RUG–IV groups on the initial 5-day, Medicare-required assessment are automatically classified as meeting the SNF level of care definition up to and including the assessment reference date (ARD) on the 5-day Medicare-required assessment.

A beneficiary assigned to any of the lower 14 RUG–IV groups is not automatically classified as either meeting or not meeting the definition, but instead receives an individual level of care determination using the existing administrative criteria. This presumption recognizes the strong likelihood that beneficiaries assigned to one of the upper 52 RUG–IV groups during the immediate post-hospital period require a covered level of care, which would be less likely for those beneficiaries assigned to one of the lower 14 RUG–IV groups.

In the July 30, 1999 final rule (64 FR 41670), we indicated that we would announce any changes to the guidelines for Medicare level of care determinations related to modifications in the case-mix classification structure. In this final rule, we continue to designate the upper 52 RUG–IV groups for purposes of this administrative presumption, consisting of all groups encompassed by the following RUG–IV categories:

- Rehabilitation plus Extensive Services.
- Ultra High Rehabilitation.
- Very High Rehabilitation.
- High Rehabilitation.
- Medium Rehabilitation.
- Low Rehabilitation.
- Extensive Services.
- Special Care High.
- Special Care Low.
- Clinically Complex.

However, we note that this administrative presumption policy does not supersede the SNF's responsibility to ensure that its decisions relating to level of care are appropriate and timely, including a review to confirm that the services prompting the beneficiary's assignment to one of the upper 52 RUG–IV groups (which, in turn, serves to trigger the administrative presumption) are themselves medically necessary. As we explained in the FY 2000 SNF PPS final rule (64 FR 41667), the administrative presumption:

> . . . is itself rebuttable in those individual cases in which the services actually received by the resident do not meet the basic statutory criterion of being reasonable and necessary to diagnose or treat a beneficiary's condition (according to section 1862(a)(1) of the Act). Accordingly, the presumption would not apply, for example, in those situations in which a resident's assignment to one of the upper . . . groups is itself based on the receipt of services that are subsequently determined to be not reasonable and necessary.

Moreover, we want to stress the importance of careful monitoring for changes in each patient's condition to determine the continuing need for Part A SNF benefits after the ARD of the 5-day assessment.

2. Consolidated Billing

Sections 1842(b)(6)(E) and 1862(a)(18) of the Act (as added by section 4432(b) of the BBA) require a SNF to submit consolidated Medicare bills to its Medicare Administrative Contractor for almost all of the services that its residents receive during the course of a covered Part A stay. In addition, section 1862(a)(18) of the Act places the responsibility with the SNF for billing Medicare for physical therapy, occupational therapy, and speech-language pathology services that the resident receives during a noncovered stay. Section 1888(e)(2)(A) of the Act excludes a small list of services from the consolidated billing provision (primarily those services furnished by physicians and certain other types of practitioners), which remain separately billable under Part B when furnished to a SNF's Part A resident. These excluded service categories are discussed in greater detail in section V.B.2. of the May 12, 1998 interim final rule (63 FR 26295 through 26297).

A detailed discussion of the legislative history of the consolidated billing provision is available on the SNF PPS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/Legislative_History_07302013.pdf*. In particular, section 103 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113, enacted on November 29, 1999) amended section 1888(e)(2)(A) of the Act by further excluding a number of individual high-cost, low probability services, identified by Healthcare Common Procedure Coding System (HCPCS) codes, within several broader categories (chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices) that otherwise remained subject to the provision. We discuss this BBRA amendment in

greater detail in the SNF PPS proposed and final rules for FY 2001 (65 FR 19231 through 19232, April 10, 2000, and 65 FR 46790 through 46795, July 31, 2000), as well as in Program Memorandum AB–00–18 (Change Request #1070), issued March 2000, which is available online at *www.cms.gov/transmittals/downloads/ab001860.pdf*.

As explained in the FY 2001 proposed rule (65 FR 19232), the amendments enacted in section 103 of the BBRA not only identified for exclusion from this provision a number of particular service codes within four specified categories (that is, chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices), but also gave the Secretary the authority to designate additional, individual services for exclusion within each of the specified service categories. In the proposed rule for FY 2001, we also noted that the BBRA Conference report (H.R. Rep. No. 106–479 at 854 (1999) (Conf. Rep.)) characterizes the individual services that this legislation targets for exclusion as high-cost, low probability events that could have devastating financial impacts because their costs far exceed the payment SNFs receive under the PPS. According to the conferees, section 103(a) of the BBRA is an attempt to exclude from the PPS certain services and costly items that are provided infrequently in SNFs. By contrast, we noted that the Congress declined to designate for exclusion any of the remaining services within those four categories (thus, leaving all of those services subject to SNF consolidated billing), because they are relatively inexpensive and are furnished routinely in SNFs.

As we further explained in the final rule for FY 2001 (65 FR 46790), and according to our longstanding policy, any additional service codes that we might designate for exclusion under our discretionary authority must meet the same statutory criteria used in identifying the original codes excluded from consolidated billing under section 103(a) of the BBRA: They must fall within one of the four service categories specified in the BBRA; and they also must meet the same standards of high cost and low probability in the SNF setting, as discussed in the BBRA Conference report. Accordingly, we characterized this statutory authority to identify additional service codes for exclusion as essentially affording the flexibility to revise the list of excluded codes in response to changes of major significance that may occur over time (for example, the development of new medical technologies or other advances in the state of medical practice) (65 FR 46791). In the FY 2017 SNF PPS proposed rule (81 FR 24242), we specifically invited public comments identifying HCPCS codes in any of these four service categories (chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices) representing recent medical advances that might meet our criteria for exclusion from SNF consolidated billing. We stated that we may consider excluding a particular service if it meets our criteria for exclusion as specified above. We also asked that commenters identify in their comments the specific HCPCS code that is associated with the service in question, as well as their rationale for requesting that the identified HCPCS code(s) be excluded.

Commenters submitted the following comments related to the proposed rule's discussion of the consolidated billing aspects of the SNF PPS. A discussion of these comments, along with our responses, appears below.

Comment: One commenter suggested excluding all high-cost oral chemotherapy drugs from consolidated billing, and proposed a threshold of $50 or more per tablet to define ''high-cost'' for this purpose. Another commenter specifically recommended for exclusion the oral chemotherapy drug Revlimid® (lenalidomide). Still another suggested that we conduct an analysis with a view toward excluding a broader range of expensive drugs beyond the category of chemotherapy alone, citing anecdotal evidence that leaving such drugs within the SNF PPS bundle may create a disincentive for admitting those patients who require them.

Response: When the Congress carved out certain exceptionally intensive chemotherapy drugs from the SNF PPS bundle in section 103 of the BBRA, it characterized those drugs as ''high-cost'' and ''low probability.'' This legislation did not categorically exclude all high-cost oral chemotherapy drugs from SNF consolidated billing. The accompanying Conference Report explained that this provision

> . . . is an attempt to exclude from the PPS certain services and costly items that are provided *infrequently* in SNFs. For example, in the case of chemotherapy drugs, [this provision has] excluded specific chemotherapy drugs from the PPS because these drugs are *not typically administered in a SNF,* or are *exceptionally expensive,* or are *given as infusions,* thus *requiring special staff expertise to administer.* Some chemotherapy drugs, which are *relatively inexpensive* and are *administered routinely in SNFs,* were excluded from this provision'' (H. Conf. Rep. No. 106–479 at 854) (emphasis added).

Accordingly, we decline to exclude all high-cost oral chemotherapy drugs as a class from consolidated billing, because any such drugs that are capable of being ''administered routinely in SNFs'' are not reasonably characterized as ''requiring special staff expertise to administer.'' We note that in the SNF PPS final rules for FYs 2009 (73 FR 46436, August 8, 2008) and 2010 (74 FR 40353, August 11, 2009), we declined to exclude certain oral medications suggested by commenters for the same reason. In addition, the BBRA Conference Report language (H. Conf. Rep. No. 106–479 at 854) further indicates that the term ''high-cost'' in this context would not serve to encompass a routinely-used chemotherapy drug merely because its cost somewhat exceeds the typical range of drug costs encountered in this setting; rather, this provision is directed specifically at those uncommon chemotherapy drugs that are so exceptionally expensive as to ''. . . have *devastating* financial impacts because their costs *far exceed* the payment [SNFs] receive under the prospective payment system'' (emphasis added). With specific reference to Revlimid®, we note that we already received a similar exclusion recommendation during the public comment period on the FY 2015 SNF PPS proposed rule, and we discussed our decision not to exclude this particular drug in that year's final rule (79 FR 45641 through 45642, August 5, 2014). Finally, in response to the suggestion that we exclude a broader range of expensive drugs beyond the category of chemotherapy alone, as we have noted repeatedly in previous rulemaking—most recently, in the FY 2016 SNF PPS final rule (80 FR 46406, August 4, 2015)—the statutory authority to designate additional services for exclusion applies *solely* to the four service categories (chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices) that are specified in the law. Accordingly, expanding the existing exclusion authority to encompass additional categories (such as non-chemotherapy drugs) is not provided for in current law.

Comment: Several commenters noted the importance of continuing to exclude prosthetic devices from consolidated billing. They suggested that the following four HCPCS codes should be added to the list of codes excluded from consolidated billing: L5010—Partial foot, molded socket, ankle height, with toe filler; L5020—Partial foot, molded socket, tibial tubercle height, with toe

filler; L5969—Addition, endoskeletal ankle-foot or ankle system, power assist, includes any type motor(s); and L5987—All lower extremity prosthesis, shank foot system with vertical loading pylon. Some also advocated excluding custom orthotics from consolidated billing as well. They stated that the custom orthotic and prosthetic professions are closely aligned, with a sizable percentage of patients who require prosthetic care also requiring custom orthotics to address orthopedic impairments of the arms, legs, spine, and neck. They further suggested that the same factors that justify exempting prosthetic devices also apply to custom orthotics, as custom orthotics are typically a high-cost, low frequency service for patients in SNFs.

Response: The recommendation to exclude certain particular prosthetics essentially reiterates a comment made during last year's SNF PPS rulemaking cycle, which recommended for exclusion certain prosthetic device codes that were already in existence—but not excluded—upon the original 1999 enactment of the customized prosthetic device exclusion in the BBRA. In response, we reiterated in the FY 2016 SNF PPS final rule our longstanding position that if a particular prosthetic code was already in existence as of the BBRA enactment date but was not designated in the BBRA for exclusion, this meant that it was intended to remain within the SNF PPS bundle, subject to a GAO review that was conducted the following year (80 FR 46407, August 4, 2015). This would apply to three of the prosthetic codes (L5010, L5020, and L5987) cited in the current comments. Regarding the fourth prosthetic code (L5969), we also noted in last year's final rule (80 FR 46407) that code L5969 actually appears already on the exclusion list under Major Category III.D. (''Customized Prosthetic Devices''), where this particular L code has, in fact, been listed ever since its initial assignment in January 2014.

With reference to orthotics, in the FY 2016 SNF PPS final rule (80 FR 46407, August 4, 2015), we explained that while the law does specify customized prosthetic devices as one of the exclusion categories, this is a separate and distinct category from orthotics and does not encompass orthotics. Moreover, as already noted in this and previous final rules, the statutory authority to designate additional services for exclusion applies *solely* to the four service categories (chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices) that are specified in the law. Accordingly, expanding the existing exclusion authority to encompass additional categories (such as orthotics) is not provided for in current law.

3. Payment for SNF-Level Swing-Bed Services

Section 1883 of the Act permits certain small, rural hospitals to enter into a Medicare swing-bed agreement, under which the hospital can use its beds to provide either acute- or SNF-level care, as needed. For critical access hospitals (CAHs), Part A pays on a reasonable cost basis for SNF-level services furnished under a swing-bed agreement. However, in accordance with section 1888(e)(7) of the Act, these services furnished by non-CAH rural hospitals are paid under the SNF PPS, effective with cost reporting periods beginning on or after July 1, 2002. As explained in the FY 2002 final rule (66 FR 39562), this effective date is consistent with the statutory provision to integrate swing-bed rural hospitals into the SNF PPS by the end of the transition period, June 30, 2002.

Accordingly, all non-CAH swing-bed rural hospitals have now come under the SNF PPS. Therefore, all rates and wage indexes outlined in earlier sections of this proposed rule for the SNF PPS also apply to all non-CAH swing-bed rural hospitals. A complete discussion of assessment schedules, the MDS, and the transmission software (RAVEN–SB for Swing Beds) appears in the FY 2002 final rule (66 FR 39562) and in the FY 2010 final rule (74 FR 40288). As finalized in the FY 2010 SNF PPS final rule (74 FR 40356 through 40357), effective October 1, 2010, non-CAH swing-bed rural hospitals are required to complete an MDS 3.0 swing-bed assessment which is limited to the required demographic, payment, and quality items. The latest changes in the MDS for swing-bed rural hospitals appear on the SNF PPS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/index.html*.

D. Other Issues

1. Skilled Nursing Facility Value-Based Purchasing Program (SNF VBP)

a. Background

Section 215 of the Protecting Access to Medicare Act of 2014 (PAMA) authorizes the SNF VBP Program by adding sections 1888(g) and (h) to the Act. These sections provide structure for the development of the SNF VBP Program, including, among other things, the requirement of only two measures—an all-cause, all-condition hospital readmission measure, which is to be replaced as soon as practicable by an all-condition risk-adjusted potentially preventable hospital readmission measure—and confidential and public reporting requirements for the SNF VBP Program. We began development of the SNF VBP Program in the FY 2016 SNF PPS final rule with, among other things, the adoption of an all-cause, all-condition hospital readmission measure, as required under section 1888(g)(1) of the Act. We will continue the process in this final rule with our adoption of an all-condition risk-adjusted potentially preventable hospital readmission measure for SNFs, which the Secretary is required to specify no later than October 1, 2016 under section 1888(g)(2) of the Act. The Act requires that the SNF VBP apply to payments for services furnished on or after October 1, 2018. The SNF VBP Program applies to freestanding SNFs, SNFs affiliated with acute care facilities, and all non-CAH swing-bed rural hospitals. We believe the implementation of the SNF VBP Program is an important step toward transforming how care is paid for, moving increasingly toward rewarding better value, outcomes, and innovations instead of merely volume.

For additional background information on the SNF VBP Program, including an overview of the SNF VBP Report to Congress and a summary of the Program's statutory requirements, we refer readers to the FY 2016 SNF PPS final rule (80 FR 46409 through 46410).

We received a number of general comments on the Program.

Comment: Some commenters urged us to broaden the SNF VBP Program to include other post-acute care outcome measures, such as measures of care transitions, resource use over care episodes, and beneficiary functional change. Commenters noted that these measures are required of all PAC providers, though implementation dates vary.

Response: We thank commenters for this feedback. However, as we stated in the FY 2016 SNF PPS final rule (80 FR 46410), we do not believe we have the authority to adopt measures covering additional clinical topics beyond those specified in sections 1888(g)(1) and (2) of the Act at this time.

Comment: Commenters urged us to monitor the Program's impact on facilities' delivery of care quality and on beneficiaries' quality of life in nursing homes.

Response: We thank the commenters for this suggestion. We intend to monitor the Program's effects on

beneficiaries, care quality, and other factors carefully.

Comment: One commenter offered several general suggestions for the Program based on New York's experience with the Nursing Home VBP Demonstration (*https://innovation.cms.gov/initiatives/Nursing-Home-Value-Based-Purchasing/*) including incomparability of specialty and general facilities, narrowly-structured measures for participating facilities, regional adjustments, measure and calculation information provided to facilities to assist with quality improvement, a focus on preventable hospitalizations, and incentive payments large enough and close enough to the performance period to maximize behavioral changes.

Response: We thank the commenter for these suggestions. We proposed to adopt a performance period that is as close as we feasibly can set it to the payment year in order to establish a clear link between quality measurement and value-based payment. We note also that the methodology for determining the size of the pool available to fund the value-based incentive payments that we will disburse under the Program is specified in the statute. We intend to provide SNFs with information to assist with quality improvement efforts, and will work with stakeholders to ensure that all SNFs are able to improve the quality of care that they provide to Medicare beneficiaries. However, we do not agree with the commenter that we should perform regional adjustments to the measures adopted under the Program. Our experience with achievement thresholds and benchmarks based on national data in the Hospital Value-Based Purchasing Program has given us confidence that regional adjustments are not necessary to ensure that achievement thresholds and benchmarks for this program are balanced, appropriate standards of high quality. Some groups of facilities may perform better or worse than other facilities on certain measures, but we do not believe it would be appropriate to raise or lower the performance standards or measured performance for a facility based on regional differences in quality measurement, because such adjustments would seem to indicate that some areas of the country should be held to higher or lower standards of care quality. We intend to monitor SNFs' performance on the measures adopted under the Program carefully and may consider further adjustments to the measures or to the scoring methodology in the future.

Comment: Commenter also suggested that we factor managed care expansions into our measure calculations, noting that many states are rapidly expanding into managed care for Medicare and Medicaid beneficiaries and that managed care delivery could affect quality measurements. Commenter also recommended that we consider major care innovations that are being developed and tested across state lines to ensure that the interventions with the greatest potential for quality improvement may proliferate among SNFs.

Response: We thank the commenter for the suggestion. However, the SNF VBP Program is limited by statute to payments made under Medicare's SNF PPS, not payments to managed-care organizations, and we therefore believe the Program is appropriately focused on Medicare quality data at this time. We may consider incorporating quality information related to care provided by managed-care organizations in the Program in the future. However, we do not have the authority to make value-based incentive payments to SNFs based on their performance with patients enrolled in managed care plans. We will monitor clinical research on the effects of managed care in comparison to care delivered under fee-for-service systems, however.

We will consider major care innovations as they arise in clinical literature and in care delivery and will work with SNFs and stakeholders in order to encourage their proliferation.

We thank the commenters for this feedback.

b. Measures

i. SNF 30-Day All-Cause Readmission Measure (SNFRM) (NQF #2510)

Per the requirement at section 1888(g)(1) of the Act, in the FY 2016 SNF PPS final rule (80 FR 46419), we finalized our proposal to specify the SNF 30-Day All-Cause Readmission Measure (SNFRM) (NQF #2510) as the SNF all-cause, all-condition hospital readmission measure for the SNF VBP Program. The SNFRM assesses the risk-standardized rate of all-cause, all-condition, unplanned inpatient hospital readmissions of Medicare fee-for-service (FFS) SNF patients within 30 days of discharge from an admission to an inpatient prospective payment system (IPPS) hospital, CAH, or psychiatric hospital. The measure is claims-based, requiring no additional data collection or submission burden for SNFs. For additional details on the SNFRM, including our responses to public comments, we refer readers to the FY 2016 SNF PPS final rule (80 FR 46411 through 46419).

We received one comment on the SNFRM.

Comment: One commenter urged us to provide more timely feedback to SNFs on their performance on the SNFRM in order to better enable performance improvement.

Response: We intend to provide as much feedback on the SNFRM as is operationally possible to SNFs, and to do so as quickly as possible. As required by section 1888(g)(5) of the Act and as discussed further below, we will provide quarterly confidential feedback reports to SNFs beginning October 1, 2016, and will continue providing as much information to SNFs on their performance on the SNFRM as possible using those reports.

ii. Skilled Nursing Facility 30-Day Potentially Preventable Readmission Measure (SNFPPR)

We proposed to specify the SNF 30-Day Potentially Preventable Readmission Measure (SNFPPR) as the SNF all-condition risk-adjusted potentially preventable hospital readmission measure to meet the requirements of section 1888(g)(2) of the Act. This proposed measure assesses the facility-level risk-standardized rate of unplanned, potentially preventable hospital readmissions for SNF patients within 30 days of discharge from a prior admission to an IPPS hospital, CAH, or psychiatric hospital. Hospital readmissions include readmissions to a short-stay acute-care hospital or CAH, with a diagnosis considered to be unplanned and potentially preventable. This proposed measure is claims-based, requiring no additional data collection or submission burden for SNFs.

Hospital readmissions among the Medicare population, including beneficiaries that utilize post-acute care, are common, costly, and often preventable.[1] [2] The Medicare Payment Advisory Commission (MedPAC) and a study by Jencks et al. estimated that 17 to 20 percent of Medicare beneficiaries discharged from the hospital were readmitted within 30 days. MedPAC found that more than 75 percent of 30-day and 15-day readmissions and 84 percent of 7-day readmissions were considered potentially preventable.[3] In

[1] Friedman, B., and Basu, J.: The rate and cost of hospital readmissions for preventable conditions. *Med. Care Res. Rev.* 61(2):225–240, 2004. doi:10.1177/1077558704263799.

[2] Jencks, S.F., Williams, M.V., and Coleman, E.A.: Rehospitalizations among patients in the Medicare Fee-for-Service Program. *N. Engl. J. Med.* 360(14):1418–1428, 2009. doi:10.1016/j.jvs.2009.05.045.

[3] MedPAC: Payment policy for inpatient readmissions, in *Report to the Congress: Promoting*

Continued

addition, MedPAC calculated that annual Medicare spending on potentially preventable readmissions would be $12B for 30-day, $8B for 15-day, and $5B for 7-day readmissions.[4] For hospital readmissions from SNFs, MedPAC deemed 76 percent of readmissions as potentially avoidable—associated with $12B in Medicare expenditures.[5] Mor et al. analyzed 2006 Medicare claims and SNF assessment data (Minimum Data Set), and reported a 23.5 percent readmission rate from SNFs, associated with $4.3B in expenditures.[6]

We have addressed the high rates of hospital readmissions in the acute care setting, as well as in PAC by developing the SNF 30-Day All-Cause Readmission Measure (NQF #2510), as well as similar measures for other PAC providers (NQF #2502 for IRFs and NQF #2512 for LTCHs).[7] These measures are endorsed by the National Quality Forum (NQF), and the NQF-endorsed measure (NQF #2510) was adopted for the SNF VBP program in the FY 2016 SNF PPS final rule (80 FR 46411 through 46419). These NQF-endorsed measures assess all-cause unplanned readmissions.

Several general methods and algorithms 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) Prevention Quality Indicators, approaches developed by MedPAC, and proprietary approaches, such as the 3M™ algorithm for Potentially Preventable Readmissions (PPR).[8] [9] [10] Recent work led by Kramer et al. for MedPAC identified 13 conditions for which readmissions were deemed as potentially preventable among SNF and IRF populations [11] [12]; however, these conditions did not differ by PAC setting or readmission window (that is, readmissions during the PAC stay or post-PAC discharge). Although much of the existing literature addresses hospital readmissions more broadly and potentially avoidable hospitalizations for specific settings like skilled nursing facilities, these findings are relevant to the development of potentially preventable readmission measures for PAC.[13] [14] [15]

Based on the evidence discussed above and to meet PAMA requirements, we proposed to specify this measure, entitled, SNF 30-Day Potentially Preventable Readmission Measure (SNFPPR), for the SNF VBP Program. The SNFPPR measure was developed by CMS to harmonize with the NQF-endorsed SNF 30-Day All-Cause Readmission Measure (NQF #2510) [16] adopted in the FY 2016 SNF final rule (80 FR 46411 through 46419) and the Hospital-Wide Risk-Adjusted All-Cause Unplanned Readmission Measure (NQF #1789) (Hospital-Wide Readmission or HWR measure [17]), finalized for the Hospital IQR Program in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53521 through 53528). Although these existing measures focus on all-cause unplanned readmissions and the SNFPPR measure assesses potentially preventable hospital readmissions, the SNFPPR will use the same statistical approach, the same time window as NQF measure #2510 (that is, 30 days post-hospital discharge), and a similar set of patient characteristics for risk adjustment. As appropriate, the potentially preventable hospital readmission measure for SNFs is being harmonized with similar measures being finalized for LTCHs, IRFs, and HHAs to meet the requirements of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185).

The SNFPPR measure estimates the risk-standardized rate of unplanned, potentially preventable hospital readmissions for Medicare FFS beneficiaries that occur within 30 days of discharge from the prior proximal hospitalization. This is a departure from readmission measures in other PAC settings, such as the two measures being adopted in the Inpatient Rehabilitation Facility (IRF) Quality Reporting Program, one of which assesses readmissions that take place during the IRF stay and the other that assesses readmissions within 30 days following discharge from the IRF. The SNFPPR measure is distinct because section 1888(h)(2) of the Act requires that only a single quality measure be implemented in the SNF VBP program at one time. A purely within-stay measure (that is, a measure that assesses readmission rates only when those readmissions occurred during a SNF stay) would perversely incentivize the premature discharge of residents from SNFs to avoid penalty. Conversely, limiting the measure to readmissions that occur within 30-days post-discharge from the SNF would not capture readmissions that occur during the SNF stay. In order to qualify for this measure, the SNF admission must take place within 1 day of discharge from a prior proximal hospital stay. The prior proximal hospital stay is defined as an inpatient admission to an acute care hospital (including IPPS, CAH, or a psychiatric hospital). Because the measure denominator is based on SNF admissions, a single Medicare beneficiary could be included in the measure multiple times within a given year. Readmissions counted in this measure are identified by examining Medicare FFS claims data for readmissions to either acute care hospitals (IPPS or CAH) that occur within 30 days of discharge from the prior proximal hospitalization, regardless of whether the readmission occurs during the SNF stay or takes

Greater Efficiency in Medicare. Washington, DC, pp. 103–120, 2007. Available from *http://www.medpac.gov/documents/reports/Jun07_EntireReport.pdf.*

[4] *Ibid.*

[5] *Ibid.*

[6] Mor, V., Intrator, O., Feng, Z., et al.: The revolving door of rehospitalization from SNFs. *Health Aff.* 29(1):57–64, 2010. doi:10.1377/hlthaff.2009.0629.

[7] National Quality Forum: *All-Cause Admissions and Readmissions Measures.* pp. 1–319, April 2015. Available from *http://www.qualityforum.org/Publications/2015/04/All-Cause_Admissions_and_Readmissions_Measures_-_Final_Report.aspx.*

[8] 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/.*

[9] Agency for Healthcare Research and Quality: *Prevention Quality Indicators Overview.* 2008.

[10] 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.*

[11] Kramer, A., Lin, M., Fish, R., et al.: *Development of Inpatient Rehabilitation Facility Quality Measures: Potentially Avoidable Readmissions, Community Discharge, and Functional Improvement.* pp. 1–42, 2015. Available from *http://www.medpac.gov/documents/contractor-reports/development-of-inpatient-rehabilitation-facility-quality-measures-potentially-avoidable-readmissions-community-discharge-and-functional-improvement.pdf?sfvrsn=0.*

[12] Kramer, A., Lin, M., Fish, R., et al.: *Development of Potentially Avoidable Readmission and Functional Outcome SNF Quality Measures.* pp. 1–75, 2014. Available from *http://www.medpac.gov/documents/contractor-reports/mar14_snfqualitymeasures_contractor.pdf?sfvrsn=0.*

[13] Allaudeen, N., Vidyarthi, A., Maselli, J., et al.: Redefining readmission risk factors for general medicine patients. *J. Hosp. Med.* 6(2):54–60, 2011. doi:10.1002/jhm.805.

[14] Gao, J., Moran, E., Li, Y.-F., et al.: Predicting potentially avoidable hospitalizations. *Med. Care* 52(2):164–171, 2014. doi:10.1097/MLR.0000000000000041.

[15] 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.

[16] National Quality Forum: All-Cause Admissions and Readmissions Measures. pp. 1–319, April 2015. National Quality Forum: *All-Cause Admissions and Readmissions Measures.* pp. 1–319, April 2015. Available from *http://www.qualityforum.org/Publications/2015/04/All-Cause_Admissions_and_Readmissions_Measures_-_Final_Report.aspx.*

[17] Available by searching for ''1789'' at *http://www.qualityforum.org/QPS/QPSTool.aspx.*

place after the patient is discharged from the SNF. Because patients differ in complexity and morbidity, the measure is risk-adjusted for case-mix. Our approach for defining potentially preventable readmissions is described below.

Potentially Preventable Readmission Measure Definition: We conducted a comprehensive environmental scan, analyzed claims data, and obtained input from a technical expert panel (TEP) to develop a working conceptual definition and list of conditions for which hospital readmissions may be considered potentially preventable. The Ambulatory Care Sensitive Conditions (ACSC)/Prevention Quality Indicators (PQI), developed by AHRQ, served as the starting point in this work. For the purposes of the SNFPPR measure, the definition of potentially preventable readmissions differs based on whether the resident is admitted to the SNF (referred to as ''within-stay'') or in the post-SNF discharge period; however, there is considerable overlap of the definitions. For patients readmitted to a hospital during within the SNF stay, potentially preventable readmissions (PPR) should be avoidable with sufficient medical monitoring and appropriate treatment. The within-stay list of PPR conditions includes the following, which are categorized by 4 clinical rationale groupings: (1) Inadequate management of chronic conditions; (2) Inadequate management of infections; (3) Inadequate management of other unplanned events; and (4) Inadequate injury prevention. For individuals in the post-SNF discharge period, a potentially preventable readmission refers to a readmission in which the probability of occurrence could be minimized with adequately planned, explained, and implemented post discharge instructions, including the establishment of appropriate follow-up ambulatory care. Our list of PPR conditions in the post-SNF discharge period includes the following, categorized by 3 clinical rationale groupings: (1) Inadequate management of chronic conditions; (2) Inadequate management of infections; and (3) Inadequate management of other unplanned events. Additional details regarding the definitions of potentially preventable readmissions are available in our Measure Specification (available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Other-VBPs/SNF-VBP.html*).

This SNFPPR measure focuses on readmissions that are potentially preventable and also unplanned. Similar to the SNF 30-Day All-Cause Readmission Measure (SNFRM) (NQF #2510), this measure uses the CMS Planned Readmission Algorithm to define planned readmissions. In addition to the CMS Planned Readmission Algorithm, this measure incorporates procedures that are considered planned in post-acute care settings, as identified in consultation with TEPs. Full details on the planned readmissions criteria used, including the additional procedures considered planned for post-acute care, can be found in the Measure Specifications (available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Other-VBPs/SNF-VBP.html*).

This measure assesses potentially preventable readmission rates while accounting for patient or resident demographics, principal diagnosis in the prior hospital stay, comorbidities, and other patient factors. The model also estimates a facility-specific effect, common to patients or residents treated in each facility. This measure is calculated for each SNF based on the ratio of the predicted number of risk-adjusted, unplanned, potentially preventable hospital readmissions that occurred within 30 days of discharge from the prior proximal hospitalization, including the estimated facility effect, to the estimated predicted number of risk-adjusted, unplanned hospital readmissions for the same individuals receiving care at the average SNF. A ratio above 1.0 indicates a higher than expected readmission rate (worse), while a ratio below 1.0 indicates a lower than expected readmission rate (better). This ratio is referred to as the standardized risk ratio or SRR. The SRR is then multiplied by the overall national raw rate of potentially preventable readmissions for all SNF stays. The resulting rate is the risk-standardized readmission rate (RSRR) of potentially preventable readmissions. The full methodology is detailed in the Measure Specifications (available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Other-VBPs/SNF-VBP.html*).

Eligible SNF stays in the measure are assessed until: (1) The 30-day period ends; or (2) the patient is readmitted to an acute care hospital (IPPS or CAH). If the readmission is classified as unplanned and potentially preventable, it is counted as a readmission in the measure calculation. If the readmission is planned or not preventable, the readmission is not counted in the measure rate.

Readmission rates are risk-adjusted for case-mix characteristics. The risk adjustment modeling estimates the effects of patient/resident characteristics, comorbidities, and select health care variables on the probability of readmission. More specifically, the risk-adjustment model for SNFs accounts for sociodemographic characteristics (age, sex, original reason for entitlement), principal diagnosis during the prior proximal hospital stay, body system specific surgical indicators, comorbidities, length of stay during the resident's prior proximal hospital stay, intensive care utilization, end-stage renal disease status, and number of prior acute care hospitalizations in the preceding 365 days. This measure is calculated using one full calendar year of data. The full measure specifications and results of the reliability testing can be found in the Measure Specifications (available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Other-VBPs/SNF-VBP.html*).

Our measure development contractor convened a TEP, which provided input on the technical specifications of this measure, including the development of an approach to define potentially preventable hospital readmissions for a number of PAC settings, including SNFs. 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 Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*. We also solicited stakeholder feedback on the development of this measure through a public comment period held from November 2 through December 1, 2015. A summary of the public comments we received is also available on the CMS Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In addition to our TEP and public comment feedback, we also considered input from the Measures Application Partnership (MAP) on the SNFPPR. The MAP is composed of multi-stakeholder groups convened by the NQF. The MAP provides input on the measures we are considering for implementation in certain quality reporting and pay-for-performance programs. In general, the MAP has noted the need for care

transition measures in PAC/LTC performance measurement programs and stated that setting-specific admission and readmission measures would address this need.[18] The SNFPPR measure that we proposed, and that we are adopting for the SNF VBP Program in this final rule, was included in the List of Measures under Consideration (MUC List) for December 1, 2015.[19]

The MAP encouraged continued development of the measure in the SNF VBP Program to meet the mandate of PAMA. Specifically, the MAP stressed the need to promote shared accountability and ensure effective care transitions. More information about the MAP's recommendations for this measure is available at *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx*. At the time, the risk-adjustment model was still under development. Following completion of that development work, we were able to test for measure validity and reliability as available in the measure specifications document provided above. Testing results are within range for similar outcome measures finalized in public reporting and value-based purchasing programs, including the SNFRM finalized for this program.

We invited public comment on our proposal to adopt this measure, the SNF 30-Day Potentially Preventable Readmission Measure (SNFPPR). The comments we received on this topic, with their responses, appear below.

Comment: One commenter called on us to establish a standardized process by which we could evaluate new measures for the Program, or alternatively a standard process to evaluate whether or not we should remove or retire a measure. The commenter suggested that we adopt the same methods under use in the Hospital IQR and Hospital VBP Programs.

Response: We do not believe that a standardized process is necessary for the SNF VBP Program because unlike the Hospital IQR and Hospital VBP Programs, we are statutorily limited in the SNF VBP Program to including only two measures (one at a time). Since we have not yet implemented the SNFPPR, we do not believe establishing a standardized process for replacing it is warranted at this time.

Comment: Some commenters supported our proposal to adopt the SNFPPR, including the measure's intent, and recognized that the measure will provide incentives for SNFs to coordinate care post-discharge. Some commenters specifically stated their support for the infectious conditions defined as potentially preventable, stating that many of these conditions are preventable using appropriate infection prevention interventions.

Response: We agree that the measure will provide strong incentives for care coordination and will appropriately capture preventable readmissions, including infection-related readmissions.

Comment: One commenter stated that SNFs should not be penalized for readmissions when the conditions that prompted them are unrelated to the reasons the patient was admitted to the SNF. The commenter also called on us to account for differences in each SNF's mix of low-income patients when calculating readmissions.

Response: We note that the SNF VBP Program's statute requires that the measures required under sections 1888(g)(1) and (2) of the Act must be ''all-condition hospital readmission'' measures, which we believe necessitates attributing readmissions to SNFs even in the case the commenter specifies.

We believe that the proposed risk adjustment methodology appropriately adjusts for SNFs' patient mix when calculating readmissions, particularly because the measure's risk adjustments were developed to harmonize with the Hospital Wide Readmission (HWR) measure (NQF #1789), and the SNFRM. We describe the risk adjustment variables in more detail in the draft SNF PPR technical report, which is available on our Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Other-VBPs/SNFPPR-Technical-Report.pdf*. We respond to commenter's point about sociodemographic or socioeconomic adjustments below in a subsequent response.

Comment: One commenter stated that we should develop additional criteria for SNFs that have implemented programs and policies to mitigate unplanned events. The commenter suggested that SNFs with standard fall precautions should not be penalized if a well-managed, low-risk dementia patient falls and sustains a fracture.

Response: We believe that SNFs with programs and policies that reduce the incidence of unplanned events may generally experience fewer readmissions over time. However, a potentially preventable readmission still presents the potential for harm to the patient and generates costs for the Medicare program. We wish to clarify that this is a measure of potentially preventable readmissions and that not all readmissions are preventable. The PPR rate is not expected to be 0. The focus of this measure is to identify excess PPR rates for the purposes of quality improvement. We believe the Program will encourage SNFs to take appropriate, effective steps to minimize this outcome for SNF patients.

Comment: One commenter suggested that we adopt a minimum denominator size for the SNFPPR measure of 25 stays, though they preferred 30, stating that 30 stays would produce more reliable results for low-volume SNFs. The commenter noted that observed variability increases substantially between 30 and 20 stays, and requested that we provide data on the variation in SNFPPR rates for SNFs with small denominator sizes.

Response: We wish to clarify that we did not propose a minimum denominator size for the SNFPPR measure. We acknowledge that increasing the denominator size for this measure may increase its reliability. However, doing so would exclude a substantial number of SNFs from the measure calculation and thus the SNF VBP Program However, as stated in the SNF PPR technical report available on our Web site (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Other-VBPs/SNFPPR-Technical-Report.pdf*), we found 1 year of data to be sufficient to calculate this measure in a statistically reliable manner.

Comment: One commenter supported the proposed risk adjustment methodology for the SNFPPR, noting that the adjustments will provide a valid assessment of a facility's care quality in preventing unplanned, preventable hospital readmissions.

Response: We thank the commenter for their comment.

Comment: One commenter expressed concern about our proposal to use claims-based data for quality measurement. The commenter believes that claims-based data are not accurate compared to other types of quality measure data, and the commenter cautioned that having performance data is not the same as having highly reliable and accurate data. The commenter suggested that claims data may be better

[18] National Quality Forum: *Measure Applications Partnership Pre-Rulemaking Report: 2013 Recommendations of Measures Under Consideration by HHS.* pp. 1–394, February 2013. Available from *https://www.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx*.

[19] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Downloads/2015-Measures-Under-Consideration-List.pdf*.

used as a supplement to traditional HAI surveillance after validation.

Response: With respect to the use of claims data to calculate this measure, multiple studies have been conducted to examine the validity of using Medicare hospital claims for several NQF-endorsed quality measures used in public reporting and value-based purchasing programs.[20] [21] [22] These studies supported the use of claims data as a valid means for risk adjustment and assessing similar outcomes. Additionally, although assessment and other data sources may be valuable for risk adjustment, we are not aware of another data source aside from Medicare claims data that could be used to reliably assess the outcome of potentially preventable hospital readmissions during this readmission window.

Comment: One commenter expressed concerns about the use of readmissions measures for SNFs, stating that the sickest individuals are the most likely to be readmitted. The commenter also noted that the sickest individuals are the most likely to die, so facilities with excessive mortality rates may have lower readmission rates. Some commenters were concerned that facilities may be incentivized to delay needed care in order to improve their readmission scores and suggested that we include ER visits in the measure.

Response: We believe that the risk adjustment approach used in calculating the SNFPPR measure appropriately adjusts for patient case-mix even among patients that may be at end-of-life. We intend to conduct ongoing evaluation and monitoring to ensure that the measure does not result in unintended consequences for patients, such as increased mortality rates.

With respect to emergency room visits, we note while such visits can certainly be negative outcomes for patients, they are not readmissions within the definitions we have adopted for measures of readmissions. We agree with commenters that mortality is also an important clinical outcome, but in other settings where we assess both readmission and mortality rates, the two types of measures seem to correlate,[23] which suggests that we do not see reductions in readmission rates as a consequence of increasing mortality rates.

Comment: One commenter suggested that we allow additional time between when we specify a quality measure for the Program and when we begin using the measures for payment purposes. The commenter stated that more lead time would better enable providers to understand new measures and address quality improvement issues.

Response: While we understand the commenter's concern, we must implement the Program in accordance with the deadlines specified in statute, and quality measure development is a lengthy process requiring significant time and testing to ensure that measures are clinically and statistically valid. We were required under section 1888(g)(1) of the Act to specify a skilled nursing facility all-cause, all-condition hospital readmission measure not later than October 1, 2015. Similarly, under section 1888(g)(2) of the Act, we are required to specify a measure of all-condition risk-adjusted potentially preventable hospital readmissions for skilled nursing facilities not later than October 1, 2016. Additionally, under section 1888(h)(1)(B) of the Act, we are required to begin making value-based incentive payments to SNFs on October 1, 2018 (the beginning of FY 2019). However, we intend to work with SNFs and other stakeholders to raise awareness and understanding of program requirements. For example, the confidential feedback reports required by PAMA are one mechanism through which we can educate SNFs about the measures and their performance on the measures prior to implementation.

Comment: One commenter was concerned that SNFs would not necessarily be able to verify the accuracy of the risk adjustment model, as they are unlikely to have access to complete information on sociodemographic characteristics, principal diagnosis during the proximal hospital stay, body system specific surgical indicators, comorbidities, length of stay during the proximal hospital stay, intensive care utilization, ESRD status, and the number of hospital stays during the prior year. The commenter suggested that we provide SNFs with verifiable prior hospitalization information used to calculate the risk adjustment.

Response: We thank the commenter for their concern over providers' ability to verify the accuracy of the data used for risk adjustment and to calculate this measure. We will take this comment under consideration as we determine which data elements would enable SNFs to verify their data and risk-standardized PPR rate. We refer readers to the review and correction subsection of this final rule for additional information.

Comment: One commenter recommended that we describe readmissions as ''potentially preventable,'' not ''preventable,'' stating that the literature on readmissions shows that they occur even when ideal care that conforms to all clinical guidelines is provided. The commenter noted that ambulatory care sensitive conditions and Patient Quality Indicators developed by AHRQ were intended to assess the availability of and access to ambulatory care services in a community, but have not been focused on individual hospitals and other providers. The commenter did not object to this focus, but requested that we modify our language and measure construction to account for the measure's use in tracking individual providers rather than the community. The commenter stated that our goal should not be zero readmissions, as SNFPPR rates of zero can only be achieved by denying hospital services to individuals.

Response: The readmissions to be measured in the SNFPPR are defined as those believed to be ''potentially preventable,'' as we understand that some SNF patients might be readmitted to the hospital even if they receive excellent care from the SNF. Both the SNFPPR and the SNFRM calculate facility-level risk-standardized readmission rates in order to provide quality of care information about individual providers rather than community-level characteristics. Given that the SNFPPR is capturing ''potentially preventable'' readmissions, the goal is not to reach zero readmissions, but is to identify excess rates of readmissions that could potentially have been avoided in order to assess the quality of care being furnished by individual SNFs.

Comment: Several commenters urged us to consider adjusting the SNFPPR for socioeconomic and/or sociodemographic factors. The commenter also urged us to conduct additional testing on the categories and codes used to identify PPRs.

Response: The categories and specific conditions used to identify potentially preventable readmissions were

[20] Bratzler DW, Normand SL, Wang Y, et al. An administrative claims model for profiling hospital 30-day mortality rates for pneumonia patients. PLoS One 2011;6(4):e17401.

[21] Keenan PS, Normand SL, Lin Z, et al. An administrative claims measure suitable for profiling hospital performance on the basis of 30-day all-cause readmission rates among patients with heart failure. Circulation 2008;1(1):29–37.

[22] Krumholz HM, Wang Y, Mattera JA, et al. An administrative claims model suitable for profiling hospital performance based on 30-day mortality rates among patients with heart failure. Circulation 2006;113:1693–1701.

[23] See *Medicare Hospital Quality Chartbook 2010,* p. 12, *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/downloads/HospitalChartBook.pdf.*

developed based on existing evidence and were vetted by a TEP, which included clinicians and post-acute care experts. We also conducted a comprehensive environmental scan to identify conditions for which readmissions may be considered potentially preventable. Results of this environmental scan and details of the TEP input received were made available on the CMS Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Readmissions may be considered potentially preventable even if they may not appear to be clinically related to the patient's original reason for SNF admission. There is substantial evidence that the conditions included in the definition are preventable with sufficient medical monitoring and appropriate patient treatment during the SNF stay or adequately planned, explained, and implemented post-discharge instructions, including effective care coordination ensuring appropriate follow-up care after SNF discharge. Furthermore, this measure is based on Medicare claims data and it may not always be feasible to determine whether a subsequent readmission is or is not clinically related to the reason why the patient was admitted to the SNF.

With respect to socioeconomic or sociodemographic adjustment, we note that the NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. This trial entails temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are encouraged to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model. Several measures developed by CMS have been brought to NQF since the beginning of the trial. We, consistent with NQF's guidance to measure developers, have tested sociodemographic factors in the measures' risk models and made recommendations about whether or not to include these factors in the endorsed measure. We intend to continue engaging in the NQF process as we consider the appropriateness of adjusting for sociodemographic factors in our outcome measures.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related recommendations and consider how they apply to our quality programs at such time as they are available.

Comment: One commenter expressed concern that the SNFPPR proposed for the Program differs from the SNF QRP's readmission measure. The commenter noted that the VBP Program's measure assesses both post-discharge PPRs as well as those occurring during a SNF stay and includes an additional category of PPR of inadequate prevention of injury. The commenter urged us to consider a single measure for both programs.

Response: We made a policy decision to use two different measures for the SNF VBP and QRP Programs. Our rationale for this decision was that the readmission window associated with each measure assesses different aspects of SNF care. The readmission window for the SNFPPR measure was developed to align with the SNFRM which was previously adopted for the SNF VBP Program, and both of which are required by the SNF VBP Program's statute. Both the SNFRM and SNFPPR measure specifications, including the readmission window, were designed to harmonize with CMS's Hospital Wide All-Cause Unplanned Readmission (HWR) measure used in the Hospital IQR Program. The advantage of this window is that it assesses readmissions both during the SNF stay and post-SNF discharge for most SNF patients, depending on the SNF length of stay (LOS). For these measures, the focus is on transitions to the SNF from the prior proximal hospital stay, and we believe the alignment to be appropriate since the SNF VBP Program's statute specifically directs us to adopt measures of hospital readmissions.

The readmission window used for the SNF measure proposed for the SNF QRP to meet the IMPACT Act requirements was developed to align with other post-acute care readmission measures. The focus of this post-PAC discharge readmission window is on assessing potentially preventable hospital readmissions during the 30 days after discharge. We believe that assessing PPRs during each of these readmission windows provides valuable information for their respective programs.

Comment: One commenter was concerned about the measure's ability to pinpoint the SNF's care for a short-stay resident who is expected to move on to the community setting, and commenter noted that SNFs often do not have easy access to information needed to improve on the measure. The commenter called on CMS to provide claims data to SNFs so that facilities can verify the measure, determine whether or not they are receiving necessary patient information, and conduct quality improvement efforts.

Response: We appreciate the commenters' feedback. We are cognizant of providers' desire for more information on quality performance, and we are considering ways to provide the best information to SNFs. As required by statute and as discussed further below, we will provide quarterly confidential feedback reports to SNFs detailing their performance on measures specified for the Program, and we are interested in SNFs' feedback on the reports and on their contents once we provide them. We will take that feedback into account as we refine the quarterly reports to be most useful to SNFs for quality improvement efforts.

Comment: Commenter noted that the SNF QRP version of the SNFPPR counts unplanned readmissions to LTCHs and asked us to clarify why the SNF VBP version of the measure does not include readmissions to LTCHs.

Response: The SNFPPR was developed to harmonize with the SNFRM, previously adopted for the SNF VBP Program, and both measures do not count planned readmissions to LTCHs. However, the potentially preventable hospital readmission measure proposed for the SNF QRP to meet the requirements of the IMPACT Act does count readmissions to LTCHs in order to align with the other IMPACT Act measures. We intend to conduct analyses to determine the impact that including readmissions to LTCHs would have on the QRP measure performance; however, we expect that this will represent a relatively small number of readmissions and will have a minimal impact.

Comment: Commenter was concerned that SNFs would not necessarily be able to verify the accuracy of the risk adjustment model, as they are unlikely to have access to complete information on sociodemographic characteristics, principal diagnosis during the proximal hospital stay, body system specific surgical indicators, comorbidities, length of stay during the proximal hospital stay, intensive care utilization,

ESRD status, and the number of hospital stays during the prior year. The commenter suggested that we provide SNFs with verifiable prior hospitalization information used to calculate the risk adjustment.

Response: We thank the commenter for their concern over providers' ability to verify the accuracy of the data used to calculate this measure. We will take this comment under consideration as we determine which data elements would enable SNFs to verify their data and risk-standardized PPR rate.

Comment: Commenter supported our proposal to adopt claims-based measures rather than measures based on self-reported data, stating that the latter are susceptible to gaming. The commenter also applauded our choice to count within-stay and post-discharge hospital readmissions in the measure. However, the commenter stated that we should extend the measured time period to 90 days, suggesting that the proposed 30-day time period is too short to capture poor care provided by a SNF. Another commenter supported the adoption of the SNFPPR and suggested that both the proposed and previously adopted measure (SNFRM) readmission measures could be improved by extending the readmission window. The commenter noted that about one-third of SNF stays are longer than the proposed 30-day window, and suggested that the current proposal could create incentives for SNFs to delay care until after the 30th day to avoid being penalized on the measure.

Response: We appreciate the commenter's support for the proposed measure, including the support for using claims data as the source for the measure's calculation. We are not aware of another data source aside from Medicare claims data that could be used to reliably assess the outcome of potentially preventable hospital readmissions for this specific readmission window.

The 30-day readmission window used in both the SNFRM (NQF #2510) and the proposed SNFPPR was developed to harmonize with measures used in the hospital setting, including the NQF-endorsed Hospital-Wide Risk-Adjusted All-Cause Unplanned Readmission Measure (NQF #1789). This readmission window was also vetted by technical expert panels. We appreciate the suggestion to consider a 90-day readmission window; however, we believe it would be difficult to ensure that potentially preventable hospital readmissions occurring up to 90 days after prior hospital discharge are attributable to the SNF care received. As we noted previously in this section, the advantage of this window is that it assesses readmissions both during the SNF stay and post-SNF discharge for most SNF patients, depending on the SNF length of stay. For these measures, the focus is on transitions to the SNF from the prior proximal hospital stay, and we believe the alignment to be appropriate since the SNF VBP Program's statute specifically directs us to adopt measures of hospital readmissions.

We intend to conduct ongoing evaluation and monitoring to assess for potential unintended consequences associated with the implementation of this measure. We will report results of our monitoring for potential unintended consequences—including the potential of SNFs to push needed care just past the 30-day window—in future SNF PPS rules.

Comment: Commenter expressed concern about our proposal to include the number of hospitalizations during the previous year as a factor in risk-adjustment. The commenter stated that this factor could result in adjusting a facility's rate for potentially preventable readmissions that occurred during the previous year. The commenter stated that a facility that did poorly preventing preventable readmissions during the prior year would receive a lower readmission target rate as a result.

Response: We agree with the comment that risk adjusting for the count of a beneficiary's prior year hospitalizations may include potentially preventable readmissions. However, we do not believe that the impact of risk adjusting for this will be driven by potentially preventable readmissions since this captures all hospital admissions as well as hospital readmissions. We have chosen to adjust for this factor at the patient-level because it is an indicator of several case-mix factors that we believe are important for risk adjustment. For example, a higher number of prior hospital stays may be indicative of a more complex or compromised clinical state. The number of prior hospital stays may also be related to otherwise unmeasured patient characteristics such as access, and patient compliance during the post-discharge period. Furthermore, we do not believe that including this as a risk adjuster will have a major impact on SNFs' performance on the measure.

Comment: Some commenters suggested that we adopt a measure that assesses the rate of readmissions of SNF beneficiaries to a hospital within 30 days of their discharge from the SNF to a lower level of care or the community.

Response: We agree that a 30-day post-discharge from SNF measure would also be valuable for assessing potentially preventable hospital readmissions; however, given the Program is limited to one measure at a time, we believe that the readmission window selected for the SNFPRR provides specific advantages for the reasons described in this section. We note that we are adopting the Potentially Preventable 30-Day Post-Discharge Readmission Measure for the SNF QRP. That measure assesses the rate of readmissions within 30 days of a SNF discharge.

Comment: Commenters stated that the SNFPPR needs additional risk adjustment in order to avoid establishing incentives for facilities to avoid admitting challenging patients. Commenters specifically called for risk adjustment for socioeconomic status, functional status, medical complexity, and cognitive impairment. Commenters specifically stated that functional and cognitive status are among the strongest predictors of future health care utilization.

Response: We developed a comprehensive claims-based risk-adjustment model that takes into account demographic and eligibility characteristics; principal diagnoses; types of surgery or procedure from the prior short-term hospital stay; comorbidities; length of stay and ICU/CCU utilization from the immediately prior short-term hospital stay; and number of admissions in the year preceding the SNF admission. We direct readers to the final measure specifications posted on the CMS Web site (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Other-VBPs/SNF-VBP.html*), which includes results of the final risk adjustment model. This comprehensive risk-adjustment model is similar to those developed for other NQF-endorsed readmission measures. Results of our testing are within range for similar outcome measures finalized in public reporting and value-based purchasing programs, including the SNFRM.

We agree with the comment that functional and cognitive status are potentially important predictors of readmission outcomes. We intend to evaluate the feasibility of including functional and cognitive status in the future, including using standardized assessment data required by the IMPACT Act when they become available. We refer readers to our reply above on the topic of socioeconomic or sociodemographic adjustment.

Comment: One commenter questioned why we exclude SNF stays where the patient had one or more intervening PAC admissions between the prior proximal hospital discharge and SNF admission or after the SNF discharge, within the 30-day risk window. The commenter also questioned why we exclude SNF admissions where the patient had multiple SNF admissions after the prior proximal hospitalization, within the 30-day risk window. The commenter believed that our stated rationale for this exclusion could apply to any PAC setting and therefore disagreed with the exclusion.

Response: This measure was developed to align with the SNFRM previously adopted for the SNF VBP Program. Both measures exclude patients who have intervening IRF or LTCH admissions before their first SNF admission. In analyses conducted for the SNFRM (NQF #2510), we found that these patients started their SNF admission later in the 30-day readmission window and received services different from those received by patients admitted directly from the hospital to the SNF. As a result, we determined patients with intervening stays present a different risk for readmission than patients admitted directly to the SNF. SNF patients with intervening IRF/LTCH stays had the lowest rates of all-cause readmission (8.6 percent) as compared with those with no intervening IRF/LTCH stay. Additionally, we found that those with intervening IRF/LTCH admissions had longer hospital lengths of stay and more prior proximal hospitalizations involving surgical procedures compared to those without an intervening stay.

This issue also impacts a relatively small number of SNF stays; previous analyses showed that 6 percent of SNF stays had an intervening PAC stay (IRF, LTCH, or another SNF) or go home from their prior proximal hospitalization and are later admitted to a SNF within the 30-day readmission window. Combined, these analyses provide justification for excluding SNF admissions with intervening IRF or LTCH admissions, or with multiple SNF stays, by showing these exclusions will not have a substantial effect on the SNFPPR. Additionally, concerns about attribution, given the mix of providers these patients have received services from during the risk period, states for the appropriateness of excluding these patients. Lastly, patients with multiple PAC stays do not cluster in a small group of facilities, so no facilities are disproportionately impacted by these exclusions. We will continue to monitor, among other unintended consequences of introducing this measure, whether patients are being shifted to other PAC providers or being sent home before arriving at SNFs.

Comment: One commenter stated that we should not exclude SNF stays with a gap of greater than one day between discharge from the prior proximal hospitalization and admission to a SNF. The commenter stated that this exclusion criterion does not consider medically complex patients treated in IRFs and subsequently readmitted for issues that may be treated as comorbidities. The commenter stated that admissions to IRFs should be considered as proximal hospitalizations since IRFs are licensed as hospitals.

Response: This measure was developed to harmonize with our other hospital readmission measures, the SNFRM, and other potentially preventable readmission measures which do not consider post-acute care settings, like IRFs, as proximal hospitalizations. Although IRFs are licensed as hospitals, we include them in the PAC continuum of care and, as such, we have proposed potentially preventable hospital readmission measures for the IRF QRP.

Comment: Commenter stated that we should not finalize the SNFPPR because the measure specifications were not published for the Technical Expert Panel or the MAP to review prior to the proposed rule's display. The commenter also noted that the risk adjustment model is new, and stated that the measure should not be rushed to meet an artificial deadline.

Response: In order to be as transparent as possible with the public, we made the specifications we had completed available to the TEP and the MAP. We then continued developing the measure in order to meet the deadline under section 1888(g)(2) of the Act to specify the measure by October 1, 2016. We also wish to note that although we were not required to make the specifications available to the MAP prior to proposing to adopt it for the SNF VBP, we did make the final specifications available to the MAP for comments and feedback. The risk-adjustment model developed for the SNFPPR measure was also made available at the time of the proposed rule.

Comment: Commenter stated that we should not finalize the SNFPPR because the MAP only recommended the measure as ''encourage further development,'' and did not vote to ''support'' or ''support with conditions.'' The commenter suggested that we should submit the measure for NQF endorsement. The commenter also noted that the SNF VBP statute specifies that the measure should be adopted ''as soon as practicable,'' and stated their belief that measures that will affect beneficiary access and quality as well as providers should undergo consensus review.

Response: Although the measure is not currently NQF-endorsed, we did conduct additional testing subsequent to the December 2015 MAP meeting where this measure was discussed. Based on that testing, we were able to complete the risk adjustment model and evaluate facilities' PPR rates, and we made the results of our analyses available at the time of the proposed rule. We found that testing results were similar to the SNFRM (NQF #2510) and allowed us to conclude that the measure is sufficiently developed, valid and reliable for adoption in the SNF VBP Program.

Comment: One commenter also stated that we should await NQF endorsement of the SNFPPR before we adopt it for use in the SNF VBP Program and at a minimum, should wait until at least 2 years after the SNFRM has been used in the Program.

Response: We intend to submit the SNFPPR to NQF for consideration of endorsement. With regard to the waiting at least 2 years before we adopt the SNFPPR for use in the SNF VBP, we will take this comment under consideration.

Comment: Commenter stated that we should use an ''actual readmission rate'' to calculate SRRs rather than predicted readmissions, or we should show how predicted and actual readmissions result in significantly different rankings in order to justify their use in the methodology. The commenter understood the statistical rationale for using the risk-adjusted estimate instead of actual readmission rate in the SRR, but did not believe that this approach provides superior or more accurate information than the actual readmission rate, and will instead be more confusing. The commenter called on us to use a simpler method.

Response: The statistical approach for this measure, including the use of the predicted to expected PPR rate, is used in several other quality measures, including the NQF-endorsed all-cause unplanned readmission measures for post-acute care and the hospital-wide all-cause readmission measure (NQF #1789) and other hospital readmission measures used in the Hospital Inpatient Quality Reporting (IQR) Program. Our decision to use this approach was influenced by work we became aware of by an independent committee appointed by the Committee of Presidents of Statistical Societies. In its White Paper

report, the committee approved CMS's approach as a valid modeling approach with preferred statistical characteristics.[24] We believe that this approach makes providers with small numbers of eligible patient stays less vulnerable to reported rates driven by the influence of random variation in performance, and, thus, will maximize the value of assessing SNFs' performance in SNF VBP. We would also like to note that facilities will be given their observed or actual readmission rates in their reports.

Comment: Commenter stated that the SNFPPR should not exclude individuals who died during the SNF stay, noting that individuals who died could still have been hospitalized for a PPR prior to dying. Commenter stated that excluding these patients will overestimate readmission rates in SNFs with high rates of within-SNF stay mortality and could create incentives to let patients die in SNFs rather than sending them to the hospital.

Response: We wish to clarify that the SNFPPR measure does not exclude patients who die during the 30-day window. If an individual died and was hospitalized for a PPR prior to dying, this readmission would in fact be included in the numerator for the facility. For additional information on the SNFPPR's calculation and methodology, we refer readers to the final specification that we will post on the SNF VBP Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Other-VBPs/SNF-VBP.html.*

Comment: Commenter called on us to harmonize the SNFPPR with other PAC PPR measures, noting that the SNFPPR is the only one of several measures that counts readmissions during a patient's stay and after discharge, depending on the SNF length of stay. The commenter stated that the MAP recommended that the measure track ''within stay'' readmissions in order to align with other measures and avoid duplication of efforts, and noted that readmissions will be counted in both the SNFPPR and the Potentially Preventable 30-Day Post-Discharge Readmission Measure for the SNF QRP measure. The commenter acknowledged our concern that not counting post-discharge hospitalizations may create incentives for SNFs to discharge patients prematurely, but stated that we have not presented any evidence that this will, in fact, occur and that we have numerous other programs available to monitor any such behavior by SNFs. This commenter stated that, if nothing else, we should reduce the readmission window to seven days post-discharge, suggesting that readmissions after seven days are more reflective of quality and access to ambulatory care.

Response: Our decision to develop the SNFPPR using this specific readmission window was intended to balance the relative advantages associated with assessing the outcome both during the SNF stay and potentially post-discharge with any possible incentives to discharge patients who represent the highest risk for readmission in order to avoid penalty. Given that this measure is the sole determinant of a value-based purchasing program for SNFs, we were limited to selecting one readmission window for the measure and believe that counting readmissions that may occur post-discharge but within the 30-day window would be most valuable, even though other quality programs outside the VBP may be available to monitor premature discharges in SNFs.

The 30-day window reflects a transitional time period wherein the acute care hospital and skilled nursing facility are responsible for coordinating the care of a patient moving from one setting to another and is consistent with readmission measures used in other value-based purchasing programs, such as the ESRD Quality Incentive Program and the Hospital Readmission Reduction Program, as well as readmission measures used in a number of quality reporting programs that apply to post-acute care providers. Furthermore, our analysis of readmission rates showed no patterns indicating that using a shorter or longer period would produce very different comparative results, though the overall rates would change. In addition, the NQF Standing Committee generally agreed that 30 days post-hospital discharge is an accepted standard for measuring readmissions. Longer windows may be subject to greater ''noise'' in the readmission rate. The measure as specified has the potential for this unintended consequence of delaying hospital care beyond the 30-day readmission window, but this is a danger that would be associated with any selected day threshold. In addition, we will continue to analyze whether there are changes in the number of days to hospital readmission over time in order to assess whether a change to the readmissions window is needed for this measure in the future.

After consideration of the public comments that we received, we are finalizing our proposal to adopt the SNF 30-Day Potentially Preventable Readmission Measure (SNFPPR) for the SNF VBP Program.

Section 1888(h)(2)(B) of the Act requires the Secretary to apply the all-condition risk-adjusted potentially preventable hospital readmission measure specified under paragraph (g)(2) instead of the measure specified under paragraph (g)(1) as soon as practicable. We will apply the measure specified under paragraph (g)(1) beginning in performance year CY 2017 for payment year FY 2019, and we will apply it until such a time as the measure specified under paragraph (g)(2) replaces the measure specified under paragraph (g)(1). We intend to propose the timing for the change to the paragraph (g)(2) measure in future rulemaking. We sought comment on when we should propose this change for the SNF VBP Program. The comments we received on this topic, with their responses, appear below.

Comment: One commenter stated that the SNFPPR should replace the SNFRM as soon as possible because the SNFPPR holds providers accountable for conditions that can be managed in the SNF. The commenter suggested that we could replace the SNFRM for scoring beginning in October 2019, after the first Program year. Still other commenters suggested that we transition the measure once it receives unconditional endorsement from NQF, or that we allow at least a full year for SNFs to receive and understand their SNFPPR data before we implement the measure. Another commenter suggested that we defer transitioning the Program from the SNFRM to the SNFPPR, citing the MAP's vote to recommend the measure to ''encourage further development'' and the commenter's belief that the measure should be subjected to additional public comments prior to its adoption.

Response: We thank commenters for these suggestions. We will consider these comments when we develop a future proposal to replace the SNFRM with the SNFPPR.

As noted previously in this section, we also intend to submit the SNFPPR to the NQF for consideration of endorsement as soon as possible.

c. Performance Standards

i. Background

Sections 1888(h)(3)(A) of the Act requires the Secretary to establish performance standards for the SNF VBP Program. Under paragraph (3)(B) of section 1888(h) of the Act, the

[24] The COPSS–CMS White Paper Committee. Statistical Issues in Assessing Hospital Performance. January 2012. Available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Statistical-Issues-in-Assessing-Hospital-Performance.pdf.*

performance standards must include levels of achievement and improvement, and under paragraph (3)(C) of such section, must be established and announced not later than 60 days prior to the beginning of the performance period for the FY involved.

In the FY 2016 SNF PPS final rule (80 FR 46419 through 46422), we summarized public comments we received on possible approaches to calculating performance standards under the SNF VBP Program. We specifically sought comment on the approaches that we have adopted for other Medicare VBP programs such as the Hospital VBP Program (Hospital VBP Program), the Hospital-Acquired Conditions Reduction Program (HAC Reduction Program), the Hospital Readmissions Reduction Program (HRRP), and the End-Stage Renal Disease Quality Incentive Program (ESRD QIP). We also sought comment on the best possible approach to measuring improvement, particularly given the SNF VBP Program's limitation to one measure for each program year.

ii. Proposed Performance Standards Calculation Methodology

We believe that an essential goal of the SNF VBP program is to provide incentives for all SNFs to improve the quality of care that they furnish to their residents. In determining what level of SNF performance would be appropriate to select as the performance standard for the quality measures specified under the SNF VBP program, we focused on selecting levels that would challenge SNFs to improve continuously or to maintain high levels of performance. To achieve this aim, we analyzed SNFRM data and examined how different achievement performance standards would impact SNFs' scores under the proposed scoring methodology described further below. As more data becomes available, we will continue to assess the appropriateness of these performance standards for the SNF VBP program and, if necessary, propose to refine these standards' definitions and calculation methodologies to better incentivize the provision of high-quality care.

(a) Proposed Achievement Performance Standard and Benchmark

Beginning with the FY 2019 SNF VBP program, we proposed to define the achievement performance standard (which we will refer to as the ''achievement threshold'') for quality measures specified under the SNF VBP program as the 25th percentile of national SNF performance on the quality measure during the applicable baseline period. We believe this achievement threshold definition represents an achievable standard of excellence and will reward SNFs appropriately for their performance on the quality measures specified for the SNF VBP program. We further believe this achievement threshold definition will provide strong incentives for SNFs to improve their performance on the measures specified for the SNF VBP Program continuously and will result in a wide range of SNF measure scores that can be used in public reporting.

We further proposed to define the ''benchmark'' for quality measures specified under the SNF VBP program as the mean of the top decile of SNF performance on the quality measure during the applicable baseline period. We believe this definition represents demonstrably high but achievable standards of excellence; in other words, the benchmark will reflect observed scores for the group of highest-performing SNFs on a given measure. This proposed benchmark policy aligns with that used by the Hospital VBP Program. As stated in the FY 2016 SNF PPS final rule (80 FR 46419 through 46420), we believe the Hospital VBP Program's performance standards methodology is a well-understood methodology under which health care providers and suppliers can be rewarded both for providing high-quality care and for improving their performance over time. We therefore believe it is appropriate to align with the Hospital VBP Program in setting benchmarks for the SNF VBP Program.

We also proposed that SNFs would receive points along an achievement range, which is the scale between the achievement threshold and the benchmark. Under this proposal, SNFs would receive achievement points if they meet or exceed the achievement threshold for the specified measure, and could increase their achievement score based on higher levels of performance. (We described the proposed scoring methodology, including how we proposed to award points for both achievement and improvement, in the scoring methodology section of the proposed rule). This proposed achievement range policy aligns with that used by the Hospital VBP Program. We refer readers to the FY 2016 SNF PPS final rule (80 FR 46419 through 46420) for a discussion of the rationale behind aligning SNF VBP Program policies with the Hospital VBP Program. As stated in that rule, we believe that the Hospital VBP Program's performance standards methodology is well-understood and would allow us to reward SNFs both for providing high-quality care and for improving their performance over time. We stated our intent to publish the final performance standards using complete data from CY 2015 in the FY 2017 SNF PPS final rule, and we have updated the numerical values in Table.

The comments we received on this topic, with their responses, appear below.

Comment: Commenters supported our proposed performance standards calculations, including our proposal to define the achievement threshold as the 25th percentile of national SNF performance during the baseline period. Commenters also supported our proposal to define the benchmark as the mean of the top decile of all SNFs' performance on proposed measures. Some commenters requested that we establish and announce the achievement threshold and benchmark earlier in the year in order to give SNFs additional time to develop quality improvement strategies.

Response: We thank the commenters for their support. However, we do not believe we can establish and announce the achievement threshold and the benchmark earlier in the year given the time needed to compile claims data and compute the readmissions measures.

We also sought comment on whether we should consider adopting either the 50th or 15th percentiles of national SNFs' performance on the quality measure during the applicable baseline period. We sought comment on data or other analysis that we should consider regarding the impact on SNFs' financial viability and service delivery to beneficiaries at either the higher or lower alternative standard. For example, while the 50th percentile would represent a more challenging threshold for care quality improvement, that standard would align with the Hospital VBP Program and would likely result in higher value-based incentive payments to top-performing SNFs than other definitions, though the actual distribution of value-based incentive payments would depend on all SNFs' performance and on the statutory rules governing their distribution. Such a standard would likely result in lower value-based incentive payments to lower-performing SNFs, which could create substantial payment disparities among participating SNFs. Conversely, the 15th percentile would likely result in higher value-based incentive payments for lower-performing SNFs than other thresholds, with the corresponding result of lower value-based incentive-payments for top-performing SNFs compared to other thresholds. The comments we received

on this topic, with their responses, appear below.

Comment: Commenter stated that we should not increase the proposed achievement threshold to 50 percent, noting that meeting such a standard may be difficult for small, rural, or frontier facilities with limited resources and low volume. The commenter also suggested that we should test the two-pronged process for performance standards for reliability and validity prior to payment and public reporting. Other commenters stated that the 2 percent withhold has a significant enough impact on providers that they need to take time to understand how to minimize payment penalties.

Response: As discussed further below, we are finalizing the definition of the achievement threshold as the 25th percentile of SNFs' performance during the applicable baseline period. We intend to monitor the effects of the performance standards' definition on SNFs' performance and on the provision of care to Medicare beneficiaries.

We are required by statute to implement the 2 percent withhold from Medicare payments for SNFs. We intend to monitor the Program's effects on the impact of care by SNFs. However, as explained more fully above, we do not believe we can allow SNFs more time than we have proposed in order to understand how to minimize payment penalties.

Comment: One commenter recommended that we adopt the 50th percentile for the achievement threshold, stating that we should maintain consistency across settings when calculating achievement scores.

Response: While we agree with the commenter in general that consistency across settings in our value-based purchasing programs is important, we also recognize that we must implement these programs differently where statutory language differs or where the different care setting necessitates a policy change from other programs. We remain concerned that adopting the 50th percentile for the definition of the achievement threshold would result in about half of SNFs receiving no points for achievement under the Program, which would mean that we are effectively unable to reward their performance, particularly in cases where they do not qualify for improvement points. Our intention with the SNF VBP Program is to provide strong incentives for SNFs to improve their performance on the Program's measures continuously, and we do not believe that effectively excluding about half of SNFs from receiving achievement points will further that objective. We balanced that intention with our desire to ensure that we award points under the Program for quality performance, and do not award substantial points for what we have measured as poor-quality care. Upon further consideration of the comments, we believe the 25th percentile appropriately balances those goals.

Comment: Commenter expressed concerns about the alternative levels of the achievement threshold presented in the rule, suggesting that the 25th percentile represents the best chance to balance incentive payments between low and high performers. The commenter urged us to test these alternatives prior to implementation and public reporting.

Response: We thank the commenter for their support, and as discussed further above, we share the commenter's concerns about the alternatives to the 25th percentile for the achievement threshold. Accordingly, we are finalizing the definition of the achievement threshold as the 25th percentile of SNFs' performance on the Program's measures during the applicable baseline period.

Comment: One commenter was concerned about the proposed definition for the benchmark under the Program, explaining their preference for additional testing of the benchmark prior to its public reporting and use in calculating incentive payments. The commenter was concerned about unintended consequences for nursing homes and medically-complex or otherwise high-risk patients.

Response: We intend to monitor the Program's effects on SNFs' provision of high-quality care to Medicare beneficiaries. However, as we stated in the proposed rule (81 FR 24246), we believe that the proposed definition of the benchmark represents a demonstrably high but achievable standard of excellence for all SNFs, including those SNFs that treat high-risk patients. We note further that the measures specified under the Program are risk adjusted for medically-complex or otherwise high-risk patients, and we believe that adjustment will mitigate the commenter's concerns about unintended consequences. We intend to monitor the effects of the measures' risk adjustment policy to ensure that SNFs serving those patients are scored appropriately and are not penalized for treating medically-complex or high-risk patients.

(b) Improvement Performance Standard

Beginning with the FY 2019 SNF VBP program, we proposed to define the improvement performance standard (which we will refer to as the ''improvement threshold'') for quality measures specified under the SNF VBP program as each specific SNF's performance on the specified measure during the applicable baseline period. As discussed further below, we will measure SNFs' performance during both the proposed performance and baseline periods, and we will award improvement points by comparing SNFs' performance to the improvement threshold. We believe this improvement performance standard ensures that SNFs will be adequately incentivized to improve continuously their performance on the quality measures specified under the SNF VBP Program, and we believe it appropriately balances our view that we should both reward SNFs for high performance and encourage improved performance over time.

We invited public comment on this proposal. The comments we received on this topic, with their responses, appear below.

Comment: Some commenters expressed concern about the proposed improvement points formula, suggesting that the formula should not require unrealistic levels of improvement from providers that are already high achievers based on their baseline period scores. Other commenters noted that we have in other rules explained that measures should be dropped or changed when performance reaches a uniformly high level.

Response: SNFs that are already high achievers based on their baseline period scores will be able to score achievement points under the proposed scoring methodology. While the commenter is correct that it may be difficult for a SNF to score a substantial number of improvement points if that SNF has a high baseline period score, the proposed methodology allows SNFs to earn ten additional points for achievement than they are able to earn for improvement. We therefore believe that SNFs that are already high achievers are well-positioned to earn high scores under the Program so long as they maintain their high performance on the specified measures.

We thank commenters for the suggestion that we should adopt a policy to drop measures or change them when performance reaches a uniformly high level. In other contexts, we have described this as a ''topped-out'' measures policy. We have not considered adopting such a policy for the SNF VBP Program to date, but we will consider whether or not to do so in future rulemaking.

(c) Publication of Performance Standard Numerical Values

Section 1888(h)(3)(C) of the Act requires the Secretary to establish and announce the performance standards for a given SNF VBP program year not later than 60 days prior to the beginning of the performance period for the FY involved. Based on the proposed performance period of CY 2017 for the FY 2019 SNF VBP Program, we believe that we must establish and announce performance standards for the FY 2019 Program not later than November 1, 2016. We intend to establish and announce performance standards for the Program in the annual SNF PPS rule, which is effective on October 1 of each year.

However, finalizing numerical values of these performance standards is often logistically difficult because it requires the collection and analysis of large amounts of quality measure data in a short period of time. For example, the data file for a full year of SNF claims data is typically completed around May of the following year. To calculate a numerical value for a performance standard, we must perform multiple levels of analyses on the data to ensure that all appropriate SNFs and patients are included in measure calculations; perform the measure calculations themselves; and then use those calculations to determine the numerical value for the performance standards. If any individual step of this process is delayed, it may preclude us from publishing finalized numerical values for the finalized performance standards in the applicable SNF PPS final rule, which is typically displayed publicly by August 1 of each year.

To retain the flexibility needed to ensure that numerical values published for the finalized performance standards are accurate, we proposed to publish these numerical values no later than 60 days prior to the beginning of the performance period but, if necessary, outside of notice-and-comment rulemaking. As noted, we intend to publish numerical values for those performance standards in the final rule when practicable. However, in instances in which we cannot complete the necessary analyses in time to include them in the SNF PPS final rule, we proposed to publish the numerical values for the performance standards on the QualityNet Web site used by SNFs to receive VBP information as soon as practicable but in no event later than the statutorily required 60 days prior to the beginning of the performance period for the fiscal year involved. In this instance, we would notify SNFs and the public of the publication of the performance standards using a listserv email and posting on the QualityNet News portion of the Web site.

We welcomed public comment on this proposal. The comments we received on this topic, with their responses, appear below.

Comment: One commenter supported our proposed timing and method for publishing the numerical values of the performance standards and for payment adjustments. The commenter appreciated the complexity of calculating hospital readmission rates and understood that we may need to publish performance standards or payment information outside of rulemaking. The commenter believed this to be a reasonable trade-off in order to have the performance period occur as close to the payment adjustment as possible.

Response: We thank the commenter for their support.

After consideration of the public comments that we received, we are finalizing our performance standards policies as proposed. Specifically, we are finalizing our definition of the achievement performance standard, which we refer to as the ''achievement threshold,'' for quality measures specified under the SNF VBP Program as the 25th percentile of national SNF performance on the quality measure during the applicable baseline period. We are finalizing our proposal to define the ''benchmark'' for quality measures specified under the SNF VBP Program as the mean of the top decile of SNF performance on the applicable quality measure during the applicable baseline period. We are also finalizing our proposals that SNFs would receive points along an achievement range, which is the scale between the achievement threshold and the benchmark.

We are also finalizing our proposal to define the improvement performance standard (which we refer to as the ''improvement threshold'') for quality measures specified under the SNF VBP Program as each specific SNF's performance on the specified measure during the applicable baseline period.

We are also finalizing our proposal to publish the numerical values of the achievement threshold and the benchmark no later than 60 days prior to the beginning of the performance period, but if necessary, outside of notice-and-comment rulemaking.

The final values for the achievement threshold and the benchmark for the FY 2019 Program are displayed below in Table 10. For clarity, and as discussed further above, we have inverted the SNFRM rate so that a higher rate represents better performance.

TABLE 10—FINAL FY 2019 SNF VBP PROGRAM PERFORMANCE STANDARDS *

Measure ID	Measure description	Achievement threshold	Benchmark
SNFRM	SNF 30-Day All-Cause Readmission Measure (NQF #2510)	0.79590	0.83601

* **Note:** Performance standards were calculated as of July 14, 2016 using CY 2015 data.

d. FY 2019 Performance Period and Baseline Period

i. Background

We refer readers to the FY 2016 SNF PPS final rule (80 FR 46422) for discussion of the considerations that we intend to take into account when specifying a performance period under the SNF VBP Program. We also explained our view that the SNF VBP Program necessitates adoption of a baseline period, similar to those adopted under the Hospital VBP Program and ESRD QIP, which we would use to establish performance standards and measure improvement.

We received public comments on this topic, and we refer readers to the FY 2016 SNF PPS final rule for a summary of those comments and our responses. We considered those comments when developing our performance and baseline period proposals for this proposed rule.

ii. Proposed FY 2019 Performance Period

In considering various performance periods that could apply for the FY 2019 SNF VBP Program, we recognized that we must balance the length of the performance period used to collect quality measure data and the amount of data needed to calculate reliable, valid

measure rates with the need to finalize a performance period through notice and comment rulemaking. We therefore proposed to adopt CY 2017 (January 1, 2017 through December 31, 2017) as the performance period for the FY 2019 SNF VBP Program, with a 90-day run out period immediately thereafter for claims processing, based on the following considerations.

We strive to link performance furnished by SNFs as closely as possible to the payment year to ensure clear connections between quality measurement and value-based payment. We also strive to measure performance using a sufficiently reliable population of patients that broadly represent the total care provided by SNFs. As such, we anticipate that our annual performance period end date must provide sufficient time for SNFs to submit claims for the patients included in our measure population. Based on past experience with claims processing in other quality reporting and value-based purchasing programs, this time lag between care delivered to patients who are included in readmission measures and application of a payment consequence linked to reporting or performance on those measures has historically been close to 1 year. We also recognize that other factors contribute to the delay between data collection and payment impacts, including: The processing time needed to calculate measure rates using multiple sources of claims needed for statistical modeling; time for determining achievement and improvement scores; time for providers to review their measure rates and included patients; and processing time needed to determine whether a payment adjustment needs to be made to a provider's reimbursement rate under the applicable PPS based on its performance. Further, our preference is to adopt at least a 12-month period as the performance period, consistent with our view that using a full year's performance period provides sufficient levels of data accuracy and reliability for scoring SNF performance on the SNFRM and SNFPPR. We also believe that adopting a 12-month period for the performance period supports the direction provided of section 1888(g)(3) of the Act that the quality measures specified under the SNF VBP Program shall be designed to achieve a high level of reliability and validity. Specifically, we believe using a full year of claims data better ensures that the variation found among SNF performance on the measures is due to real differences between SNFs, and not within-facility variation due to issues such as seasonality. Additionally, we believe that adopting 12-month performance and baseline periods enables us to measure SNFs' performance on the specified measures in sequence, which we believe is necessary in order to measure SNFs on both achievement and improvement, as required by section 1888(h)(3)(B) of the Act.

Finally, we also considered the time necessary to calculate SNF-specific performance on the SNFRM after the conclusion of the performance period and to develop and provide SNF VBP scoring reports, including the requirement under section 1888(h)(7) of the Act that we inform each SNF of the adjustments to the SNF's payments as a result of the program not later than 60 days prior to the FY involved. Based on the requirements and concerns discussed above, we believe a 12-month time period is the only operationally feasible performance period for the SNF VBP Program.

We invited public comments on this proposal, and we respond to them in the next section.

iii. Proposed FY 2019 Baseline Period

As we have done in the Hospital VBP Program and the ESRD QIP, we proposed to adopt a baseline period for use in the SNF VBP Program.

We proposed to adopt calendar year 2015 claims (January 1, 2015 through December 31, 2015) as the baseline period for the FY 2019 SNF VBP Program and to use that baseline period as the basis for calculating performance standards. We stated that, as with the performance period, we will allow for a 90-day claims run out following the last date of discharge (December 31, 2015) before incorporating the 2015 claims in our database into the measure calculation.

We welcomed public comment on this proposal. The comments we received on this topic, as well as the comments that we received on the proposed performance period, with their responses, appear below.

Comment: One commenter supported our baseline and performance period proposals, stating their appreciation that we proposed a performance period as close to the payment period as possible.

Response: We thank the commenter for the support and agree. When developing these policies, we attempted to balance the length of the performance period with its proximity to the payment period, and we believe we have appropriately balanced those two factors.

Comment: One commenter was concerned about the delay between quality measurement and incentive payments or penalties, stating that providers need a clear link between practice and outcomes.

Response: As explained previously in this section, we believe that the proposed performance period is as close to the payment period as we can implement practically given the time necessary for claims submission and processing, as well as for scoring under the Program.

Comment: One commenter recommended that we expand the performance period for low-volume SNFs (which the commenter defined as SNFs having less than 25 stays) to 24 months, and that we exclude from the program SNFs that have fewer than 25 stays during the 2-year performance period. The commenter stated that this suggested exemption's effects would be insignificant on SNFs' scores in the aggregate, pointing to analysis that a similarly-structured 20-stay exclusion would only exempt about 7.4 percent of SNFs and just 1 percent of stays. The commenter noted that increasing the minimum stays count to 25 would increase the number of exempted SNFs to approximately 9.2 percent of all SNFs and about 1.6 percent of Medicare SNF stays, but also noted that expanding the performance period for low-volume SNFs would reduce the number of exempted SNFs and stays to 4.8 percent and 0.4 percent respectively. The commenter believed that these relatively low numbers of exempted SNFs and stays are justifiable since those SNFs are likely serving isolated areas or providing specialized care.

Response: We are sensitive to the effects the SNF VBP could have on beneficiaries' access to SNF care, and especially how the program might affect access to SNF care in rural and low-volume facilities.

However, while we appreciate the commenters' intent to ensure as broad participation as possible in the Program, we do not believe that a separate performance period for low-volume SNFs is feasible. Under section 1888(h)(3)(C) of the Act, we are required to establish and announce performance standards for a fiscal year not later than 60 days prior to the beginning of the performance period for that fiscal year. We do not believe we would comply with that requirement by establishing a longer performance period for certain SNFs. In addition, because we would not know which SNFs would have had fewer than 25 stays in their measure denominator until after the performance period concluded, it would be impossible for us to have provided the appropriate notice to those SNFs as required under section 1888(h)(3)(C) of

the Act. Moreover, unless we established a separate baseline period for low-volume SNFs, we would be comparing performance and baseline periods of different durations, which raises questions about the validity of those performance comparisons over time. Further, we do not believe that a separate 24-month baseline period is appropriate, as it would require wholly separate calculations of measured performance using an additional year's claims data, which is both time-consuming and costly. Finally, we do not believe that low-volume SNFs are penalized by participating in the Program. The measures of readmissions adopted under the Program include an adjustment that reduces variability in low-volume SNFs' measured performance called ''shrinkage estimation,'' and we believe that this adjustment ensures that the measures are sufficiently reliable for the Program's purposes. However, we will continue to test and evaluate the Program's measures and will take this recommendation under consideration prior to transitioning from the SNFRM to the proposed SNFPPR measure in the SNF VBP Program.

After consideration of the public comments that we received, we are finalizing our proposals to adopt CY 2015 as the baseline period for the FY 2019 SNF VBP Program, and CY 2017 as the performance period for the same Program year.

e. SNF VBP Performance Scoring

i. Background

We refer readers to the FY 2016 SNF PPS final rule (80 FR 46422 through 46425) for a discussion of other Medicare VBP scoring methodologies, including the methodologies used by the Hospital VBP Program and HAC Reduction Program. We also discussed policy considerations related to the Hospital Readmission Reduction Program and the ESRD QIP in the performance standards section of that final rule (80 FR 46420 through 46421). We also discussed the potential application of an exchange function (80 FR 46424 through 46425) to translate SNF performance scores into value-based incentive payments under the SNF VBP Program.

We considered those issues, as well as comments we received on these issues, when developing our performance scoring policy below.

ii. SNF VBP Program Scoring Methodology

Section 1888(h)(4)(A) of the Act requires the Secretary develop a methodology for assessing the total performance of each SNF based on the performance standards established under section 1888(h)(3) of the Act for the measure applied under section 1888(h)(2) of the Act. Section 1888(h)(3)(B) of the Act further requires that these performance standards include levels of achievement and improvement and that, in calculating a facility's SNF performance score, the Secretary use the higher of either improvement or achievement.

After carefully reviewing and evaluating a number of scoring methodologies for the SNF VBP Program, we proposed to adopt a scoring model for the SNF VBP Program similar conceptually to that used by the Hospital VBP Program and the ESRD QIP, with certain modifications to allow us to better differentiate between SNFs' performance on the quality measures specified under the SNF VBP Program.[25] We believe this hybrid appropriately accounts for the SNF VBP Program's statutory limitation to a single measure, will maintain consistency and alignment with other VBP programs already in place, and in doing so, will better enable SNFs to understand the SNF VBP Program. Specifically, we proposed to implement a 0 to 100-point scale for achievement scoring and a 0 to 90-point scale for improvement scoring. In addition, as discussed previously, we proposed to set the achievement threshold for the SNF VBP Program at the 25th percentile of SNF national performance on the quality measure during the baseline period rather than the 50th percentile achievement threshold used in the Hospital VBP Program, though as noted above, we also sought comment on whether or not we should consider adopting the 50th percentile or the 15th percentile.

We believe using wider scales of 0 to 100 points and 0 to 90 points instead of the 0 to 10 and 0 to 9 scales used in the Hospital VBP Program and ESRD QIP will allow us to calculate more granular performance scores for individual SNFs and provide greater differentiation between facilities' performance. We further believe that setting the achievement threshold for the SNF VBP Program at the 25th percentile of national SNF performance on the quality measure during the baseline period is preferable to the Hospital VBP Program's achievement threshold of the 50th percentile of national facility performance for this Program because it accounts for the statutory requirement that the SNF VBP Program include only one quality measure at a time. Unlike the Hospital VBP Program, which contains many measures across multiple domains, the SNF VBP Program is limited by statute to a single quality measure at a time. As a result, a hospital participating in the Hospital VBP Program could perform below the 50th percentile of national performance on one or more measures without experiencing a dramatic drop in its Total Performance Score because the hospital's performance on other measures would contribute to its total performance score. By contrast, if the SNF VBP Program used an achievement threshold of the 50th percentile of national SNF performance, approximately one-half of all SNFs nationwide would automatically receive 0 achievement points assuming no national improvement trends between baseline and performance periods. While these SNFs could still receive improvement points, we believe it is preferable to set a lower achievement threshold that would award the majority of SNFs at least some achievement points, thereby enabling us to differentiate performance among the lower-performing half of SNFs and enabling SNFs to continually increase their achievement score based on higher levels of performance. As stated above, as more data becomes available, we will continue to assess the appropriateness of this achievement threshold for the SNF VBP program and, if necessary, propose to refine these standards' definitions and calculation methodologies to better incentivize the provision of high-quality care.

For these reasons, we proposed to adopt the following scoring methodology beginning with the FY 2019 SNF VBP Program.

(a) Scoring of SNF Performance on the SNFRM

Because the SNF VBP Program uses only one measure to incentivize and assess facility performance and improvement, we believe it is important to ensure that SNFs and the public are able to understand these measure scores easily. SNFRM rates represent the percentage of qualifying patients at a facility that were readmitted within the risk window for the measure. As a result, lower SNFRM rates indicate lower rates of readmission, and are therefore an indicator of higher quality care. For example, a SNFRM rate of 0.14159 means that approximately 14.2 percent of qualifying patients discharged from that SNF were readmitted during the risk window.

[25] We refer readers to the FY 2013 IPPS final rule for a discussion of the Hospital VBP Program scoring methodology (76 FR 2466 through 2470).

We understand that the use of a ''lower is better'' rate could cause confusion among SNFs and the public. Therefore, we proposed to calculate scores under the Program by first inverting SNFRM rates using the following calculation:

SNFRM Inverted Rate = 1 − Facility's SNFRM Rate

This calculation inverts SNFs' SNFRM rates such that higher SNFRM performance reflects better performance on the SNFRM. As a result, the same SNFRM rate presented above (0.14159) would result in a SNFRM inverted rate of 0.85841, which means that approximately 86 percent of qualifying patients discharged from that SNF were not readmitted during the risk window. We believe this inversion is important to incentivize improvement in a clear and understandable manner, and will also simplify public reporting of SNF performance for use in consumer, family, and caregiver decision-making. Further, under this proposal, all SNFRM inverted rates would be rounded to the fifth significant digit.

(b) Scoring SNFs' Performance Based on Achievement

We proposed that a SNF would earn an achievement score of 0 to 100 points based on where its performance on the specified measure fell relative to the achievement threshold (which we proposed above to define for the quality measures specified under the SNF VBP program as the 25th percentile of SNF performance on the quality measure during the applicable baseline period) and the benchmark (which we proposed to define as the mean of the top decile of SNF performance on the measure during the baseline period). As with the Hospital VBP Program, we proposed to award points to SNFs based on their performance as follows:

- If a SNF's SNFRM inverted rate was equal to or greater than the benchmark, the SNF would receive 100 points for achievement;
- If a SNF's SNFRM inverted rate was less than the achievement threshold (that is, the lower bound of the achievement range), the SNF would receive 0 points for achievement.
- If a SNF's SNFRM inverted rate was equal to or greater than the achievement threshold, but less than the benchmark, we would award between 0 and 100 points to the SNF according to the following formula:

$$\textbf{SNF Achievement Score} = \left(\left[9\,x\left(\frac{(\textbf{SNF's Perf. Period Inverted Rate} - \textbf{Achievement Threshold})}{(\textbf{Benchmark} - \textbf{Achievement Threshold})}\right)\right] + .5\right) x\ 10$$

The results of this formula would be rounded to the nearest whole number.

The SNF achievement score would therefore range between 0 and 100 points, with a higher achievement score indicating higher performance.

(c) Scoring SNF Performance Based on Improvement

We proposed that a SNF would earn an improvement score of 0 to 90 points based on how much its performance on the specified measure during the performance period improved from its performance on the measure during the baseline period. Under this proposal, a unique improvement range would be established for each SNF that defines the distance between the SNF's baseline period score and the national benchmark for the measure (which we propose to define as the mean of the top decile of SNF performance on the measure during the baseline period). We would then calculate a SNF improvement score for each SNF depending on its performance period score:

- If the SNF's performance period score was equal to or lower than its improvement threshold, the SNF would receive 0 points for improvement.
- If the SNF's performance period score was equal to or higher than the benchmark, the SNF would receive 90 points for improvement.
- If the SNF's performance period score was greater than its improvement threshold, but less than the benchmark, we would award between 0 and 90 points for improvement according to the following formula:

$$\textbf{SNF Improvement Score} = \left(\left[10\,x\left(\frac{(\textbf{SNF Perf. Period Inverted Rate} - \textbf{SNF Baseline Period Inverted Rate})}{(\textbf{Benchmark} - \textbf{SNF Baseline Period Inverted Rate})}\right)\right] - .5\right)\ \textbf{x 10}$$

The results of this formula would be rounded to the nearest whole number.

(d) Establishing SNF Performance Scores

Consistent with sections 1888(h)(3)(B) and 1888(h)(4)(A) of the Act, we proposed to use the higher of a SNF's achievement and improvement scores to serve as the SNF's performance score for a given year of the SNF VBP Program. The resulting SNF performance score would be used as the basis for ranking SNF performance on the quality measures specified under the SNF VBP Program and establishing the value-based incentive payment percentage for each SNF for a given FY.

(e) Examples of the Proposed FY 2019 SNF VBP Program Scoring Methodology

In the proposed rule, we provided two examples to illustrate the proposed scoring methodology for the FY 2019 SNF VBP Program using hypothetical SNFs A, B, and C. The benchmark calculated for the SNFRM for all of these hypotheticals is 0.83915 (the mean of the top decile of SNF performance on the SNFRM in 2014), and the achievement threshold is 0.79551 (the 25th percentile of national SNF performance on the SNFRM in 2014). We noted that, as discussed previously, our proposal for scoring SNF performance on the SNFRM inverts the measure rates so that a higher rate represents better performance.

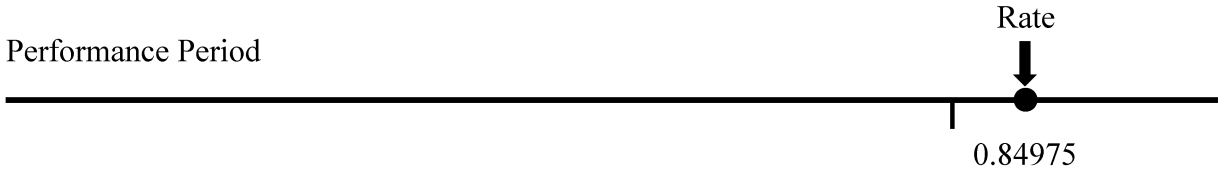
Figure AA shows the scoring for SNF A. SNF A's SNFRM rate of 0.15025 means that approximately 15 percent of qualifying patients discharged from SNF A were readmitted during the 30-day risk window. Under the proposed SNFRM scoring methodology, SNF A's SNFRM inverted rate would be calculated as follows:

Facility a SNFRM Inverted Rate =
1 − 0.15025

As a result of this calculation, Facility A's SNFRM inverted rate would be 0.84975 on the SNFRM for the performance period. This result indicates that approximately 85 percent of SNF A's qualifying patients were *not* readmitted during the 30-day risk window. Because SNF A's SNFRM inverted rate of 0.84975 exceeds the benchmark (that is, the mean of the top decile of facility performance, or 0.83915), SNF A would receive 100 points for achievement. Because SNF A has earned the maximum number of points possible for the SNFRM, its improvement score would not be calculated.

FIGURE AA: SNF A Performance Scoring

SNF A Performance



SNF A Earns: 100 points for achievement performance exceeding the benchmark during the performance period
SNF A's SNF Performance Score: 100 points

Figure BB shows the scoring for SNF B. As can be seen below, SNF B's performance on the SNFRM went from 0.21244, for a SNFRM inverted rate of 0.78756 (below the achievement threshold) in the baseline period to 0.18322, for a SNFRM inverted rate of 0.81668 (above the achievement threshold) in the performance period. Applying the achievement scoring methodology proposed above, SNF B would earn [49] achievement points for this measure, calculated as follows:

$$\boldsymbol{SNF\ Achievement\ Score} = \left(\left[9\ x\ \left(\frac{(0.81668 - 0.79551)}{(0.83915 - 0.79551)}\right)\right] + .5\right)\ x\ 10$$

$$\boldsymbol{SNF\ Achievement\ Score} = \left(\left[9\ x\ \left(\frac{(0.02117)}{(0.04364)}\right)\right] + .5\right)\ x\ 10$$

$$\boldsymbol{SNF\ Achievement\ Score} = ([9\ x\ (0.48511)] + .5)\ x\ 10$$

$$\boldsymbol{SNF\ Achievement\ Score} = ([4.3659] + .5)\ x\ 10$$

$$\boldsymbol{SNF\ Achievement\ Score} = 4.8659\ x\ 10$$

$$\boldsymbol{SNF\ Achievement\ Score} = 49$$

However, because SNF B's performance during the performance period is greater than its performance during the baseline period, but below the benchmark, we would calculate an improvement score as well. According to the improvement scale, based on SNF B's improved SNFRM inverted rate from 0.78756 to 0.81668, SNF B would receive 51 improvement points, calculated as follows:

$$SNF\ Improvement\ Score = \left(\left[10\ x\ \left(\frac{(0.81668 - 0.78756)}{(0.83915 - 0.78756)}\right)\right] - .5\right)\ x\ 10$$

$$SNF\ Improvement\ Score = \left(\left[10\ x\ \left(\frac{(0.02912)}{(0.05159)}\right)\right] - .5\right)\ x\ 10$$

$$SNF\ Improvement\ Score = ([10\ x\ (0.56445)] - .5)\ x\ 10$$

$$SNF\ Improvement\ Score = ([5.6445] - .5)\ x\ 10$$

$$SNF\ Improvement\ Score = 5.1445\ x\ 10$$

$$SNF\ Improvement\ Score = 51$$

FIGURE BB: SNF B Performance Scoring

SNF B Performance

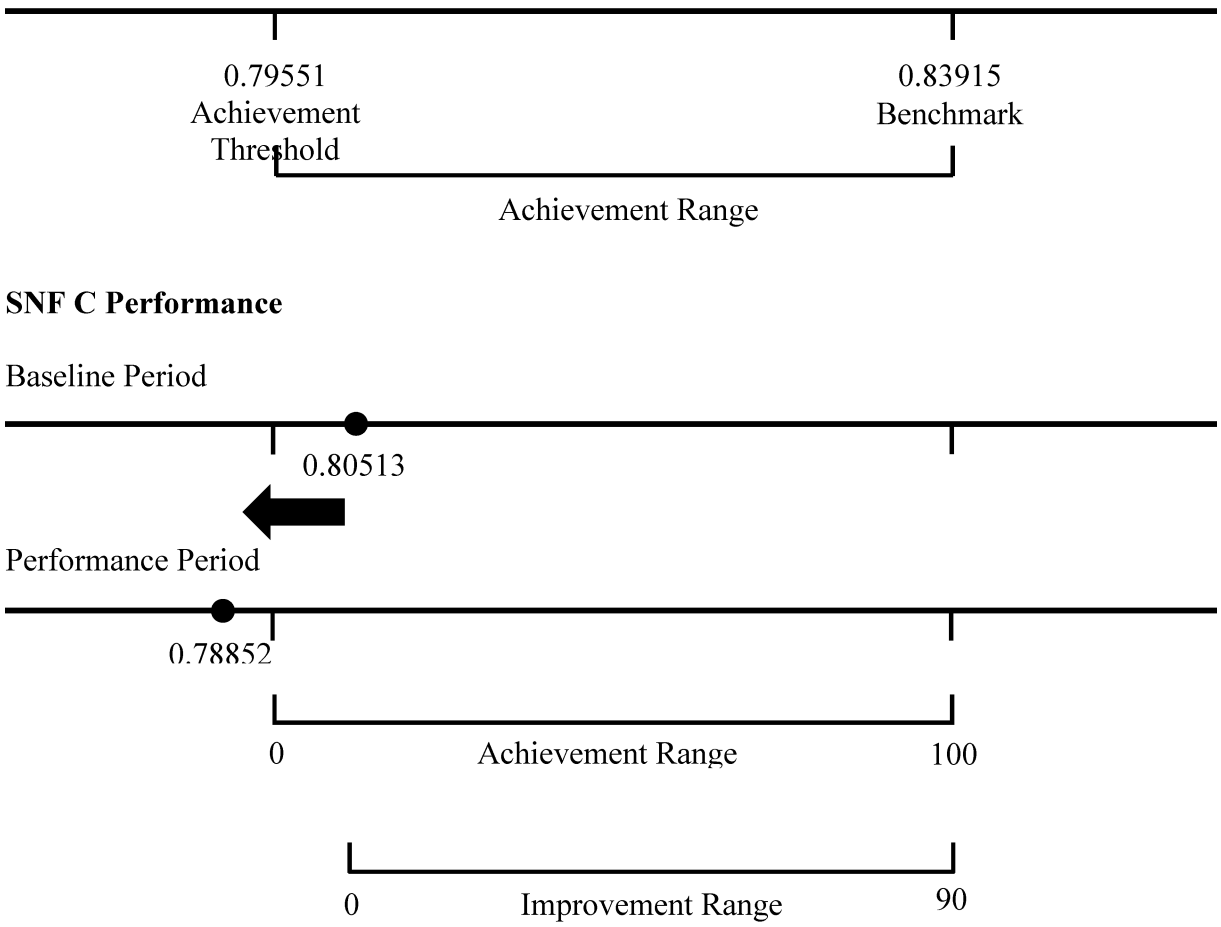
SNF B Earns: 49 points for achievement performance
51 points for improvement performance

SNF B SNF Performance Score: Higher of achievement or improvement
51 points

In Figure CC, SNF C's performance on the SNFRM drops from 0.19487, for a SNFRM inverted rate of 0.80513, in the baseline period to 0.21148, for a SNFRM inverted rate 0.78852, in the performance period (a decline of 0.01661). Because this SNF's performance during the performance period is lower than the achievement

threshold of 0.79551, it receives 0 points based on achievement. It would also receive 0 points for improvement, because its performance during the performance period is lower than its performance period during the baseline period. In this example, SNF C would receive 0 points for its SNF performance score.

FIGURE CC: SNF C Performance Scoring



The comments we received on this topic, with their responses, appear below.

Comment: One commenter supported the proposed scoring methodology, characterizing it as a reasonable approach that appropriately rewards achievement more than improvement.

Response: We thank the commenter for this feedback and agree. We believe the proposed scoring methodology complies with the Program's statutory requirement to score SNFs on both achievement and improvement while reserving the maximum scores for SNFs that are high achievers.

Comment: Some commenters appreciated our proposal to invert SNFs' performance rates on readmission measures to show that higher performance is better, particularly given the requirement to rank SNFs under the program.

Response: We thank the commenters for this feedback.

Comment: Some commenters supported the proposed 0 to 100 scoring approach, and called on us to monitor performance over time to ensure that the scores continue to reflect meaningful differences in care. Other commenters noted the proposed methodology's similarity to the HVBP program and expressed their support accordingly. Commenters also supported our proposed improvement scoring methodology, expressing appreciation that we intend to award fewer improvement points than achievement points. Commenters agreed that including the improvement score creates strong incentives for all SNFs to improve over time.

Response: We thank the commenters for their support.

Comment: One commenter suggested that we consider two additional factors for scoring adjustments, including the best ways to encourage palliative care without harming performance scores and how to adjust for individuals with specialized conditions that present increased risks of hospitalizations.

Response: We do not believe that the Program will discourage palliative care because the Program's measures do not hold SNFs accountable for admissions to hospice or other forms of palliative care, and we believe that the measures' risk adjustment appropriately controls for variations related to individuals' clinical status. However, we will monitor the Program's effects on access to care, and if necessary, will consider additional adjustments in the future.

After consideration of the public comments that we received, we are finalizing the scoring methodology for the SNF VBP Program as proposed.

f. SNF Value-Based Incentive Payments

i. Background

Paragraphs (5), (6), (7), and (8) of section 1888(h) of the Act outline several requirements for value-based incentive payments under the SNF VBP Program. Section 1888(h)(5)(A) of the Act requires that the Secretary increase the adjusted Federal per diem rate for skilled nursing facilities by the value-based incentive payment amount determined under section 1888(h)(5)(B) of the Act. That amount is to be determined by the product of the adjusted federal per diem rate and the value-based incentive payment percentage specified under section 1888(h)(5)(C) of the Act for each SNF for a FY.

Section 1888(h)(5)(C) of the Act requires that the value-based incentive payment percentage be based on the SNF performance score and must be appropriately distributed so that the highest-ranked SNFs receive the highest payments, the lowest-ranked SNFs receive the lowest payments, and that the payment rate for services furnished by SNFs in the lowest 40 percent of the rankings be less than would otherwise apply. Finally, the total amount of value-based incentive payments must be greater than or equal to 50 percent, but not greater than 70 percent, of the total amount of the reductions to payments for the FY specified under section 1888(h)(6) of the Act, as estimated by the Secretary. As discussed further below, we will propose to adopt in future rulemaking an exchange function to ensure that the total amount of value-based incentive payments made under the program each year meets those criteria.

Section 1888(h)(7) of the Act requires the Secretary, not later than 60 days prior to the fiscal year involved, to inform each SNF of the adjustments to its Medicare payments for services furnished by the SNF during the FY. Section 1888(h)(8) of the Act requires that the value-based incentive payment and payment reduction only apply for the FY involved, and not be taken into account in making payments to a SNF in a subsequent year.

We received a number of comments on incentive payments that will be made under the Program.

Comment: Several commenters recommended that we disburse the maximum 70 percent of payments withheld from SNFs as value-based incentive payments, stating that the larger the incentive, the greater the behavioral change. Commenters believed that making the largest amount of funds available would have the greatest impact on changing care practices.

Response: We thank commenters for this feedback. We will address the topic of value-based incentive payments under the Program in future rulemaking. We agree with commenters that the Program's incentive payments should be substantial enough to promote quality improvement through changing care practices.

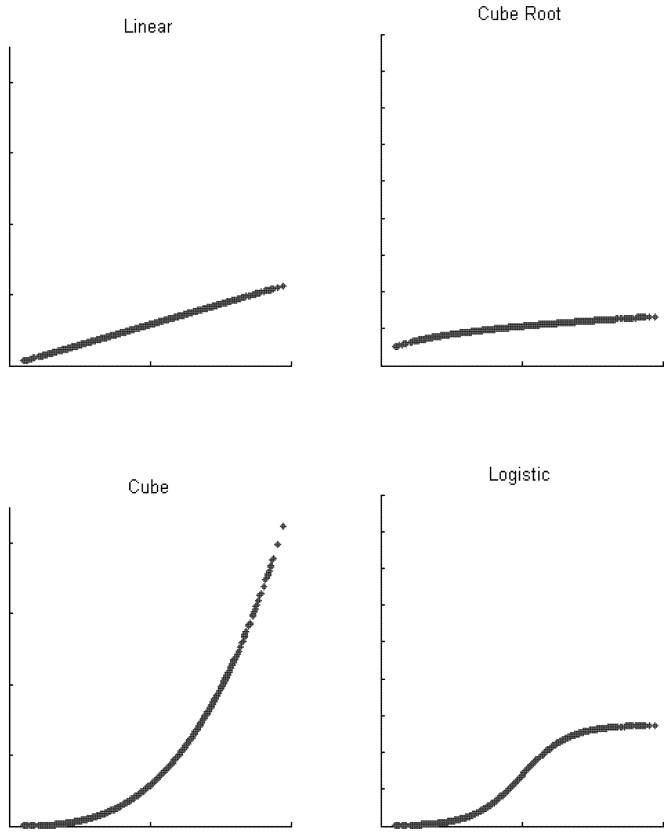
Comment: One commenter stated that the SNF VBP Program should be budget-neutral, and suggested that we should reconsider the 50 to 70 percent payback to facilities under the Program.

Response: Section 1888(h)(5)(C)(ii)(III) of the Act requires that the total amount of value-based incentive payments available under the Program for a fiscal year range from between 50 percent and 70 percent of the total amount of the reductions to the adjusted Federal per diem rates otherwise applicable to skilled nursing facilities for that fiscal year, as estimated by the Secretary. As a result, we do not believe we have the authority to make the SNF VBP Program budget-neutral, or to vary the total amount that we will disburse in value-based incentive payments beyond the 50 to 70 percent range specified under the statute.

ii. Request for Comment on Exchange Function

As we discussed in the FY 2016 SNF PPS final rule (80 FR 46424 through 46425), we use a linear exchange function to translate a hospital's Total Performance Score under the Hospital VBP Program into the percentage multiplier to be applied to each Medicare discharge claim submitted by the hospital during the applicable FY. We intend to adopt a similar methodology to translate SNF performance scores into value-based incentive payment percentages under the SNF VBP Program. When considering that methodology, we sought public comments on the appropriate form and slope of the exchange function to determine how best to reward high performance and encourage SNFs to improve the quality of care provided to Medicare beneficiaries. As illustrated in Figure DD, we considered the following four mathematical exchange function options: Straight line (linear); concave curve (cube root function); convex curve (cube function); and S-shape (logistic function).

FIGURE DD: Exchange Function Options.



We received numerous public comments on the FY 2016 SNF PPS proposed rule, and we sought further public comments to inform our policies on this topic. We requested additional public comments on the specific form of the exchange function that we should propose in the future, including any additional forms beyond the four examples that we have illustrated above, and any considerations we should take into account when selecting an exchange function form that would best support quality improvement in SNFs.

Additionally, we will determine the precise slope of the exchange function after the performance period has concluded, because the distribution of SNFs' performance scores will form the basis for value-based incentive payments under the program. However, two additional considerations will affect the exchange function's slope. As required in section 1888(h)(5)(C)(ii)(II)(cc) of the Act, SNFs in the lowest 40 percent of the ranking determined under paragraph (4)(B) must receive a payment that is less than the payment rate for such services that would otherwise apply. Additionally, as described in this section, section 1888(h)(5)(C)(ii)(III) of the Act requires that the total amount of value-based incentive payments under the Program be greater than or equal to 50 percent, but not greater than 70 percent, of the total amount of reductions to SNFs' payments for the FY, as estimated by the Secretary. We intend to ensure that both of these requirements, as well as all other statutory requirements under the Program, are fulfilled when we specify the exchange function's slope.

We invited public comments on this topic. The comments we received on this topic, with their responses, appear below.

Comment: Commenter offered several principles for us to consider when developing our exchange function proposals in the future. The commenter suggested that top performing SNFs should receive an increase in their Medicare rates, that we should maximize the number of SNFs that do not receive a cut in their rates, that we should allow for continuous improvement, even for SNFs that are already high performers, and that differences in rehospitalization scores should be tied to meaningful differences in incentive payments. The commenter recommended that we adopt the logistic function and recommended against the cube root function, stating that the former balances incentives for low and high performers and that the latter creates very little incentive for performance improvement.

Response: We thank the commenter for this feedback, and we will take it into account as we develop proposals for the exchange function in the future.

g. SNF VBP Reporting

i. Confidential Feedback Reports

Section 1888(g)(5) of the Act requires that we provide quarterly confidential feedback reports to SNFs on their performance on the measures specified under sections 1888(g)(1) and (2) of the Act. Section 1888(g)(5) of the Act also requires that we begin providing those reports on October 1, 2016.

In order to meet the statutory deadline, we are developing the feedback reports, operational systems, and implementation guidance related to those reports. We intend to provide these reports to SNFs via the QIES system CASPER files currently used by SNFs to report quality performance.

We invited public comments on the appropriateness of the QIES system, and any considerations we should take into account when designing and providing

these feedback reports. The comments we received on this topic, with their responses, appear below.

Comment: One commenter supported our proposal to use the QIES system to deliver feedback reports to SNFs. The commenter suggested that we provide these reports in a spreadsheet-based format to allow data aggregation within organizations.

Response: We thank the commenter for this feedback.

Comment: One commenter requested that trade organizations and other organizations that represent the interests of SNFs be provided access to SNFs' quarterly feedback reports. The commenter believed that these organizations can assure that SNF VBP data affecting each SNF will be protected and only shared with representatives for that particular SNF. The commenter noted that many SNFs are members of larger organizations, and that allowing further data distribution would enable these organizations to aggregate these reports rather than manually enter data voluntarily provided by each SNF. Commenter also requested that we provide a national data file with SNF VBP performance to these organizations that can help disseminate performance information to individual SNFs or their parent organizations.

Response: Section 1888(g)(5) of the Act requires us to provide confidential feedback reports to SNFs. We do not believe that we have the authority to share those confidential feedback reports with other entities.

Comment: One commenter requested that we consider using the QIES system to provide real-time data updates, or as close to real-time updates as possible. Commenter noted that we update our MDS data weekly to capture SNFs' most current measure rates in order to facilitate quality improvement efforts and suggested that we could do something similar with Part A claims and the Program's measures.

Response: Although we agree that SNFs would benefit from receiving the most up-to-date information as possible, it is not operationally feasible to provide SNFs with real-time data updates at this time. Unlike MDS data, claims-based measures require significant time to compute and are based on large pools of data. While we will, as described above, provide quarterly confidential feedback reports, we do not believe more frequent updates are possible at this time.

Comment: One commenter suggested several data elements that we could consider including in SNFs' quarterly reports, including readmission counts during and after the Part A stay, names of beneficiaries triggering readmissions, number of readmissions by PPR diagnosis, predicted and expected rates used to calculate the SSR for the prior rolling 12-month window, and national rates used to calculate achievement and improvement scores.

Response: We thank the commenter for this feedback. As we continue the Program's implementation, we will refine the quarterly reports in accordance with SNFs' feedback, and will take these suggestions into consideration.

ii. Proposed Two-Phase SNF VBP Data Review and Correction Process

(a) Background

Section 1888(g)(6) of the Act requires the Secretary to establish procedures to make public performance information on the measures specified under paragraphs (1) and (2) of such section. The procedures must ensure that a SNF has the opportunity to review and submit corrections to the information that will be made public for the facility prior to its being made public. This public reporting is also required by statute to begin no later than October 1, 2017. Additionally, section 1888(h)(9) of the Act requires the Secretary to make available to the public information regarding SNFs' performance under the SNF VBP Program, specifically including each SNF's performance score and the ranking of SNFs for each fiscal year.

Accordingly, we proposed to adopt a two-phase review and correction process for (1) SNFs' measure data that will be made public under section 1888(g)(6) of the Act, which will consist of each SNFs' performance on the measures specified under sections 1888(g)(1) and (2) of the Act, and (2) SNFs' performance information that will be made public under section 1888(h)(9) of the Act.

(b) Phase One: Review and Correction of SNFs' Quality Measure Information

We view the quarterly confidential feedback reports described previously in this section, as one possible means to provide SNFs an opportunity to review and provide corrections to their performance information. However, collecting SNF measure data and calculating measure performance scores takes a number of months following the end of a measurement period. Because it is not feasible to provide SNFs with an updated measure rate for each quarterly report or engage in review and corrections on a quarterly basis, we proposed to use one of the four reports each year to provide SNFs an opportunity to review their data slated for public reporting. In this specific quarterly report, we intend to provide SNFs: (1) A count of readmissions; (2) the number of eligible stays at the SNF; (3) the SNF's risk-standardized readmissions ratio; and (4) the national SNF measure performance rate. In addition, we intend to provide the patient-level information used in calculating the measure rate. However, we sought comment on what patient-level information would be most useful to SNFs and how we should make this information available if requested. We intend to address the topic of what specific information will be provided if requested in this specific quarterly report in future rulemaking, where we intend to propose a process for SNFs' requests for patient-level data. We intend to notify SNFs of this report's release via listserv email and posting on the QualityNet News portion of the Web site.

Therefore, we proposed to fulfill the statutory requirement that SNFs have an opportunity to review and correct information that is to be made public under section 1888(g)(6) of the Act by providing SNFs with an annual confidential feedback report that we intend to provide via the QIES system CASPER files. We further proposed that SNFs must, if they believe the report's contents to be in error, submit a correction request to *SNFVBPinquiries@cms.hhs.gov* with the following information:

- SNF's CMS Certification Number (CCN).
- SNF Name.
- The correction requested and the SNF's basis for requesting the correction. More specifically, the SNF must identify the error for which it is requesting correction, and explain its reason for requesting the correction. The SNF must also submit documentation or other evidence, if available, supporting the request. Additionally, any requests made during phase one of the proposed process will be limited to the quality measure information at issue.

We further proposed that SNFs must make any correction requests within 30 days of posting the feedback report via the QIES system CASPER files, not counting the posting date itself. For example, if we provide reports on October 1, 2017, SNFs must review those reports and submit any correction requests by October 31, 2017. We will not consider any requests for correction to quality measure data that are received after the close of the first phase of the proposed review and correction process. As discussed further in this section, any corrections sought during phase two of

the proposed process will be limited to the SNF performance score calculation and the ranking.

We will review all timely phase one correction requests that we receive and will provide responses to SNFs that have requested corrections as soon as practicable.

(c) Phase Two: Review and Correction of SNF Performance Scores and Ranking

As required by section 1888(h)(7) of the Act, we intend to inform each SNF of its payment adjustments as a result of the SNF VBP Program not later than 60 days prior to the fiscal year involved. For the FY 2019 SNF VBP Program, we intend to notify SNFs of those payment adjustments via a SNF performance score report not later than 60 days prior to October 1, 2018. We intend to address the specific contents of that report in future rulemaking.

In that report, however, we also intend to provide SNFs with their SNF performance scores and ranking. By doing so, we intend to use the performance score report's provision to SNFs as the beginning of the second phase of the proposed review and correction process. By completing phase one, SNFs will have an opportunity to verify that their quality measure data are fully accurate and complete and as a result, phase two will be limited only to corrections to the SNF performance score's calculation and the SNF's ranking. Any requests to correct quality measure data that are received during phase two will be denied.

We intend to set out specific requirements for phase two of the proposed review and correction process in future rulemaking. To inform those proposals, we sought comments on what information would be most useful for us to provide to SNFs to facilitate their review of their SNF performance scores and ranking. As with the phase one process, we intend to adopt a 30-day time period for phase two review and corrections, beginning with the date on which we provide SNF performance score reports.

We invited public comments on this proposed two-phase review and correction process. The comments we received on this topic, with their responses, appear below.

Comment: One commenter only supported the 30-day deadline for correction requests if sufficient information is included in the quarterly reports. The commenter noted that SNFs may not be able to submit documentation or other evidence supporting a correction request within 30 days if they do not receive the names of the beneficiaries who were readmitted, when the readmission occurred, and the readmission diagnosis. Commenter appreciated that we may receive many correction requests, and suggested that we consider allowing corrections for missing data only annually, but corrections for when patients' admissions are listed incorrectly quarterly in order to streamline our reviews of correction requests. Another commenter requested that we provide SNF and hospital inpatient Part A claims to SNFs on a quarterly basis, both to facilitate quality improvement and correction requests. Commenter suggested that we could provide patient identifiable files to organizations that have a Business Associate Agreement with the SNF and allow the organizations to share data with the SNF. Commenter noted that many facilities do not have the capacity to analyze claims data, but many large organizations are working with SNFs to provide this service. Another commenter opposed the ability of SNFs to request data corrections in phase two of the proposed review and correction process unless all data in phase two is also included in the quarterly feedback reports in phase one, and the last quarterly report in phase one includes the final data used to calculate the rehospitalization score. Commenter explained that if SNFs will not be able to file correction requests based on phase two feedback reports, all of the data used to calculate the rehospitalization score needs to be in the phase one reports.

Response: We thank the commenters for this feedback. As we discuss further below in response to other comments, we are finalizing a policy whereby we will accept corrections on any quarterly report provided during a calendar year until the following March 31.

However, the feedback reports that we must provide to SNFs under the requirements at section 1888(g)(5) of the Act are specifically required to remain confidential. We do not believe that we have the authority to share those confidential feedback reports with other organizations than SNFs themselves. We note that SNFs are free to share their feedback reports with other organizations at their discretion.

We would like to clarify the distinction between the two phases of the proposed review and correction process. As we discussed in the proposed rule (81 FR 24255), the first phase is intended to allow SNFs to review and correct patient-level information that we used to calculate the measure rates. The second phase is intended to allow SNFs to review and correct only their performance scores and the ranking, not their measure rates. Although the two phases are separate, they will, taken together, provide SNFs with an opportunity to correct both the measure rates that are used to generate their performance scores and ranking, as well as their actual performance scores and ranking. We do not believe that we should conflate the two, or allow corrections to quality measure data (that is, phase one requests) during the phase two process, because the two phases are aimed at two separate purposes. We believe it to be necessary to finalize the claims data that SNFs will be able to correct in phase one so that those data may form the basis for performance calculations that SNFs will be able to review in phase two.

Comment: One commenter recommended that SNFs be provided access to the information used to calculate their rehospitalization scores and also information to estimate their adjustment factor based on the final exchange function. Commenter explained that SNFs will want to replicate their scores, so they will need their predicted rates, expected rates, national average, baseline period rates, and major ''cut points'' used to determine achievement and improvement points. The commenter also suggested that the ranking of achievement and improvement scores could be helpful to SNFs as well.

Response: We will take these comments into account as we develop the first quarterly feedback reports for SNFs, and look forward to additional feedback from SNFs after we provide them.

Comment: Commenter expressed support for the proposed review and corrections process

Response: We thank the commenter for their support.

Comment: Commenter supported our proposal to provide feedback reports to SNFs via the QIES system. However, the commenter did not support our plan to allow SNFs to seek corrections on an annual basis, and commenter recommended instead that we allow corrections on a quarterly basis with an annual deadline. The commenter suggested that the quarterly data that we provide should be sufficient to allow SNFs to verify the accuracy of their measured performance and suggested as a result that SNFs should be allowed to submit corrections quarterly.

Response: We understand the commenter's concern about the deadline following each quarterly confidential feedback report, and we will instead finalize a policy under which we will accept corrections to any quarterly report provided during a calendar year

until the following March 31. We believe that this policy appropriately balances our desire to ensure that the measure data are sufficiently accurate with SNFs' need for sufficient information with which to evaluate the accuracy of those reports, and provides SNFs with more time to review each quarter's data than the 30 days that we initially proposed.

After consideration of the public comments that we received, we are finalizing the two-phase review and correction process as proposed, with the exception stated above that we will accept corrections to SNFs' quarterly confidential feedback reports during a calendar year until the following March 31.

iii. SNF VBP Public Reporting

Section 1888(h)(9)(A) of the Act requires that we make available to the public on the *Nursing Home Compare* Web site or its successor information regarding the performance of individual SNFs with respect to a FY, including the performance score for each SNF for the FY and each SNF's ranking, as determined under section 1888(h)(4)(B) of the Act. Additionally, section 1888(h)(9)(B) of the Act requires that we periodically post aggregate information on the SNF VBP Program on the *Nursing Home Compare* Web site or its successor, including the range of SNF performance scores, and the number of SNFs receiving value-based incentive payments and the range and total amount of those payments.

We intend to address this topic in future rulemaking. However, we invited public comments on the best means by which to display the SNF-specific and aggregate performance information for public consumption. The comments we received on this topic, with their responses, appear below.

Comment: Commenter supported public posting of SNFs performance scores, but not their rehospitalization rates, achievement or improvement scores. The commenter stated that achievement and improvement scores are not required to be posted publicly by statute and that they are not necessarily helpful to consumers. The commenter also stated against posting the risk adjusted SNFRM or SNFPPR rates, noting that these measures differ from other rehospitalization measures publicly posted by CMS.

Response: We thank the commenter for this feedback. We will propose details on public reporting of SNF VBP Program performance information in the future and will take these comments into account at that time.

Comment: Commenter supported posting of the aggregate value-based incentive payments, as well as the range of those payments and the number of SNFs receiving payment adjustments, but did not support posting individual SNF payments. The commenter noted that individual SNF payments are the product of rehospitalization scores, volume of admissions and patient case mix RUG payments, so actual payment adjustments could be confusing to the public.

Response: We thank the commenter for this feedback and agree that we will need to communicate clearly with the public about the information that we post publicly. We will take these comments into account when we propose details on public posting of SNF VBP payments information in the future.

iv. Ranking SNF Performance

Section 1888(h)(4)(B) of the Act requires ranking the SNF performance scores determined under paragraph (A) of such section from low to high. Additionally, and as discussed in this section, we are required to publish the ranking of SNF performance scores for a FY on *Nursing Home Compare* or a successor Web site.

To meet these requirements, we proposed to order SNF performance scores from low to high and publish those rankings on both the *Nursing Home Compare* and QualityNet Web sites. However, because SNF performance scores will not be calculated until after the performance period concludes after CY 2017 (that is, during CY 2018), and because SNFs must be provided their value-based incentive payment adjustments not later than 60 days prior to the FY involved, we intend to publish the ranking for FY 2019 SNF VBP payment implications after August 1, 2018.

We invited public comments on the most appropriate format and Web site for the ranking's publication. The comments we received on this topic, with their responses, appear below.

Comment: Commenter stated that any public posting of SNFs' ranking under the Program must be clearly indicated, and suggested that rank number 1 should be reserved for the SNF with the best rehospitalization score, not the worst score. Commenter explained that the public may be confused about the ranking unless clear and easy to understand information on the ranking's direction is posted. Commenter also supported our plan to post the ranking on the Nursing Home Compare Web site.

Response: We thank the commenter for this feedback and will take it into account as we develop the ranking that will be publicly posted. We agree with the commenter that we will need to be clear about what the ranking means when it is posted. We note that section 1888(h)(4)(B) of the Act directs that the ranking of SNF performance scores (not SNF rehospitalization rates) under the Program be ordered from low to high, and we intend to be as clear as possible about SNFs' placements on the ranking.

We will address this topic further in future rulemaking. We note that, because we will compute FY 2019 SNF performance scores after the completion of the performance period (finalized above as CY 2017), we will not publish the ranking or other SNF-specific performance information for the FY 2019 Program until at least the summer of CY 2018.

2. Skilled Nursing Facility (SNF) Quality Reporting Program (QRP)

a. Background and Statutory Authority

We seek to promote higher quality and more efficient health care for Medicare beneficiaries, and our efforts are furthered by QRPs coupled with public reporting of that information.

The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) added section 1899B to the Act that imposed new data reporting requirements for certain PAC providers, including SNFs, and required that the Secretary implement a SNF quality reporting program (SNF QRP). Section 1888(e)(6)(B)(i)(II) of the Act requires that each SNF submit, for FYs beginning on or after the specified application date (as defined in section 1899B(a)(2)(E) of the Act), data on quality measures specified under section 1899B(c)(1) of the Act and data on resource use and other measures specified under section 1899B(d)(1) of the Act in a manner and within the time frames specified by the Secretary. In addition, section 1888(e)(6)(B)(i)(III) of the Act requires, for FYs beginning on or after October 1, 2018, that each SNF submit standardized patient assessment data required under section 1899B(b)(1) of the Act in a manner and within the time frames specified by the Secretary. Section 1888(e)(6)(A)(i) of the Act requires that, for FYs beginning with FY 2018, if a SNF does not submit data, as applicable, on quality and resource use and other measures in accordance with section 1888(e)(6)(B)(i)(II) of the Act and on standardized patient assessment in accordance with section 1888(e)(6)(B)(i)(III) of the Act for such FY, the Secretary must reduce the

market basket percentage described in section 1888(e)(5)(B)(ii) of the Act by 2 percentage points. The SNF QRP applies to freestanding SNFs, SNFs affiliated with acute care facilities, and all non-CAH swing-bed rural hospitals.

We refer readers to the FY 2016 SNF PPS final rule (80 FR 46427 through 46429) for information on the requirements of the IMPACT Act

In the FY 2016 SNF PPS final rule, we finalized the general timeline and sequencing of activities under the SNF QRP. Please refer to the FY 2016 SNF PPS final rule (80 FR 46427 through 46429) for more information on these topics.

In addition, in implementing the SNF QRP and IMPACT Act requirements in the FY 2016 SNF PPS final rule, we established our approach for identifying cross-setting measures and processes for the adoption of measures including the application and purpose of the Measure Application Partnership (MAP) and the notice and comment rulemaking process. For more information on these topics, please refer to the FY 2016 SNF PPS final rule (80 FR 46427 through 46429).

b. General Considerations Used for Selection of Measures for the SNF QRP

We refer readers to the FY 2016 SNF PPS final rule (80 FR 46429 through 46431) for a detailed discussion of the considerations we apply in measure selection for the SNF QRP, such as alignment with the CMS Quality Strategy,[26] which incorporates the three broad aims of the National Quality Strategy.[27] Overall, we strive to promote high quality and efficiency in the delivery of health care to the beneficiaries we serve. Performance improvement leading to the highest quality health care requires continuous evaluation to identify and address performance gaps and reduce the unintended consequences that may arise in treating a large, vulnerable, and aging population. QRPs, coupled with public reporting of quality information, are critical to the advancement of health care quality improvement efforts. Valid, reliable, and relevant quality measures are fundamental to the effectiveness of our QRPs. Therefore, selection of quality measures is a priority for CMS in all of its QRPs.

In the FY 2017 SNF PPS proposed rule, we proposed to adopt for the SNF QRP one measure that we are specifying under section 1899B(c)(1)(C) of the Act to meet the Medication Reconciliation domain: (1) Drug Regimen Review Conducted with Follow-Up for Identified Issues—Post-Acute Care Skilled Nursing Facility Quality Reporting Program. Further, we proposed to adopt for the SNF QRP three measures to meet the resource use and other measure domains identified in section 1899B(d)(1) of the Act: (1) Medicare Spending per Beneficiary—Post-Acute Care Skilled Nursing Facility Quality Reporting Program; (2) Discharge to Community—Post Acute Care Skilled Nursing Facility Quality Reporting Program; and (3) Potentially Preventable 30-Day Post-Discharge Readmission Measure for Skilled Nursing Facility Quality Reporting Program.

In our development and specification of measures, we employ a transparent process in which we seek input from stakeholders and national experts and engage in a process that allows for pre-rulemaking input on each measure, as required by section 1890A of the Act.

To meet this requirement, we provided the following opportunities for stakeholder input. Our measure development contractor convened technical expert panels (TEPs) that included stakeholder experts and patient representatives on July 29, 2015 for the Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP, on August 25, 2015, September 25, 2015, and October 5, 2015 for the Discharge to Community—PAC SNF QRP, on August 12 and 13, 2015 and October 14, 2015 for the Potentially Preventable 30-Day Post-Discharge Readmission Measure for SNF QRP, and on October 29 and 30, 2015 for the Medicare Spending per Beneficiary measures. In addition, we released draft quality measure specifications for public comment on the Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP from September 18, 2015 to October 6, 2015, for the Discharge to Community—PAC SNF QRP from November 9, 2015 to December 8, 2015, for the Potentially Preventable 30-Day Post-Discharge Readmission Measure for SNF QRP from November 2, 2015 to December 1, 2015, and for the Medicare Spending per Beneficiary measures from January 13, 2016 to February 5, 2016. Further, we implemented a public mailbox, *PACQualityInitiative@cms.hhs.gov*, for the submission of public comments. This PAC mailbox is accessible on our post-acute care quality initiatives Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-of-2014-Data-Standardization-and-Cross-Setting-MeasuresMeasures.html*.

Additionally, we sought public input from the MAP PAC, Long-Term Care Workgroup during the annual in-person meeting held December 14 and 15, 2015. The final MAP report is available at *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC–LTC.aspx*. The MAP is composed of multi-stakeholder groups convened by the NQF, our current contractor under section 1890(a) of the Act, tasked to provide input on the selection of quality and efficiency measures described in section 1890(b)(7)(B) of the Act.

The MAP reviewed each measure that we proposed in the proposed rule for use in the SNF QRP. For more information on the MAP, we refer readers to the FY 2016 SNF PPS final rule (80 FR 46430 through 46431). Further, for more information on the MAP's recommendations, we refer readers to the MAP 2015–2016 Considerations for Implementing Measures in Federal Programs public report at *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC–LTC.aspx*.

We received a number of general comments on our measure selection process.

Comment: Many commenters supported the goals of the IMPACT Act, including the implementation of cross-setting measures across PAC settings. One of these commenters stated that the use of standardized and interoperable patient assessment data will allow for better cross-setting comparisons of quality and will support the development of better quality measures with uniform risk standardization. The commenter also recognized that the standardization of data collected across PAC settings is an ongoing process and will require continued refinement.

Response: We appreciate the commenters' support for the implementation of cross-setting measures across PAC settings as required by the IMPACT Act. We believe that standardizing patient assessment data will allow for the exchange of data among PAC providers in order to facilitate care coordination and improve patient outcomes.

Comment: Several commenters expressed concern with the compressed timeline in which CMS is adopting measures for the SNF QRP.

[26] *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html.*

[27] *http://www.ahrq.gov/workingforquality/nqs/nqs2011annlrpt.htm.*

Additionally, one commenter believes the ''hurried pace'' of the development process may lead to negative unintended consequences and may preclude stakeholder input. The commenter suggested that a less compressed comment period and implementation timeline provided would be less disruptive to measure development. Several commenters suggested that the measures be refined further prior to their implementation in the SNF QRP.

Response: We recognize the timeline and pace to implement the requirements of the IMPACT Act is ambitious. However, we have taken steps to ensure the scientific rigor of measure development, including testing measures under development and soliciting stakeholder feedback during both the measure development and rulemaking process. We have also worked to be responsive to stakeholder concerns about the length of various comment periods, and in response to those concerns, we have extended our public comment periods for measures under development on several occasions. We also encourage feedback through our IMPACT Act PAC Quality Initiative resource and feedback mailbox at *PACQualityInitiative@cms.hhs.gov* or at the SNF QRP resource and feedback mailbox at *SNFQualityQuestions@cms.hhs.gov*. We intend to continually monitor, refine, and update all measures if necessary to ensure that they do not result in unintended consequences. With regard to refining measures prior to their implementation, we interpret this to refer to further refinement of the measures prior to adoption. We understand and agree that measures should be developed prior to adoption and have engaged in several activities to ensure further refinement which are described in the specifc measure sections below.

Comment: One commenter expressed concern that SNFs will be held responsible for outcomes of care when other care coordination arrangements such as Accountable Care Organizations, Medicare bundled payments, and Medicaid managed care arrangements for dual eligibles are available. The commenter believes that overlapping care coordination initiatives and SNF QRP measures will cause confusion and diffuse accountability for the outcomes of care. One commenter suggested streamlining measures to reduce the redundancy of reporting. Another commenter was concerned that SNFs would be confused by the various measures, and thought that there would be unintended consequences as a result.

Response: Although we recognize that there might be some overlap along the lines suggested by the commenters, the SNF QRP is being designed to assess the quality care specific furnished by SNFs to Medicare beneficiaires. We believe that this information will be important for quality improvement purposes. We will continue to provide outreach and education to SNFs including trainings and National Provider Calls to help them understand the requirements and measures adopted for the SNF QRP. We also appreciate the concern that SNF QRP measures be aligned to minimize reporting requirements when possible. We will nonetheless seek, where feasible, to align the SNF QRP with existing reporting requirements.

Comment: We received several comments regarding NQF endorsement of the proposed measures. One commenter voiced support of the measures and encouraged submission of the measures for NQF endorsement. Several commenters expressed concern about the lack of NQF endorsement for measures and suggested additional measure testing and development. One commenter requested that CMS provide a timeline for submission of the measures to NQF. Additionally, commenters recommended NQF endorsement prior to public reporting.

Response: We recognize the importance of consensus endorsement and, where possible, seek to adopt measures for the SNF QRP that are endorsed by the NQF. To the extent that we adopt measures under our exception authority, we intend to seek NQF-endorsement of those measures and will do so as soon as is feasible. Regardless of whether the measures are or are not NQF-endorsed at the time we adopt them, they have all been tested for reliability and validity, and we believe that the results of that testing support our conclusion that they are sufficiently reliable and valid to warrant their adoption in the SNF QRP. The results of our reliability and validity testing for these measures may be found in Measure Specifications for Measures Adopted in the FY 2017 SNF QRP Final Rule, posted on the CMS SNF QRP Web page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html*.

Comment: Several commenters stated that the NQF MAP committee did not support the proposed measures; instead, they recommended that we delay measure implementation until the measures are fully developed and tested and brought back to the MAP for further consideration. One commenter suggested that TEP members and other stakeholders who provided feedback in the measure development process did not support the measures moving forward without further testing.

Response: We interpret this comment to address the activities of the Measures Application Partnership, a multi-stakeholder partnership convened by NQF that provides input to the U.S. Department of Health and Human Services (HHS) on its selection of measures for certain Medicare programs. We would like to clarify that the MAP provided the recommendation of ''encourage continued development'' for the proposed measures. According to the MAP, the term ''encourage continued development,'' is applied when a measure addresses a critical program objective or promotes alignment but is in an earlier stage of development. In contrast, the MAP uses the phrase ''do not support'' when it does not support a measure at all.

Since the MAP recommendation of ''encourage continued development'' for the proposed measures during the December 2015 NQF-convened PAC LTC MAP meeting, we have further refined the measure specifications based on additional validity and reliability testing. Our efforts included: A pilot test in 12 post-acute care settings, including SNFs, to determine the feasibility of assessment items for use in calculation of the Drug Regimen Review Conducted with Follow-Up for Identified Issues measure and further development of risk-adjusted models for the Discharge to Community, Medicare Spending per Beneficiary and Potentially Preventable Readmissions measures. Additional information regarding testing that was performed since the MAP Meeting, TEP meetings, and public comment periods is further described below in our responses to comments on individual proposed measures.

For these reasons, we believe that the measures have been fully and robustly developed, and believe they are appropriate for implementation and should not be delayed.

Comment: One commenter expressed concern about a lack of consistency and comparability of measures across PAC settings and believed it inappropriate to compare performance across provider types due to the lack of appropriate risk adjustment. We also received comments from MedPAC conveying that findings from their work on a unified PAC payment system suggest overlap in where Medicare beneficiaries are treated for similar care in PAC settings. As a result of this work, MedPAC

recommended that the IMPACT Act measures use a uniform definition, specification, and risk adjustment method to facilitate quality comparison across PAC settings to inform Medicare beneficiary choice, and so that Medicare can evaluate the value of services it pays for. MedPAC further noted that differences in rates should reflect differences in quality of care rather than differences in the way rates are constructed.

Response: For each of the proposed measures, we applied consistent models where feasible in order to develop their definitions, other technical specifications and approach to risk-adjustment.

However, there are nuances among the four PAC provider types which must be taken into account in order to address issues such as patient acuity and medical complexity. As a result, we have risk-adjusted measures and included provider-specific refinements. For example, for the Discharge to Community measure, risk adjustment for ventilator use is included in LTCH and SNF settings, but not IRF settings. We investigated the need for risk adjustment for ventilator use in IRFs, but found that less than 0.01 percent of the IRF population had ventilator use in the IRF. Given the low frequency of ventilator use in IRFs, any associated estimates would not be reliable; thus, ventilator use is not included as a risk adjuster in the IRF setting measure. We believe that the measures proposed for the SNF QRP will inform beneficiaries on the differences in quality rather than differences in measure construction because we have taken into account the factors necessary to ensure meaningful comparability within the SNF providers and as able, across the post-acute providers.

Comment: A number of commenters expressed concerns regarding the validity and reliability of IMPACT Act measures and encouraged us to analyze data to ensure comparability across post-acute care settings, prior to implementation.

Response: We have tested for validity and reliability all of the IMPACT Act measures, and the results of that testing is available in Measure Specifications for Measures Adopted in the FY 2017 SNF QRP Final Rule, posted on the CMS SNF QRP Web page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html.*

We intend to continue to monitor the reliability and validity of the SNF QRP measures, including whether the measures are reliable and valid for cross-setting purposes.

Comment: One commenter expressed concern that the proposed measures could adversely affect low-volume or rural SNFs. Another commenter expressed concerns about the ability to compare measure rates across facilities due to varying patient volumes, recommending the use of patient days as the denominator for SNF quality measures.

Response: We do not believe the proposed measures will adversely affect low-volume or rural SNFs. We wish to clarify that our measures and/or our proposals to implement these measures were designed to mitigate any potential impact that may be caused by low volume. For example, the statistical approach used for two of the claims-based measures incorporates a shrinkage estimator intended to ensure that smaller facilities are not vulnerable to rates driven by the influence of random variation in their raw rates. Additionally, for some of the measures, public reporting requirements exclude reporting of facilities with fewer than 25 resident stays during the reporting period. We would like to clarify that the quality, resource use and other measures in the SNF QRP are based on stay-level outcomes, not day-level outcomes. The measures examine events occurring at SNF discharge or after SNF discharge; therefore, the measures are based on number of discharges. For example, the proposed quality measure Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP would not be appropriate for data calculation on a daily basis. The data collected for this measure is at admission and discharge and reflects data recorded throughout the entire patient stay.

Comment: One commenter expressed concern that the proposed measures will incentivize SNFs to avoid admitting medically complex residents, which would result in unintended consequences.

Response: To mitigate the risk of creating incentives for SNFs to avoid admitting medically complex residents, who may be at higher risk for poor outcomes and higher costs, we have included factors related to medical complexity in the risk adjustment methodology used in our measures. We also intend to conduct ongoing monitoring to assess for potential unintended consequences associated with the implementation of these measures.

c. Policy for Retaining SNF QRP Measures Adopted for Future Payment Determinations

In the FY 2016 SNF PPS final rule (80 FR 46431 through 46432), we finalized our policy for measure removal and also finalized that when we adopt a measure for the SNF QRP for a payment determination, this measure will be automatically retained in the SNF QRP for all subsequent payment determinations unless we propose to remove, suspend, or replace the measure. We did not propose any new policies related to measure retention or removal in the FY 2017 SNF PPS proposed rule. For further information on how measures are considered for removal, suspension, or replacement, please refer to the FY 2016 SNF PPS final rule (80 FR 46431 through 46432).

d. Process for Adoption of Changes to SNF QRP Measures

In the FY 2016 SNF PPS final rule (80 FR 46432), we finalized our policy pertaining to the process for adoption of non-substantive and substantive changes to SNF QRP measures. We did not propose to make any changes to this policy.

e. Quality Measures Previously Finalized for Use in the SNF QRP

The SNF QRP quality measures for the FY 2018 payment determinations and subsequent years are presented in Table 11. Measure specifications for the previously adopted measures adapted from non-SNF settings are available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html* under the downloads section at the bottom of the page.

TABLE 11—QUALITY MEASURES PREVIOUSLY FINALIZED FOR USE IN THE SNF QRP

Measure title and NQF #	SNF PPS final rule	Data collection start date	Annual payment determination: Initial and subsequent APU years
Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678).	Adopted in the FY 2016 SNF PPS Final Rule (80 FR 46433 through 46440).	October 1, 2016	FY 2018 and subsequent years.
Application of the NQF-endorsed Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674).	Adopted in the FY 2016 SNF PPS Final Rule (80 FR 46440 through 46444).	October 1, 2016	FY 2018 and subsequent years.
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).	Adopted in the FY 2016 SNF PPS Final Rule (80 FR 46444 through 46453).	October 1, 2016	FY 2018 and subsequent years.

f. SNF QRP Quality, Resource Use and Other Measures for FY 2018 Payment Determinations and Subsequent Years

For the FY 2018 payment determination and subsequent years, in addition to the quality measures identified in Table 11 that we are retaining under our policy described in section V.B.3., we proposed to adopt three new measures for the SNF QRP. These three measures were developed to meet the requirements of the IMPACT Act. They are: (1) Medicare Spending per Beneficiary—PAC SNF QRP; (2) Discharge to Community—PAC SNF QRP; and (3) Potentially Preventable 30-Day Post-Discharge Readmission Measure for SNF QRP. Through the use of standardized quality measures and standardized data, the intent of the Act, among other obligations, is to enable interoperability and access to longitudinal information for such providers to facilitate coordinated care, improved outcomes, and overall quality comparisons. The measures are described in more detail below.

For the risk adjustment of the resource use and other measures, we understand the important role that sociodemographic status plays in the care of patients. However, we continue to have concerns about holding providers to different standards for the outcomes of their patients of diverse sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on providers' results on our measures.

The NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. For 2-years, NQF will conduct a trial of temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are expected to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

We invited public comment on how socioeconomic and demographic factors should be used in risk adjustment for the resource use and other measures. The comments we received on this topic, with their responses, appear below.

Comment: Several commenters supported the inclusion of sociodemographic status adjustment in quality measures, resource use, and other measures. Commenters suggested that failure to account for these patient characteristics could penalize SNFs for providing care to a more medically-complex and socioeconomically disadvantaged patient population and affect provider performance. Some commenters expressed concerns about standardization and interoperability of the measures as it pertains to risk-adjusting, particularly for SDS characteristics. Many commenters recommended incorporating socioeconomic factors as risk-adjustors for the measures and several commenters suggested conducting additional testing and/or NQF endorsement prior to implementation of these measures. In addition, many commenters recommended including functionality as an additional risk-adjustment factor, and several commenters suggested risk-adjustment for cognitive impairment. One commenter recommended varied standards for patient outcomes with individuals of diverse SDS statuses.

A few commenters, including MedPAC, did not support risk-adjustment of measures by SES or SDS status. One commenter did not support risk-adjustment because it can hide disparities and create different standards of care for SNFs based on the demographics in the facility. MedPAC stated that risk adjustment can hide disparities in care and suggested that risk-adjustment reduces pressure on providers to improve quality of care for low-income Medicare beneficiaries. Instead, MedPAC supported peer provider group comparisons with providers of similar low-income beneficiary populations. Another commenter stated that SDS factors should not be included in measures that assess the resident outcome during a SNF stay, but should only be considered for measures evaluating care after the SNF discharge.

Response: We appreciate the considerations and suggestions conveyed in relation to the measures and the importance in balancing appropriate risk adjustment along with ensuring access to high quality care. We note that in the measures that are risk adjusted we do take into account characteristics associated with medical complexity, as well as factors such as age where appropriate to do so. For those cross-setting post-acute measures such as those intended to satisfy the IMPACT Act domains that use the

patient assessment-based data elements for risk adjustment, we have either made such items standardized, or intend to do so as feasible. With regard to the incorporation of additional factors, such as cognitive impairment and function, we have and will continue to take such factors into account, which would include further testing as part of our ongoing measure development monitoring activities. As discussed previously, we intend to seek NQF endorsement for our measures.

We also received suggestions pertaining to the incorporation of socioeconomic factors as risk-adjustors for the measures, including in those measures that pertain to after the resident was discharged from the SNF, additional testing and/or NQF endorsement prior to implementation of these measures, and comments that pertain to potential consequences associated with such risk adjustors and alternative approaches to grouping comparative data. We wish to reiterate that as previously discussed, NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. This trial entails temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are encouraged to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model. Several measures developed by CMS have been brought to NQF since the beginning of the trial. CMS, in compliance with NQF's guidance, has tested sociodemographic factors in the measures' risk models and made recommendations about whether or not to include these factors in the endorsed measure. We intend to continue engaging in the NQF process as we consider the appropriateness of adjusting for sociodemographic factors in our outcome measures.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

i. Measure That Addresses the IMPACT Act Domain of Resource Use and Other Measures: Total Estimated MSPB–PAC SNF QRP

We proposed an MSPB–PAC SNF QRP measure for inclusion in the SNF QRP for the FY 2018 payment determination and subsequent years. Section 1899B(d)(1)(A) of the Act requires the Secretary to specify resource use measures, including total estimated Medicare spending per beneficiary, on which PAC providers consisting of SNFs, Inpatient Rehabilitation Facilities (IRFs), Long-Term Care Hospitals (LTCHs), and Home Health Agencies (HHAs) are required to submit necessary data specified by the Secretary.

Rising Medicare expenditures for post-acute care as well as wide variation in spending for these services underlines the importance of measuring resource use for providers rendering these services. Between 2001 and 2013, Medicare PAC spending grew at an annual rate of 6.1 percent and doubled to $59.4 billion, while payments to inpatient hospitals grew at an annual rate of 1.7 percent over this same period.[28] A study commissioned by the Institute of Medicine found that variation in PAC spending explains 73 percent of variation in total Medicare spending across the United States.[29]

We reviewed the NQF's consensus-endorsed measures and were unable to identify any NQF-endorsed resource use measures for PAC settings. As such, we proposed this MSPB–PAC SNF QRP measure under the Secretary's authority to specify non—NQF-endorsed measures under section 1899B(e)(2)(B) of the Act. Given the current lack of resource use measures for PAC settings, our MSPB–PAC SNF QRP measure would provide valuable information to SNF providers on their relative Medicare spending in delivering services to approximately 1.7 million Medicare beneficiaries.[30]

The MSPB–PAC SNF QRP episode-based measure would provide actionable and transparent information to support SNF providers' efforts to promote care coordination and deliver high quality care at a lower cost to Medicare. The MSPB–PAC SNF QRP measure holds SNF providers accountable for the Medicare payments within an ''episode of care'' (episode), which includes the period during which a patient is directly under the SNF's care, as well as a defined period after the end of the SNF treatment, which may be reflective of and influenced by the services furnished by the SNF. MSPB–PAC SNF QRP episodes, constructed according to the methodology described below, have high levels of Medicare spending with substantial variation. In FY 2014, Medicare FFS beneficiaries experienced 1,534,773 MSPB–PAC SNF QRP episodes. The mean payment-standardized, risk-adjusted episode spending for these episodes is $26,279. There is substantial variation in the Medicare payments for these MSPB–PAC SNF QRP episodes—ranging from approximately $6,090 at the 5th percentile to approximately $60,050 at the 95th percentile. This variation is partially driven by variation in payments occurring after SNF treatment.

Evaluating Medicare payments during an episode creates a continuum of accountability between providers that should improve post-treatment care planning and coordination. While some stakeholders throughout the measure development process supported the MSPB–PAC measures and felt that measuring Medicare spending was critical for improving efficiency, others believed that resource use measures did not reflect quality of care in that they do not take into account patient outcomes or experience beyond those observable in claims data. However, SNFs involved in the provision of high-quality PAC care as well as appropriate discharge planning and post-discharge care coordination would be expected to perform well on this measure since beneficiaries would likely experience fewer costly adverse events (for example, avoidable hospitalizations, infections, and emergency room usage). Further, it is important that the cost of care be explicitly measured so that, in conjunction with other quality measures, we can publicly report which SNFs provide high quality care at lower cost.

We developed a MSPB–PAC measure for each of the four PAC settings. We proposed an LTCH-specific MSPB–PAC measure in the FY 2017 IPPS/LTCH proposed rule (81 FR 25216 through 25220), an IRF-specific MSBP–PAC measure in the FY 2017 IRF proposed rule (81 FR 24197 through 24201), a SNF-specific MSPB–PAC measure in the FY 2017 SNF proposed rule (81 FR 24258 through 24262), and a HHA-specific MSBP–PAC measure in the CY

[28] MedPAC, ''A Data Book: Health Care Spending and the Medicare Program,'' (2015). 114.

[29] Institute of Medicine, ''Variation in Health Care Spending: Target Decision Making, Not Geography,'' (Washington, DC: National Academies 2013). 2.

[30] 2013 figures. MedPAC, ''Medicare Payment Policy,'' Report to the Congress (2015). xvii-xviii.

2017 HH proposed rule (81 FR 43760 through 43764). The four setting-specific MSPB–PAC measures are closely aligned in terms of episode construction and measure calculation. Each MSPB–PAC measure assesses Medicare Part A and Part B spending within an episode, and the numerator and denominator are defined similarly. However, setting-specific measures allow us to account for differences between settings in payment policy, the types of data available, and the underlying health characteristics of beneficiaries.

The MSPB–PAC measures mirror the general construction of the inpatient prospective payment system (IPPS) hospital MSPB measure, which was adopted for the Hospital IQR Program beginning with the FY 2014 program, and was implemented in the Hospital VBP Program beginning with the FY 2015 program. The measure was endorsed by the NQF on December 6, 2013 (NQF #2158).[31] The hospital MSPB measure evaluates hospitals' Medicare spending relative to the Medicare spending for the national median hospital during a hospital MSPB episode. It assesses Medicare Part A and Part B payments for services performed by hospitals and other healthcare providers within a hospital MSPB episode, which is comprised of the periods immediately prior to, during, and following a patient's hospital stay.[32] [33] Similarly, the MSPB–PAC measures assess all Medicare Part A and Part B payments for fee-for-service (FFS) claims with a start date during the episode window (which, as discussed in this section, is the time period during which Medicare FFS Part A and Part B services are counted towards the MSPB–PAC SNF QRP episode). There are differences between the MSPB–PAC measures and the hospital MSPB measure to reflect differences in payment policies and the nature of care provided in each PAC setting. For example, the MSPB–PAC measures exclude a limited set of services (for example, for clinically unrelated services) provided to a beneficiary during the episode window, while the hospital MSPB measure does not exclude any services.

MSPB–PAC episodes may begin within 30 days of discharge from an inpatient hospital as part of a patient's trajectory from an acute to a PAC setting. A SNF stay beginning within 30 days of discharge from an inpatient hospital would therefore be included once in the hospital's MSPB measure, and once in the SNF provider's MSPB–PAC measure. Aligning the hospital MSPB and MSPB–PAC measures in this way creates continuous accountability and aligns incentives to improve care planning and coordination across inpatient and PAC settings.

We sought and considered the input of stakeholders throughout the measure development process for the MSPB–PAC measures. We convened a TEP consisting of 12 panelists with combined expertise in all of the PAC settings on October 29 and 30, 2015 in Baltimore, Maryland. A follow-up email survey was sent to TEP members on November 18, 2015 to which seven responses were received by December 8, 2015. The MSPB–PAC TEP Summary Report is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Technical-Expert-Panel-on-Medicare-Spending-Per-Beneficiary.pdf*. The measures were also presented to the MAP Post-Acute Care/Long-Term Care (PAC/LTC) Workgroup on December 15, 2015. As the MSPB–PAC measures were under development, there were three voting options for members: Encourage continued development, do not encourage further consideration, and insufficient information.[34] The MAP PAC/LTC workgroup voted to ''encourage continued development'' for each of the MSPB–PAC measures.[35] The MAP PAC/LTC workgroup's vote of ''encourage continued development'' was affirmed by the MAP Coordinating Committee on January 26, 2016.[36] The MAP's concerns about the MSPB–PAC measures, as outlined in their final report ''MAP 2016 Considerations for Implementing Measures in Federal Programs: Post-Acute Care and Long-Term Care'' and Spreadsheet of Final Recommendations, were taken into consideration during the measure development process and are discussed as part of our responses to public comments, described below.[37] [38]

Since the MAP's review and recommendation of continued development, CMS continued to refine risk adjustment models and conduct measure testing for the IMPACT Act measures consistent with the MAP's recommendations. The IMPACT Act measures are consistent with the information submitted to the MAP and support the scientific acceptability of these measures for use in quality reporting programs.

In addition, a public comment period, accompanied by draft measures specifications, was open from January 13 to 27, 2016 and extended to February 5. A total of 45 comments on the MSPB–PAC measures were received during this 3.5 week period. The comments received also covered each of the MAP's concerns as outlined in their Final Recommendations.[39] The MSPB–PAC Public Comment Summary Report is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/2016_03_24_mspb_pac_public_comment_summary_report.pdf* and the MSPB–PAC Public Comment Supplementary Materials are available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/2016_03_24_mspb_pac_public_comment_summary_report_supplementary_materials.pdf*: These documents contain the public comments, along with our responses including statistical analyses. The MSPB–PAC SNF QRP measure, along with the other MSPB–PAC measures, as applicable, will be submitted for NQF endorsement when feasible.

To calculate the MSPB–PAC SNF QRP measure for each SNF provider, we first

[31] QualityNet, ''Measure Methodology Reports: Medicare Spending per Beneficiary (MSPB) Measure,'' (2015). *http://www.qualitynet.org/dcs/ContentServer?pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772053996.*

[32] QualityNet, ''Measure Methodology Reports: Medicare Spending per Beneficiary (MSPB) Measure,'' (2015). *http://www.qualitynet.org/dcs/ContentServer?pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772053996.*

[33] FY 2012 IPPS/LTCH PPS Final Rule (76 FR 51619).

[34] National Quality Forum, Measure Applications Partnership, ''Process and Approach for MAP Pre-Rulemaking Deliberations, 2015–2016'' (February 2016) *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81693.*

[35] National Quality Forum, Measure Applications Partnership Post-Acute Care/Long-Term Care Workgroup, ''Meeting Transcript—Day 2 of 2'' (December 15, 2015) 104–106 *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81470.*

[36] National Quality Forum, Measure Applications Partnership, ''Meeting Transcript—Day 1 of 2'' (January 26, 2016) 231–232 *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81637.*

[37] National Quality Forum, Measure Applications Partnership, ''MAP 2016 Considerations for Implementing Measures in Federal Programs: Post-Acute Care and Long-Term Care'' Final Report, (February 2016) *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx.*

[38] National Quality Forum, Measure Applications Partnership, ''Spreadsheet of MAP 2016 Final Recommendations'' (February 1, 2016) *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593.*

[39] National Quality Forum, Measure Applications Partnership, ''Spreadsheet of MAP 2016 Final Recommendations'' (February 1, 2016) *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593.*

define the construction of the MSPB–PAC SNF QRP episode, including the length of the episode window as well as the services included in the episode. Next, we apply the methodology for the measure calculation. The specifications are discussed further in this section. More detailed specifications for the MSPB–PAC measures, including the MSPB–PAC SNF QRP measure, are available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html*.

The comments we received on this topic, with their responses, appear below.

Comment: Several commenters expressed concern about the lack of NQF endorsement for proposed measures; some believed that the measure should not be finalized until NQF endorsement is obtained.

Response: We thank the commenters for their concern regarding the lack of NQF endorsement and refer readers to section III.D.2.b. where we also discuss this topic.

Comment: Several commenters noted the NQF MAP committee did not endorse the proposed measure, believing that the measure should not be finalized until the support of the MAP is obtained.

Response: We appreciate the comments about the NQF MAP committee, and direct readers to section III.D.2.b. where we also discuss this topic.

Comment: Some commenters recommended the use of uniform single MSPB–PAC measure that could be used to compare providers' resource use across settings, but they also recognized that we do not have a uniform PPS for all the PAC settings currently. In the absence of a single PAC PPS, they recommend a single MSPB–PAC measure for each setting that could be used to compare providers within a setting. Under a single measure, the episode definitions, service inclusions/exclusions, and risk adjustment methods would be the same across all PAC settings.

Response: We thank the commenters. The four separate MSPB–PAC measures reflect the unique characteristics of each PAC setting and the population it serves. The four setting specific MSPB–PAC measures are defined as consistently as possible across settings given the differences in the payment systems for each setting, and types of patients served in each setting. We have taken into consideration these differences and aligned the specifications, such as episode definitions, service inclusions/exclusions and risk adjustment methods for each setting, to the extent possible while ensuring the accuracy of the measures in each PAC setting.

Each of the measures assess Medicare Part A and Part B spending during the episode window which begins upon admission to the provider's care and ends 30 days after the end of the treatment period. The service-level exclusions are harmonized across settings. The definition of the numerator and denominator is the same across settings. However, specifications differ between settings when necessary to ensure that the measures accurately reflect patient care and align with each setting's payment system. For example, Medicare pays LTCHs and IRFs a stay-level payment based on the assigned MS–LTC–DRG and CMG, respectively, while SNFs are paid a daily rate based on the RUG level, and HHA providers are reimbursed based on a fixed 60-day period for standard home health claims. While the definition of the episode window is consistent across settings and is based on the period of time that a beneficiary is under a given provider's care, the duration of the treatment period varies to reflect how providers are reimbursed under the PPS that applies to each setting. The length of the post-treatment period is consistent between settings. There are also differences in the services covered under the PPS that applies to each setting: For example, durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) claims are covered LTCH, IRF, and SNF services but are not covered HHA services. This affects the way certain first-day service exclusions are defined for each measure.

We recognize that beneficiaries may receive similar services as part of their overall treatment plan in different PAC settings, but believe that there are some important differences in beneficiaries' care profiles that are difficult to capture in a single measure that compares resource use across settings.

Also, the risk adjustment models for the MSPB–PAC measures share the same covariates to the greatest extent possible to account for patient case mix. However, the measures also incorporate additional setting-specific information where available to increase the predictive power of the risk adjustment models. For example, the MSPB–PAC LTCH QRP risk adjustment model uses MS–LTC–DRGs and Major Diagnostic Categories (MDCs) and the MSPB–PAC IRF QRP model includes Rehabilitation Impairment Categories (RICs). The HH and SNF settings do not have analogous variables that directly reflect a patient's clinical profile.

We will continue to work towards a more uniform measure across settings as we gain experience with these measures, and we plan to conduct further research and analyses about comparability of resource use measures across settings for clinically similar patients, different treatment periods and windows, risk adjustment, service exclusions, and other factors.

Comment: A few commenters noted that the MSPB–PAC measures are resource use measures that are not a standalone indicator of quality.

Response: We appreciate the comment regarding the proposed MSPB–PAC measures as resource use measures. The MSPB–PAC SNF QRP measure is one of four QRP measures that were proposed in the FY 2017 SNF PPS proposed rule for inclusion in the SNF QRP: In addition to the MSPB–PAC SNF QRP measure, these proposed measures were the Discharge to Community—PAC SNF QRP measure (81 FR 24262 through 24264), the Potentially Preventable 30-Day Post-Discharge Readmission Measure for SNF QRP (81 FR 24264 through 24267), and the Drug Regimen Review Conducted With Follow-Up for Identified Issues—PAC SNF QRP measure (81 FR 24267 through 24269). As part of the SNF QRP, the MSPB–PAC SNF QRP measure will be paired with quality measures; we direct readers to section III.D.2.e. for a discussion of quality measures previously finalized for use in the SNF QRP. We believe it is important that the cost of care be explicitly measured so that, in conjunction with other quality measures, we can publicly report which SNF providers are involved in the provision of high quality care at lower cost.

Comment: One commenter expressed concern over the short timeframe available for stakeholder input.

Response: We appreciate the feedback regarding the timing issues related to IMPACT Act implementation. It is our intent to move forward with IMPACT Act implementation in a manner in which the measure development process continues to be transparent, and includes input and collaboration from experts, the PAC provider community, and the public at large. It is of the utmost importance to us to continue to engage stakeholders, including providers as well as residents and their families, throughout the measure development lifecycle through their participation in our measure development public comment periods,

the pre-rulemaking process, TEPs convened by our measure development contractors, open door forums and other opportunities. We have provided multiple opportunities for stakeholder input on the MSPB–PAC measures, including the TEP, NQF MAP public comment period and in-person meeting, pre-rulemaking public comment period, and 60-day public comment period on the proposed SNF QRP rule. A summary of TEP proceedings, the MSPB–PAC Public Comment Summary Report and MSPB–PAC Public Comment Supplementary Materials are available at the links provided above. We thank all stakeholders for their thoughtful feedback on and engagement with the measure development and rulemaking process.

(a) Episode Construction

An MSPB–PAC SNF QRP episode begins at the episode trigger, which is defined as the patient's admission to a SNF. The admitting facility is the attributed provider, for whom the MSPB–PAC SNF QRP measure is calculated. The episode window is the time period during which Medicare FFS Part A and Part B services are counted towards the MSPB–PAC SNF QRP episode. Because Medicare FFS claims are already reported to the Medicare program for payment purposes, SNF providers would not be required to report any additional data to CMS for calculation of this measure. Thus, there would be no additional data collection burden from the implementation of this measure.

The episode window is comprised of a treatment period and an associated services period. The treatment period begins at the trigger (that is, on the day of admission to the SNF) and ends on the day of discharge from that SNF. Readmissions to the same facility occurring within 7 or fewer days do not trigger a new episode, and instead are included in the treatment period of the original episode. When two sequential stays at the same SNF occur within 7 or fewer days of one another, the treatment period ends on the day of discharge for the latest SNF stay. The treatment period includes those services that are provided directly or reasonably managed by the SNF provider that are directly related to the beneficiary's care plan. The associated services period is the time during which Medicare Part A and Part B services (with certain exclusions) are counted towards the episode. The associated services period begins at the episode trigger and ends 30 days after the end of the treatment period. The distinction between the treatment period and the associated services period is important because clinical exclusions of services may differ for each period. Certain services are excluded from the MSPB–PAC SNF QRP episodes because they are clinically unrelated to SNF care, and/or because SNF providers may have limited influence over certain Medicare services delivered by other providers during the episode window. These limited service-level exclusions are not counted towards a given SNF provider's Medicare spending to ensure that beneficiaries with certain conditions and complex care needs receive the necessary care. Certain services that are determined to be outside of the control of a SNF provider include planned hospital admissions, management of certain preexisting chronic conditions (for example, dialysis for end-stage renal disease (ESRD), and enzyme treatments for genetic conditions), treatment for preexisting cancers, organ transplants, and preventive screenings (for example, colonoscopy and mammograms). Exclusion of such services from the MSPB–PAC SNF QRP episode ensures that facilities do not have disincentives to treat patients with certain conditions or complex care needs.

An MSPB–PAC episode may begin during the associated services period of an MSPB–PAC SNF QRP episode in the 30 days post-treatment. One possible scenario occurs where a SNF provider discharges a beneficiary who is then admitted to an IRF within 30 days. The IRF claim would be included once as an associated service for the attributed provider of the first MSPB–PAC SNF QRP episode and once as a treatment service for the attributed provider of the second MSPB–PAC IRF QRP episode. As in the case of overlap between hospital and PAC episodes discussed earlier, this overlap is necessary to ensure continuous accountability between providers throughout a beneficiary's trajectory of care, as both providers share incentives to deliver high quality care at a lower cost to Medicare. Even within the SNF setting, one MSPB–PAC SNF QRP episode may begin in the associated services period of another MSPB–PAC SNF QRP episode in the 30 days post-treatment. The second SNF claim would be included once as an associated service for the attributed SNF provider of the first MSPB–PAC SNF QRP episode and once as a treatment service for the attributed SNF provider of the second MSPB–PAC SNF QRP episode. Again, this ensures that SNF providers have the same incentives throughout both MSPB–PAC SNF QRP episodes to deliver quality care and engage in patient-focused care planning and coordination. If the second MSPB–PAC SNF QRP episode were excluded from the second SNF provider's MSPB–PAC SNF QRP measure, that provider would not share the same incentives as the first SNF provider of first MSPB–PAC SNF QRP episode. The MSPB–PAC SNF QRP measure was designed to benchmark the resource use of each attributed provider against what its spending is expected to be as predicted through risk adjustment. As discussed further in this section, the measure takes the ratio of observed spending to expected spending for each episode and then takes the average of those ratios across all of the attributed provider's episodes. The measure is not a simple sum of all costs across a provider's episodes, thus mitigating concerns about double counting.

The comments we received on this topic, with their responses, appear below.

Comment: One commenter expressed concern about how claims are counted and attributed to providers.

Response: We appreciate the commenter's concern, but note that there were no further specifics detailing the nature of this concern. We designed the attribution process to hold SNF providers accountable for the Medicare payments within an ''episode of care'' (episode), which includes the period during which a patient is directly under the SNF's care, as well as a defined period after the end of the SNF treatment. An MSPB–PAC SNF QRP episode begins at the episode trigger, which is defined as the patient's admission to a SNF. The admitting facility is the attributed provider, for whom the MSPB–PAC SNF QRP measure is calculated. The episode window is the time period during which Medicare FFS Part A and Part B services are counted towards the MSPB–PAC SNF QRP episode. The standardized allowed amounts on the claims for those services are summed to calculate observed episode spending. Further details on episode construction and attribution, as they relate to how claims are counted are in the MSPB–PAC Measure Specifications, a link for which has been provided above.

(b) Measure Calculation

Medicare payments for Part A and Part B claims for services included in MSPB–PAC SNF QRP episodes, defined according to the methodology above, are used to calculate the MSPB–PAC SNF QRP measure. Measure calculation involves determination of the episode exclusions, the approach for standardizing payments for geographic payment differences, the methodology

for risk adjustment of episode spending to account for differences in patient case mix, and the specifications for the measure numerator and denominator.

(i) Exclusion Criteria

In addition to service-level exclusions that remove some payments from individual episodes, we exclude certain episodes in their entirety from the MSPB–PAC SNF QRP measure to ensure that the MSPB–PAC SNF QRP measure accurately reflects resource use and facilitates fair and meaningful comparisons between SNF providers. The episode-level exclusions are as follows:

- Any episode that is triggered by a SNF claim outside the 50 states, DC, Puerto Rico, and U.S. Territories.
- Any episode where the claim(s) constituting the attributed SNF provider's treatment have a standard allowed amount of zero or where the standard allowed amount cannot be calculated.
- Any episode in which a beneficiary is not enrolled in Medicare FFS for the entirety of a 90-day lookback period (that is, a 90-day period prior to the episode trigger) plus episode window (including where the beneficiary dies), or is enrolled in Part C for any part of the lookback period plus episode window.
- Any episode in which a beneficiary has a primary payer other than Medicare for any part of the 90-day lookback period plus episode window.
- Any episode where the claim(s) constituting the attributed SNF provider's treatment include at least one related condition code indicating that it is not a prospective payment system bill.

The comments we received on this topic, with their responses, appear below.

Comment: One commenter expressed general support for the list of episode-level exclusions proposed for the MSPB–PAC SNF QRP measure.

Response: We thank the commenter for its support.

(ii) Standardization and Risk Adjustment

Section 1899B(d)(2)(C) of the Act requires that the MSPB–PAC measures are adjusted for the factors described under section 1886(o)(2)(B)(ii) of the Act, which include adjustment for factors such as age, sex, race, severity of illness, and other factors that the Secretary determines appropriate. Medicare payments included in the MSPB–PAC SNF QRP measure are payment standardized and risk-adjusted. Payment standardization removes sources of payment variation not directly related to clinical decisions and facilitates comparisons of resource use across geographic areas. We proposed to use the same payment standardization methodology that was used in the NQF-endorsed hospital MSPB measure. This methodology removes geographic payment differences, such as wage index and geographic practice cost index (GPCI), incentive payment adjustments, and other add-on payments that support broader Medicare program goals including indirect graduate medical education (IME) and hospitals serving a disproportionate share of uninsured patients (DSH).[40]

Risk adjustment uses patient claims history to account for case-mix variation and other factors that affect resource use but are beyond the influence of the attributed SNF provider. To assist with risk adjustment, we create mutually exclusive and exhaustive clinical case mix categories using the most recent institutional claim in the 60 days prior to the start of the MSPB–PAC SNF QRP episode. The beneficiaries in these clinical case mix categories have a greater degree of clinical similarity than the overall SNF patient population, and allow us to more accurately estimate Medicare spending. Our MSPB–PAC SNF QRP measure, adapted for the SNF setting from the NQF-endorsed hospital MSPB measure uses a regression framework with a 90-day hierarchical condition category (HCC) lookback period and covariates including the clinical case mix categories, HCC indicators, age brackets, indicators for originally disabled, ESRD enrollment, and long-term care status, and selected interactions of these covariates where sample size and predictive ability make them appropriate. We sought and considered public comment regarding the treatment of hospice services occurring within the MSPB–PAC SNF QRP episode window. Given the comments received, we proposed to include the Medicare spending for hospice services but risk adjust for them, such that MSPB–PAC SNF QRP episodes with hospice services are compared to a benchmark reflecting other MSPB–PAC SNF QRP episodes with hospice services. We believe this strikes a balance between the measure's intent of evaluating Medicare spending and ensuring that providers do not have incentives against the appropriate use of hospice services in a patient-centered continuum of care.

We understand the important role that sociodemographic factors, beyond age, play in the care of patients. However, we continue to have concerns about holding providers to different standards for the outcomes of their patients of diverse sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We will monitor the impact of sociodemographic status on providers' results on our measures.

The NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. For 2 years, NQF will conduct a trial of temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are expected to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as required by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

While we conducted analyses on the impact of age by sex on the performance of the MSPB–PAC SNF QRP risk-adjustment model, we did not propose to adjust the MSPB–PAC SNF QRP measure for socioeconomic factors. As this MSPB–PAC SNF QRP measure would be submitted for NQF endorsement, we prefer to await the results of this trial and study before deciding whether to risk adjust for socioeconomic factors. We will monitor the results of the trial, studies, and recommendations. We invited public comment on how socioeconomic and demographic factors should be used in risk adjustment for the MSPB–PAC SNF QRP measure. The comments we received on this topic, with their responses, appear below.

[40] QualityNet, ''CMS Price (Payment) Standardization—Detailed Methods'' (Revised May 2015) *https://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772057350.*

Comment: Several commenters recommended that the risk adjustment model for the MSPB–PAC SNF QRP measure include variables for SES/SDS factors. A commenter recommended that a ''fairer'' approach than using SES/SDS factors as risk adjustment variables would be to compare resource use levels that have not been adjusted for SES/SDS factors across peer providers (that is, providers with similar shares of beneficiaries with similar SES characteristics).

Response: With regard to the suggestions that the model include sociodemographic factors and the suggestion pertaining to an approach with which to convey data comparisons, we refer readers to section III.D.2.f. where we also discuss these topics.

Comment: Some commenters recommended that additional variables be included in risk adjustment to better capture clinical complexity. A few commenters suggested the inclusion of functional and cognitive status and other patient assessment data. Commenters recommended that additional variables should include obesity, amputations, CVAs (hemiplegia/paresis), and ventilator status.

Response: We thank the commenters for their suggestions. The HCC indicators that are already included in the risk adjustment model account for amputations, hemiplegia, and paresis. We believe that the other risk adjustment variables adequately adjust for ventilator dependency and obesity by accounting for HCCs, clinical case mix categories, and prior inpatient and ICU length of stay.

We recognize the importance of accounting for beneficiaries' functional and cognitive status in the calculation of predicted episode spending. We considered the potential use of functional status information in the risk adjustment models for the MSPB–PAC measures. However, we decided to not include this information derived from current setting-specific assessment instruments given the move towards standardized data as mandated by the IMPACT Act. We will revisit the inclusion of functional status in these measures' risk adjustment models in the future when the standardized functional status data mandated by the IMPACT Act-mandated become available. Once they are available, we will take a gradual and systematic approach in evaluating how they might be incorporated. We intend to implement any changes if appropriate based on testing.

Comment: One commenter expressed concern that the measures will give incentive to SNFs to avoid admitting medically complex residents, which would result in unintended consequences.

Response: To mitigate the risk of creating incentives for SNFs to avoid admitting medically complex residents, who may be at higher risk for poor outcomes and higher costs, we have included factors related to medical complexity in the risk adjustment methodology for the MSPB–PAC SNF QRP measure. We also intend to conduct ongoing monitoring to assess for potential unintended consequences associated with the implementation of this measure.

Comment: One commenter recommended that SNFs providing palliative care should be treated the same way as SNFs providing hospice care.

Response: We thank the commenter for their concern and note that the risk adjustment model used in the MSPB–PAC SNF QRP measure does not adjust for the type of care provided in the SNF, such as hospice-type or palliative care services. However, the episode spending for beneficiaries who receive hospice care within the episode window is benchmarked only against the expected episode-level spending of similar beneficiaries. This is achieved through the inclusion of a risk adjustment indicator for beneficiaries for whom Medicare pays hospice claims during the episode window. We adjust for beneficiaries with hospice claims as these patients have different characteristics from those who are not receiving hospice care services; one requirement of eligibility for hospice services under Part A is that beneficiaries must be terminally ill with a life expectancy of 6 months or less. In contrast, palliative care services can encompass any comfort care services (such as pain medication) at any stage of treatment of illness or condition. Given the challenges of identifying the range of services that could indicate palliative care and the wide variety of patients receiving this type of care, we believe that adjusting for the presence of hospice claims and not palliative care services supports the goal of providing fair comparisons between providers.

(iii) Measure Numerator and Denominator

The MPSB–PAC SNF QRP measure is a payment-standardized, risk-adjusted ratio that compares a given SNF provider's Medicare spending against the Medicare spending of other SNF providers within a performance period. Similar to the hospital MSPB measure, the ratio allows for ease of comparison over time as it obviates the need to adjust for inflation or policy changes.

The MSPB–PAC SNF QRP measure is calculated as the ratio of the MSPB–PAC Amount for each SNF provider divided by the episode-weighted median MSPB–PAC Amount across all SNF providers. To calculate the MSPB–PAC Amount for each SNF provider, one calculates the average of the ratio of the standardized episode spending over the expected episode spending (as predicted in risk adjustment), and then multiplies this quantity by the average episode spending level across all SNF providers nationally. The denominator for a SNF provider's MSPB–PAC SNF QRP measure is the episode-weighted national median of the MSPB–PAC Amounts across all SNF providers. An MSPB–PAC SNF QRP measure of less than 1 indicates that a given SNF provider's resource use is less than that of the national median SNF provider during a performance period. Mathematically, this is represented in equation (A) below:

$$(A)\ MSPB\text{-}PAC\ SNF\ Measure_{\ j} = \frac{MSPB\text{-}PAC\ Amount_j}{National\ Median\ MSPB\text{-}PAC\ Amount} = \frac{\left(\frac{1}{n_j}\sum_{i\in\{I_j\}}\frac{Y_{ij}}{\widehat{Y_{ij}}}\right)\left(\frac{1}{n}\sum_j\sum_{i\in\{I_j\}}Y_{ij}\right)}{Episode\text{-}Weighted\ Median\ of\ SNF\ Providers'\ MSPB\text{-}PAC\ Amount}$$

Where

- Y_{ij} = attributed standardized spending for episode *i* and provider *j*
- $\widehat{Y_{ij}}$ = expected standardized spending for episode *i* and provider *j,* as predicted from risk adjustment

- n_j = number of episodes for provider j
- n = total number of episodes nationally
- $i \in \{I_j\}$ = all episodes i in the set of episodes attributed to provider j.

The comments we received on this topic, with their responses, appear below.

Comment: A few commenters expressed concern about comparing mean to median values leading to inaccurate measure calculation. Commenters requested clarification on proposed values to ensure fairness.

Response: We appreciate the commenters' concerns. As noted in the MSPB–PAC Public Comment Summary Report for which a link has been provided above, we clarify that a provider's MSPB–PAC Amount is the average of observed over expected spending across a provider's episodes. Comparing a provider's MSPB–PAC Amount to the national median MSPB–PAC Amount does not affect the rank ordering of providers, and will therefore not lead to inaccurate measure calculations because the attributed provider's rank relative to the median will not change.

Comment: One commenter recommended including payments made by the SNF to non-Medicare payers so that providers cannot simply shift costs to other payers.

Response: We thank the commenter for the input and note that this measure only includes beneficiaries who are continuously enrolled in Medicare FFS for the entirety of a 90-day lookback period (that is, a 90-day period prior to the episode trigger) plus episode window. We do not have the ability to assess payments made by private payers or track beneficiary coinsurance or deductibles paid for plans outside of Medicare. CMS will monitor this issue using administrative claims data from Medicare as a part of ongoing measure monitoring and evaluation.

Comment: One commenter recommended that a geographic-specific (for example, state or regional) median should be used instead of the national median, citing differences in cost, patient population, and regulation.

Response: We appreciate the commenter's input. As noted in the proposed rule, (81 FR 24260), we proposed to use the same payment standardization methodology as that used in the NQF-endorsed hospital MSPB measure to account for variation in Medicare spending. This methodology removes geographic payment differences, such as wage index and geographic practice cost index (GPCI), incentive payment adjustments, and other add-on payments that support broader Medicare program goals including indirect graduate medical education (IME) and hospitals serving a disproportionate share of uninsured patients (DSH). We believe that this approach accounts for the differences that the commenter raises while also maintaining consistency with the NQF-endorsed hospital MSPB measure's methodology for addressing regional variation through payment standardization.

(c) Data Sources

The MSPB–PAC SNF QRP resource use measure is an administrative claims-based measure. It uses Medicare Part A and Part B claims from FFS beneficiaries and Medicare eligibility files.

(d) Cohort

The measure cohort includes Medicare FFS beneficiaries with a SNF treatment period ending during the data collection period.

(e) Reporting

We intend to provide initial confidential feedback to providers, prior to public reporting of this measure, based on Medicare FFS claims data from discharges in CY 2016. We intend to publicly report this measure using claims data from discharges in CY 2017.

We proposed to use a minimum of 20 episodes for reporting and inclusion in the SNF QRP. For the reliability calculation, as described in the measure specifications, a link for which has been provided above, we used data from FY 2014. The reliability results support the 20 episode case minimum, and 100 percent of SNF providers had moderate or high reliability (above 0.4).

The comments we received on this topic, with their responses, appear below.

Comment: Several commenters supported a period during which providers would be able to preview and correct measure and quality data.

Response: We appreciate the comments, and direct readers to section III.D.2.n. where we discuss this topic in detail.

Comment: Some commenters recommended an initial confidential data preview period for providers, prior to public reporting.

Response: Providers will receive a confidential preview report with 30 days for review in advance of their data and information being publicly displayed.

Comment: Some commenters recommended that the MSPB–PAC SNF QRP measure be tested for reliability and validity prior to finalization.

Response: The MSPB–PAC SNF QRP measure has been tested for reliability using FY 2014 data. The reliability results support the 20 episode case minimum, and 100 percent of SNF providers had moderate or high reliability (above 0.4). Further details on the reliability calculation are provided in the MSPB–PAC Measure Specifications, a link for which has been provided above.

Comment: One commenter suggested that descriptive statistics on the measure score by provider-level characteristics (for example, rural/urban status and bed size) would be useful to evaluate measure design decisions.

Response: We thank the commenter for their input. The following table 12 shows the MSPB–PAC SNF provider scores by provider characteristics, calculated using FY 2014 data.

TABLE 12—MSPB–PAC SNF SCORES BY PROVIDER CHARACTERISTICS

Provider characteristic	Number of providers	Mean score	Score percentile						
			1st	10th	25th	50th	75th	90th	99th
All Providers	15,446	1.01	0.38	0.66	0.84	1.01	1.18	1.35	1.69
Urban/Rural:									
Urban	10,656	1.03	0.46	0.73	0.87	1.02	1.18	1.35	1.68
Rural	4,786	0.96	0.29	0.56	0.74	0.96	1.16	1.35	1.71
Unknown	4	1.12	0.89	0.89	0.90	1.05	1.34	1.51	1.51
Ownership Type:									
For profit	10,705	1.07	0.47	0.77	0.92	1.06	1.22	1.39	1.72
Non-profit	3,693	0.87	0.32	0.56	0.70	0.86	1.03	1.18	1.56
Government	1,008	0.89	0.20	0.49	0.66	0.87	1.12	1.31	1.66
Unknown	40	0.52	0.18	0.31	0.38	0.52	0.62	0.79	0.89

TABLE 12—MSPB–PAC SNF SCORES BY PROVIDER CHARACTERISTICS—Continued

Provider characteristic	Number of providers	Mean score	Score percentile						
			1st	10th	25th	50th	75th	90th	99th
Census Division:									
New England	943	0.91	0.44	0.68	0.79	0.91	1.04	1.14	1.40
Middle Atlantic	1,708	1.00	0.46	0.69	0.84	1.00	1.16	1.30	1.59
East North Central	3,009	1.07	0.50	0.76	0.92	1.06	1.21	1.39	1.69
West North Central	1,989	0.82	0.27	0.52	0.67	0.82	0.97	1.12	1.43
South Atlantic	2,369	1.03	0.41	0.75	0.90	1.03	1.17	1.31	1.60
East South Central	1,083	1.07	0.34	0.64	0.88	1.08	1.28	1.44	1.72
West South Central	2,076	1.13	0.40	0.75	0.96	1.13	1.31	1.49	1.79
Mountain	732	0.90	0.23	0.61	0.78	0.92	1.05	1.15	1.46
Pacific	1,529	1.03	0.43	0.68	0.84	1.01	1.20	1.40	1.75
Other	8	0.51	0.39	0.39	0.43	0.53	0.56	0.68	0.68
Bed Count:									
0–49	1,877	0.82	0.24	0.49	0.61	0.79	1.00	1.20	1.70
50–99	5,799	1.00	0.36	0.64	0.82	0.99	1.17	1.36	1.70
100–199	6,846	1.06	0.52	0.78	0.91	1.05	1.20	1.36	1.67
200–299	726	1.08	0.55	0.78	0.91	1.06	1.23	1.42	1.69
300 +	198	1.03	0.45	0.75	0.87	1.01	1.16	1.35	1.62
No. of Episodes:									
0–99	10,048	1.01	0.33	0.63	0.82	1.01	1.20	1.40	1.73
100–249	4,298	1.01	0.52	0.75	0.88	1.01	1.15	1.28	1.53
250–499	960	0.96	0.52	0.69	0.83	0.97	1.08	1.20	1.45
500–1000	136	0.96	0.57	0.74	0.88	0.96	1.08	1.19	1.35
1000 +	4	0.86	0.73	0.73	0.80	0.87	0.92	0.98	0.98

In summary, after consideration of the public comments we received, we are finalizing the specifications of the MSPB–PAC SNF QRP resource use measure, as proposed. A link for the measure specifications has been provided above.

Specifically, we are finalizing the definition of an MSPB–PAC SNF QRP episode, beginning from episode trigger. An episode window comprises a treatment period beginning at the trigger and ending upon discharge, and an associated services period beginning at the trigger and ending 30 days after the end of the treatment period. Readmissions to the same SNF within 7 or fewer days do not trigger a new episode and are instead included in the treatment period of the first episode.

We exclude certain services that are clinically unrelated to SNF care and/or because SNF providers may have limited influence over certain Medicare services delivered by other providers during the episode window. We also exclude certain episodes in their entirety from the MSPB–PAC SNF QRP measure, such as where a beneficiary is not enrolled in Medicare FFS for the entirety of the lookback period plus episode window.

We finalize the inclusion of Medicare payments for Part A and Part B claims for services included in the MSPB–PAC SNF QRP episodes to calculate the MSPB–PAC SNF QRP measure.

We are finalizing our proposal to risk adjust using covariates including age brackets, HCC indicators, prior inpatient stay length, ICU stay length, clinical case mix categories, and indicators for originally disabled, ESRD enrollment, long-term care status, and hospice claim in episode window. The measure also adjusts for geographic payment differences such as wage index and GPCI, and adjusts for Medicare payment differences resulting from IME and DSH.

We calculate the individual providers' MSPB–PAC Amount which is inclusive of MSPB–PAC SNF QRP observed episode spending over the expected episode spending as predicted through risk adjustment. Individual SNF providers' scores are calculated as their individual MSPB–PAC Amount divided by the median MSPB–PAC amount across all SNFs.

ii. Measure to Address the IMPACT Act Domain of Resource Use and Other Measures: Discharge to Community—Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP)

Sections 1899B(d)(1)(B) and 1899B(a)(2)(E)(ii) of the Act require the Secretary to specify a measure to address the domain of discharge to community by SNFs, LTCHs, and IRFs by October 1, 2016, and HHAs by January 1, 2017. We proposed to adopt the measure, Discharge to Community—PAC SNF QRP, for the SNF QRP for the FY 2018 payment determination and subsequent years as a Medicare FFS claims-based measure to meet this requirement.

This measure assesses successful discharge to the community from a SNF setting, with successful discharge to the community including no unplanned rehospitalizations and no death in the 31 days following discharge from the SNF. Specifically, this measure reports a SNF's risk-standardized rate of Medicare FFS residents who are discharged to the community following a SNF stay, and do not have an unplanned readmission to an acute care hospital or LTCH in the 31 days following discharge to community, and who remain alive during the 31 days following discharge to community. The term ''community'', for this measure, is defined as home or self care, with or without home health services, based on Patient Discharge Status Codes 01, 06, 81, and 86 on the Medicare FFS claim.[41] [42] This measure is conceptualized uniformly across the PAC settings, in terms of the definition of the discharge to community outcome, the approach to risk adjustment, and the measure calculation.

Discharge to a community setting is an important health care outcome for

[41] National Uniform Billing Committee Official UB–04 Data Specifications Manual 2017, Version 11, July 2016, Copyright 2016, American Hospital Association.

[42] This definition is not intended to suggest that board and care homes, assisted living facilities, or other settings included in the definition of ''community'' for the purpose of this measure are the most integrated setting for any particular individual or group of individuals under the Americans with Disabilities Act (ADA) and section 504.

many residents for whom the overall goals of post-acute care include optimizing functional improvement, returning to a previous level of independence, and avoiding institutionalization. Returning to the community is also an important outcome for many residents who are not expected to make functional improvement during their SNF stay, and for residents who may be expected to decline functionally due to their medical condition. The discharge to community outcome offers a multi-dimensional view of preparation for community life, including the cognitive, physical, and psychosocial elements involved in a discharge to the community.[43] [44]

In addition to being an important outcome from a resident and family perspective, patients and residents discharged to community settings, on average, incur lower costs over the recovery episode, compared with those discharged to institutional settings.[45] [46] Given the high costs of care in institutional settings, encouraging SNFs to prepare residents for discharge to community, when clinically appropriate, may have cost-saving implications for the Medicare program.[47] Also, providers have discovered that successful discharge to community was a major driver of their ability to achieve savings, where capitated payments for post-acute care were in place.[48] For residents who require long-term care due to persistent disability, discharge to community could result in lower long-term care costs for Medicaid and for residents' out-of-pocket expenditures.[49]

Analyses conducted for ASPE on PAC episodes, using a 5 percent sample of 2006 Medicare claims, revealed that relatively high average, unadjusted Medicare payments are associated with discharge to institutional settings from IRFs, SNFs, LTCHs or HHAs, as compared with payments associated with discharge to community settings.[50] Average, unadjusted Medicare payments associated with discharge to community settings ranged from $0 to $4,017 for IRF discharges, $0 to $3,544 for SNF discharges, $0 to $4,706 for LTCH discharges, and $0 to $992 for HHA discharges. In contrast, payments associated with discharge to non-community settings were considerably higher, ranging from $11,847 to $25,364 for IRF discharges, $9,305 to $29,118 for SNF discharges, $12,465 to $18,205 for LTCH discharges, and $7,981 to $35,192 for HHA discharges.[51]

Measuring and comparing facility-level discharge to community rates is expected to help differentiate among facilities with varying performance in this important domain, and to help avoid disparities in care across resident groups. Variation in discharge to community rates has been reported within and across post-acute settings; across a variety of facility-level characteristics, such as geographic location (for example, regional location, urban or rural location), ownership (for example, for-profit or nonprofit), and freestanding or hospital-based units; and across patient-level characteristics, such as race and gender.[52] [53] [54] [55] [56] [57]

Discharge to community rates in the IRF setting have been reported to range from about 60 to 80 percent.[58] [59] [60] [61] [62] [63] Longer-term studies show that rates of discharge to community from IRFs have decreased over time as IRF length of stay has decreased.[64] [65] Greater variation in discharge to community rates is seen in the SNF setting, with rates ranging from 31 to 65 percent.[66] [67] [68] [69] In the

[43] El-Solh AA, Saltzman SK, Ramadan FH, Naughton BJ. Validity of an artificial neural network in predicting discharge destination from a postacute geriatric rehabilitation unit. Archives of physical medicine and rehabilitation. 2000;81(10):1388–1393.

[44] Tanwir S, Montgomery K, Chari V, Nesathurai S. Stroke rehabilitation: Availability of a family member as caregiver and discharge destination. *European journal of physical and rehabilitation medicine.* 2014;50(3):355–362.

[45] Dobrez D, Heinemann AW, Deutsch A, Manheim L, Mallinson T. Impact of Medicare's prospective payment system for inpatient rehabilitation facilities on stroke patient outcomes. *American journal of physical medicine & rehabilitation/Association of Academic Physiatrists.* 2010;89(3):198–204.

[46] Gage B, Morley M, Spain P, Ingber M. Examining Post Acute Care Relationships in an Integrated Hospital System. Final Report. RTI International;2009.

[47] *Ibid.*

[48] Doran JP, Zabinski SJ. Bundled payment initiatives for Medicare and non-Medicare total joint arthroplasty patients at a community hospital: Bundles in the real world. The journal of arthroplasty. 2015;30(3):353–355.

[49] Newcomer RJ, Ko M, Kang T, Harrington C, Hulett D, Bindman AB. Health Care Expenditures After Initiating Long-term Services and Supports in the Community Versus in a Nursing Facility. Medical Care. 2016; 54(3):221–228.

[50] Gage B, Morley M, Spain P, Ingber M. Examining Post Acute Care Relationships in an Integrated Hospital System. Final Report. RTI International;2009.

[51] *Ibid.*

[52] Reistetter TA, Karmarkar AM, Graham JE, et al. Regional variation in stroke rehabilitation outcomes. *Archives of physical medicine and rehabilitation.* 2014; 95(1):29–38.

[53] El-Solh AA, Saltzman SK, Ramadan FH, Naughton BJ. Validity of an artificial neural network in predicting discharge destination from a postacute geriatric rehabilitation unit. Archives of physical medicine and rehabilitation. 2000; 81(10):1388–1393.

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[57] Berges IM, Kuo YF, Ostir GV, Granger CV, Graham JE, Ottenbacher KJ. Gender and ethnic differences in rehabilitation outcomes after hip-replacement surgery. *American journal of physical medicine & rehabilitation/Association of Academic Physiatrists.* 2008; 87(7):567–572.

[58] Galloway RV, Granger CV, Karmarkar AM, et al. The Uniform Data System for Medical Rehabilitation: Report of patients with debility discharged from inpatient rehabilitation programs in 2000–2010. *American journal of physical medicine & rehabilitation/Association of Academic Physiatrists.* 2013; 92(1):14–27.

[59] Morley MA, Coots LA, Forgues AL, Gage BJ. Inpatient rehabilitation utilization for Medicare beneficiaries with multiple sclerosis. *Archives of physical medicine and rehabilitation.* 2012; 93(8):1377–1383.

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[61] Gagnon D, Nadeau S, Tam V. Clinical and administrative outcomes during publicly-funded inpatient stroke rehabilitation based on a case-mix group classification model. *Journal of rehabilitation medicine.* 2005; 37(1):45–52.

[62] DaVanzo J, El-Gamil A, Li J, Shimer M, Manolov N, Dobson A. *Assessment of patient outcomes of rehabilitative care provided in inpatient rehabilitation facilities (IRFs) and after discharge.* Vienna, VA: Dobson DaVanzo & Associates, LLC; 2014.

[63] Kushner DS, Peters KM, Johnson-Greene D. Evaluating Siebens Domain Management Model for Inpatient Rehabilitation to Increase Functional Independence and Discharge Rate to Home in Geriatric Patients. *Archives of physical medicine and rehabilitation.* 2015; 96(7):1310–1318.

[64] Galloway RV, Granger CV, Karmarkar AM, et al. The Uniform Data System for Medical Rehabilitation: Report of patients with debility discharged from inpatient rehabilitation programs in 2000–2010. *American journal of physical medicine & rehabilitation/Association of Academic Physiatrists.* 2013; 92(1):14–27.

[65] Mallinson T, Deutsch A, Bateman J, et al. Comparison of discharge functional status after rehabilitation in skilled nursing, home health, and medical rehabilitation settings for patients after hip fracture repair. *Archives of physical medicine and rehabilitation.* 2014; 95(2):209–217.

[66] El-Solh AA, Saltzman SK, Ramadan FH, Naughton BJ. Validity of an artificial neural network in predicting discharge destination from a postacute geriatric rehabilitation unit. *Archives of physical medicine and rehabilitation.* 2000; 81(10):1388–1393.

[67] Hall RK, Toles M, Massing M, et al. Utilization of acute care among patients with ESRD discharged home from skilled nursing facilities. *Clinical journal of the American Society of Nephrology: CJASN.* 2015; 10(3):428–434.

[68] Stearns SC, Dalton K, Holmes GM, Seagrave SM. Using propensity stratification to compare patient outcomes in hospital-based versus freestanding skilled-nursing facilities. *Medical care research and review: MCRR.* 2006; 63(5):599–622.

[69] Wodchis WP, Teare GF, Naglie G, et al. Skilled nursing facility rehabilitation and discharge to home after stroke. *Archives of physical medicine and rehabilitation.* 2005; 86(3):442–448.

SNF Medicare FFS population, using CY 2013 national claims data, we found that approximately 44 percent of residents were discharged to the community. A multi-center study of 23 LTCHs demonstrated that 28.8 percent of 1,061 patients who were ventilator-dependent on admission were discharged to home.[70] A single-center study revealed that 31 percent of LTCH hemodialysis patients were discharged to home.[71] One study noted that 64 percent of beneficiaries who were discharged from the home health episode did not use any other acute or post-acute services paid by Medicare in the 30 days after discharge.[72] However, significant numbers of patients were admitted to hospitals (29 percent) and lesser numbers to SNFs (7.6 percent), IRFs (1.5 percent), home health (7.2 percent) or hospice (3.3 percent).[73]

Discharge to community is an actionable health care outcome, as targeted interventions have been shown to successfully increase discharge to community rates in a variety of post-acute settings.[74] [75] [76] [77] Many of these interventions involve discharge planning or specific rehabilitation strategies, such as addressing discharge barriers and improving medical and functional status.[78] [79] [80] [81] The effectiveness of these interventions suggests that improvement in discharge to community rates among post-acute care residents is possible through modifying provider-led processes and interventions.

A TEP convened by our measure development contractor was strongly supportive of the importance of measuring discharge to community outcomes, and implementing the measure, Discharge to Community—PAC SNF QRP in the SNF QRP. The panel provided input on the technical specifications of this measure, including the feasibility of implementing the measure, as well as the overall measure reliability and validity. A summary of the TEP proceedings is available on the PAC Quality Initiatives Downloads and Videos Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We also solicited stakeholder feedback on the development of this measure through a public comment period held from November 9, 2015, through December 8, 2015. Several stakeholders and organizations, including the MedPAC, among others, supported this measure for implementation. The public comment summary report for the measure is available on the CMS Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

The NQF-convened MAP met on December 14 and 15, 2015, and provided input on the use of this Discharge to Community—PAC SNF QRP measure in the SNF QRP. The MAP encouraged continued development of the measure to meet the mandate of the IMPACT Act. The MAP supported the alignment of this measure across PAC settings, using standardized claims data. More information about the MAP's recommendations for this measure is available at *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC–LTC.aspx*.

Since the MAP's review and recommendation of continued development, we have continued to refine risk-adjustment models and conduct measure testing for this measure, as recommended by the MAP. This measure is consistent with the information submitted to the MAP, and the original MAP submission and our continued refinements support its scientific acceptability for use in quality reporting programs. As discussed with the MAP, we fully anticipate that additional analyses will continue as we submit this measure to the ongoing measure maintenance process.

We reviewed the NQF's consensus-endorsed measures and were unable to identify any NQF-endorsed resource use or other measures for post-acute care focused on discharge to community. In addition, we are unaware of any other post-acute care measures for discharge to community that have been endorsed or adopted by other consensus organizations. Therefore, we proposed the measure, Discharge to Community—PAC SNF QRP, under the Secretary's authority to specify non—NQF-endorsed measures under section 1899B(e)(2)(B) of the Act.

We proposed to use data from the Medicare FFS claims and Medicare eligibility files to calculate this measure. We proposed to use data from the ''Patient Discharge Status Code'' on Medicare FFS claims to determine whether a resident was discharged to a community setting for calculation of this measure. In all PAC settings, we tested the accuracy of determining discharge to a community setting using the ''Patient Discharge Status Code'' on the PAC claim by examining whether discharge to community coding based on PAC claim data agreed with discharge to community coding based on PAC assessment data. We found agreement between the two data sources in all PAC settings, ranging from 94.6 percent to 98.8 percent. Specifically, in the SNF setting, using 2013 data, we found 94.6 percent agreement in discharge to community codes when comparing discharge status codes on claims and the Discharge Status (A2100) on the Minimum Data Set (MDS) 3.0 discharge assessment, when the claims and MDS assessment had the same discharge date. We further examined the accuracy of the ''Patient Discharge Status Code'' on the PAC claim by assessing how frequently discharges to

[70] Scheinhorn DJ, Hassenpflug MS, Votto JJ, et al. Post-ICU mechanical ventilation at 23 long-term care hospitals: A multicenter outcomes study. *Chest.* 2007;131(1):85–93.

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[72] Wolff JL, Meadow A, Weiss CO, Boyd CM, Leff B. Medicare home health patients' transitions through acute and post-acute care settings. *Medical care.* 2008;46(11):1188–1193.

[73] *Ibid.*

[74] Kushner DS, Peters KM, Johnson-Greene D. Evaluating Siebens Domain Management Model for Inpatient Rehabilitation to Increase Functional Independence and Discharge Rate to Home in Geriatric Patients. *Archives of physical medicine and rehabilitation.* 2015;96(7):1310–1318.

[75] Wodchis WP, Teare GF, Naglie G, et al. Skilled nursing facility rehabilitation and discharge to home after stroke. *Archives of physical medicine and rehabilitation.* 2005;86(3):442–448.

[76] Berkowitz RE, Jones RN, Rieder R, et al. Improving disposition outcomes for patients in a geriatric skilled nursing facility. *Journal of the American Geriatrics Society.* 2011;59(6):1130–1136.

[77] Kushner DS, Peters KM, Johnson-Greene D. Evaluating use of the Siebens Domain Management Model during inpatient rehabilitation to increase functional independence and discharge rate to home in stroke patients. *PM & R: The journal of injury, function, and rehabilitation.* 2015;7(4):354–364.

[78] Kushner DS, Peters KM, Johnson-Greene D. Evaluating Siebens Domain Management Model for Inpatient Rehabilitation to Increase Functional Independence and Discharge Rate to Home in Geriatric Patients. *Archives of physical medicine and rehabilitation.* 2015;96(7):1310–1318.

[79] Wodchis WP, Teare GF, Naglie G, et al. Skilled nursing facility rehabilitation and discharge to home after stroke. *Archives of physical medicine and rehabilitation.* 2005;86(3):442–448.

[80] Berkowitz RE, Jones RN, Rieder R, et al. Improving disposition outcomes for patients in a geriatric skilled nursing facility. *Journal of the American Geriatrics Society.* 2011;59(6):1130–1136.

[81] Kushner DS, Peters KM, Johnson-Greene D. Evaluating use of the Siebens Domain Management Model during inpatient rehabilitation to increase functional independence and discharge rate to home in stroke patients. *PM & R: The journal of injury, function, and rehabilitation.* 2015;7(4):354–364.

an acute care hospital were confirmed by follow-up acute care claims. We discovered that 88 percent to 91 percent of IRF, LTCH, and SNF claims with acute care discharge status codes were followed by an acute care claim on the day of, or day after, PAC discharge. We believed these data support the use of the claims ''Patient Discharge Status Code'' for determining discharge to a community setting for this measure. In addition, this measure can feasibly be implemented in the SNF QRP because all data used for measure calculation are derived from Medicare FFS claims and eligibility files, which are already available to CMS.

Based on the evidence discussed above, we proposed to adopt the measure, Discharge to Community—PAC SNF QRP, for the SNF QRP for FY 2018 payment determination and subsequent years. This measure is calculated using 1 year of data. We proposed a minimum of 25 eligible stays in a given SNF for public reporting of the measure for that SNF. Since Medicare FFS claims data are already reported to the Medicare program for payment purposes, and Medicare eligibility files are also available, SNFs will not be required to report any additional data to CMS for calculation of this measure. The measure denominator is the risk-adjusted expected number of discharges to community. The measure numerator is the risk-adjusted estimate of the number of residents who are discharged to the community, do not have an unplanned readmission to an acute care hospital or LTCH in the 31-day post-discharge observation window, and who remain alive during the post-discharge observation window. The measure is risk-adjusted for variables such as age and sex, principal diagnosis, comorbidities, ventilator status, ESRD status, and dialysis, among other variables. For technical information about the proposed measure, including information about the measure calculation, risk adjustment, and denominator exclusions, we referred readers to the document titled, Proposed Measure Specifications for Measures Proposed in the FY 2017 SNF QRP Proposed Rule available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html*.

We stated in the proposed rule that we intend to provide initial confidential feedback to SNFs, prior to public reporting of this measure, based on Medicare FFS claims data from discharges in CY 2016. We intend to publicly report this measure using claims data from discharges in CY 2017. We plan to submit this measure to the NQF for consideration for endorsement.

We invited public comment on our proposal to adopt the measure, Discharge to Community—PAC SNF QRP, for the SNF QRP. The comments we received on this topic, with our responses, appear below.

Comment: Several commenters, including MedPAC, supported the Discharge to Community—PAC SNF QRP measure, noting that it is a critical measure assessing the ability of a PAC provider to rehabilitate patients and enable them to return to the home and community-based setting. One commenter noted that measuring the rate that the various PAC settings discharge patients to the community, without an admission (or readmission) to an acute care hospital within 30 days, is one of the most relevant patient-centered measures that exists in the post-acute care area. Commenters noted that most older adults want to live independently in their homes and communities, that returning home following care was an important concern of Medicare beneficiaries, and that successful transitions to community would decrease potentially preventable readmissions. Two commenters supported CMS's efforts to develop aligned yet distinctive risk-adjusted discharge to community measures for IRFs, SNFs and LTCHs, given the inherent variability in patient/resident profiles across these settings. Commenters agreed that discharge to community was an important outcome not just for patients expected to make functional improvement and return to their previous level of independence, but also for patients not expected to make functional improvement, or those who may be expected to decline functionally due to their medical condition. One commenter stated that achieving a standardized and interoperable patient assessment data set and stable quality measures as quickly as possible would allow for better cross-setting comparisons and the evolution of better quality measures with uniform risk standardization. One commenter expressed support for the use of claims data over assessment data in calculating the Discharge to Community—PAC SNF QRP measure, stating that assessment data could be susceptible to gaming by providers.

Response: We thank the commenters for their support of the Discharge to Community—PAC SNF QRP measure, and their recognition of its patient-centeredness, its relevance for patients with a range of functional abilities and prognosis, and its potential to reduce post-discharge readmissions. We also thank commenters for their support of use of claims data, and their support of standardized and interoperable patient assessment data and quality measures. As mandated by the IMPACT Act, we are moving toward the goal of standardized patient assessment data and quality measures across PAC settings.

Comment: One commenter interpreted our measure proposal language as suggesting that functional improvement is not a requirement, and encouraged that Medicare coverage for maintenance nursing and therapy be ensured and reflected by the measure.

Response: Our intent in the measure proposal was to acknowledge that discharge to community can be an important goal even for patients who may not be able to make functional improvement. This measure does not impact Medicare coverage rules for maintenance nursing and therapy.

Comment: Several commenters requested that ''home'' be defined broadly to reflect the place an individual calls ''home'', including assisted living facilities, residential care settings, or other congregate community housing.

Response: We agree with the commenters that ''home'' should be defined broadly for the discharge to community measure. In addition to home, our definition of community includes settings such as group home, foster care, and independent living and other residential care arrangements.[82] For further details on measure specifications, including the definition of community, we refer readers to the Measure Specifications for Measures Adopted in the FY 2017 SNF QRP Final Rule, posted on the CMS SNF QRP Web page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html*.

Comment: Several commenters expressed concerns regarding the use of the Patient Discharge Status Code variable to define community discharges. Commenters emphasized that it was important to ensure that only home and community based settings were included in the definition of

[82] National Uniform Billing Committee Official UB–04 Data Specifications Manual 2017, Version 11, July 2016, Copyright 2016, American Hospital Association.

community, and were concerned that Code 01 (Discharge to home or self care), which is included in the definition of community, included institutional settings such as jail or law enforcement. One commenter expressed that many settings included under Code 01 do not satisfy the home and community based settings rule, and may be inconsistent with the integration mandate of the Americans with Disabilities Act. Commenters strongly recommended that we either revise discharge status code 01 to exclude non community-based settings, or use alternative variables to capture discharge to community.

Response: We agree with the commenters that the discharge to community measure should only capture discharges to home and community based settings. We believe that the comment referring to the ''home and community based settings rule'' refers to Medicaid regulations applicable to services authorized under sections 1915(c), 1915(i) and 1915(k) of the Act, which are provided through waivers or state plans amendments approved by CMS. We would like to clarify that this measure only captures discharges to home and community based settings, not to institutional settings, and is consistent with both Medicaid regulations requiring home and community based settings to support integration, and also with the Americans with Disabilities Act (ADA), based on Patient Discharge Status Codes 01, 06, 81, and 86 on the Medicare FFS PAC claim.[83] Discharges to jail or law enforcement are not included under Code 01 of the Patient Discharge Status Code; rather these are included under Code 21 (Discharged/transferred to Court/Law Enforcement).

We also note that Title II of the ADA regulations requires public entities to administer services, programs, and activities in the most integrated setting appropriate to the needs of qualified individuals with disabilities (28 CFR 35.130(d)). The preamble discussion of the ''integration regulation'' explains that ''the most integrated setting'' is one that enables individuals with disabilities to interact with nondisabled persons to the fullest extent possible. Integrated settings are those that provide individuals with disabilities opportunities to live, work, and receive services in the greater community, like individuals without disabilities (28 CFR part 35, app. A (2010) (addressing § 35.130)).

Comment: Several commenters stated that PAC patients/residents discharged to a nursing facility as long-term care residents should not be considered discharges to community, particularly if they were discharged to the nursing facility from the Medicare-certified skilled nursing part of the same nursing home, and even if they resided in a long-term nursing facility at baseline. Commenters emphasized that a nursing home does not represent an individual's own home in their own community. These commenters interpreted the proposed measure specifications as allowing these discharges to a nursing facility to be coded as ''group home'', ''foster care'', or ''other residential care arrangement'' under discharge status code 01. Commenters expressed concern that coding discharges from the SNF to residential/long-term care facility within the same nursing home as discharges to community would unfairly advantage SNFs and artificially inflate their discharge to community rates, would disadvantage other PAC providers, would negate the value of the measure, and would miscommunicate facility's actual discharge to community performance to the average Medicare beneficiary. Commenters also noted that including nursing facility discharges as community discharges could incentivize SNFs to not do the hard work that actual, meaningful discharge planning to the community requires.

Response: We agree with the commenters that discharges to long-term care nursing facilities, or any other institutional settings, should not be coded as discharges to community. We also recognize the differences in required discharge planning processes and resources for discharging a patient/resident to the community compared with discharging to a long-term nursing facility. The discharge to community measure only captures discharges to home and community based settings as discharges to community, based on Patient Discharge Status Codes 01, 06, 81, and 86 on the Medicare FFS PAC claim.[84] These codes do not include discharges to long-term care nursing facilities or any other institutional setting that may violate the integration mandate of title II of the ADA. Instead, depending on the nature of the facility to which patients/residents are discharged, such discharges may be coded on the Medicare FFS claim as 04, 64, 84, 92, or another appropriate code for an institutional discharge.

In response to the commenters' concerns that SNFs may be unfairly advantaged by this measure as compared with other PAC providers, we would like to note that, in our measure development samples, the national discharge to community rate for SNFs was 47.26 percent, while this rate for IRFs was considerably higher (69.51 percent). Further, using an MDS-claims linked longitudinal file, we found that, of SNF stays that had a pre-hospitalization non-PPS MDS assessment suggesting prior nursing facility residence, two-thirds had a discharge status code of 30 (still patient), and approximately 18 percent had a discharge status code of 02 (acute hospital); less than 5 percent of these patients had a discharge status code of 01 (discharge to home or self care).

Comment: Several commenters recommended that the discharge to community measure should entirely exclude baseline long-stay nursing facility residents, as they could not be reasonably expected to discharge to the community after their PAC stay. One commenter noted that the measure fails to consider when a patient's ''home'' is a custodial nursing facility and the patient's post-acute episode involves a discharge back to his or her ''home.'' Another commenter noted that baseline nursing facility residents have a very different discharge process back to the nursing facility compared with patients discharged to the community. This commenter recommended that different measures be developed for the baseline nursing facility resident population, such as return to prior level of function, improvement in function, prevention of further functional decline, development of pressure ulcers, or accidental falls. This commenter also recognized our current efforts in monitoring transitions of care and quality requirements in long-term care facilities. One commenter suggested that we use the Minimum Data Set to identify and exclude baseline nursing facility residents.

Response: We appreciate the commenters' concerns and their recommendation to exclude baseline nursing facility residents from the discharge to community measure, and to distinguish baseline custodial nursing facility residents who are discharged back to the nursing facility after their SNF stay. We recognize that patients/residents who permanently lived in a nursing facility at baseline may not be expected to discharge back to a home and community based setting after their PAC stay. We also recognize that, for baseline nursing facility residents, a discharge back to their nursing facility represents a discharge to their baseline residence. We agree with the commenter about the differences in discharge planning processes when discharging a patient/resident to the community

[83] *Ibid.*

[84] *Ibid.*

compared with discharging to a long-term nursing facility. However, using Medicare FFS claims alone, we are unable to accurately identify baseline nursing facility residents. Potential future modifications of the measure could include the assessment of the feasibility and impact of excluding baseline nursing facility residents from the measure through the addition of patient assessment-based data. However, we note that, currently, the IRF-PAI is the only PAC assessment that contains an item related to pre-hospital baseline living setting.

Comment: One commenter raised concerns that the measure does not exclude individuals admitted to a SNF for Part A services, but who have an expressed goal to remain in the facility for long-term care and never be discharged back to community. The commenter specifically noted that there appears to be a relationship between SNF turnover rate and discharge to community rates. They noted that SNFs with low turnover, which they offered as a marker for being a primarily long-term care facility, had low discharge to community rates compared with SNFs with high turnover.

Response: This measure risk adjusts for several case-mix variables that may be related to preferences for facility-based long-term care such as age, diagnoses from the prior acute stay, comorbidities in the year preceding PAC admission, length of prior acute stay, number of prior hospitalizations in the past year, and ventilator use. Further, by excluding patients on hospice and those whose prior acute stay was for medical treatment of cancer, we are excluding SNF residents who may be more likely to transfer to a nursing facility at the end of their SNF stay. There are no claims data we could currently use to identify residents with an expressed goal to remain in the nursing home for long-term care. As we agree this is an important aspect of this measure work, we will consider assessing the ability to identify residents with an expressed goal to remain in the nursing home for long-term care, and the impact of such an exclusion on the measure performance.

Comment: MedPAC recommended that we confirm discharge to a community setting with the absence of a subsequent claim to a hospital, IRF, SNF, or LTCH, to ensure that discharge to community rates reflect actual facility performance. Other commenters also recommended that we assess the reliability and validity of the Patient Discharge Status code on PAC claims, expressing concerns about the accuracy of these data without further definition and validation. Commenters cited MedPAC and other studies, noting that Patient Discharge Status Codes often have low reliability, and this could impact accurate portrayal of measure performance.

Response: We are committed to developing measures based on reliable and valid data. This measure does confirm the absence of hospital or LTCH claims following discharge to a community setting. Unplanned hospital and LTCH readmissions following the discharge to community, including those on the day of SNF discharge, are considered an unfavorable outcome. We will consider verifying the absence of IRF and SNF claims following discharge to a community setting, as we continue to refine this measure. Nonetheless, we would like to note that an ASPE report on post-acute care relationships found that, following discharge to community settings from IRFs, LTCHs, or SNFs in a 5 percent Medicare sample, IRFs or SNFs were very infrequently reported as the next site of post-acute care.[85]

Because the discharge to community measure is a measure of discharge destination from the PAC setting, we have chosen to use the PAC-reported discharge destination (from the Medicare FFS claims) to determine whether a patient/resident was discharged to the community (based on discharge status codes 01, 06, 81, 86). We assessed the reliability of the claims discharge status code by examining agreement between discharge status on claims and assessment instruments for the same stay in all four PAC settings. We found between 94 and 99 percent agreement in coding of community discharges on matched claims and assessments in each of the PAC settings. We also assessed how frequently discharges to acute care, as indicated on the PAC claim, were confirmed by follow-up acute care claims, and found that 88 percent to 91 percent of IRF, LTCH, and SNF claims indicating acute care discharge were followed by an acute care claim on the day of, or day after, PAC discharge. We believe that these data support the use of the ''Patient Discharge Status Code'' from the PAC claim for determining discharge to a community setting for this measure.

The use of the claims discharge status code to identify discharges to the community was discussed at length with the TEP convened by our measure development contractor. TEP members did not express significant concerns regarding the accuracy of the claims discharge status code in coding community discharges, nor about our use of the discharge status code for defining this quality measure. A summary of the TEP proceedings is available on the PAC Quality Initiatives Downloads and Videos Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Comment: One commenter recommended that, in all PAC settings, patients who are discharged home and then admitted to a SNF or nursing facility during the 31-day post-discharge window not be counted as successful discharges to the community. The commenter suggested that MDS data could be used to identify individuals admitted to nursing homes.

Response: We agree that it is important to track whether patients remain in the community in the post-discharge observation window in order to ensure that facilities are appropriately discharging patients to the community. In the measure, we examine post-discharge unplanned acute care or LTCH readmissions, thereby accounting for more serious, acute readmissions in the post-discharge window. In future versions of the measure, we will consider looking for IRF, SNF, and nursing facility admissions and readmissions in the 31-day post-discharge window when examining discharge to community outcomes.

Comment: A few commenters requested clarification on the calculation of the discharge to community measure rates. One commenter questioned why estimates were used rather than observed rates.

Response: A successful discharge to community outcome includes patients discharged to the community who remain alive for 31 days post-discharge with no unplanned readmission. The method used requires the use of estimates because the observed rates are statistically adjusted to account for patient mix in each facility. The statistical model also estimates facility-level effects. In brief, we first calculate the sum of the probabilities of discharge to community of all patients/residents in the facility, including both the impact of patient/resident characteristics and the impact of the facility; this equals the ''predicted number'' of discharges to community after adjusting for the facility's case mix. We then calculate the ''expected number'' of discharges to community for the same

[85] Gage B, Morley M, Spain P, Ingber M. Examining Post Acute Care Relationships in an Integrated Hospital System Final Report. RTI International; 2009.

patients/residents at the average facility. The ratio of the predicted-to-expected number of discharges to community is a measure of the degree to which discharges to community are higher or lower than what would otherwise be expected at the average facility. This ratio is multiplied by the mean discharge to community rate for all facility stays for the measure, yielding the risk-standardized discharge to community rate for each facility.

Details on the risk adjustment methodology and measure calculation algorithm for the discharge to community measure are available in the Measure Specifications for Measures Adopted in the FY 2017 SNF QRP Final Rule, posted on the CMS SNF QRP Web page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html.* Specifically, we refer readers to Sections 2.1.8—Statistical Risk Model and Risk Adjustment Covariates, and 2.1.9—Measure Calculation Algorithm.

Comment: One commenter had concerns that there was overlap between the potentially preventable readmission measure and the discharge to community measure under the SNF QRP. The commenter noted that using two separate measures may be confusing to consumers and providers, making it challenging for SNFs to track and improve performance on these metrics.

Response: There are distinct differences between the discharge to community and potentially preventable readmission measures under the SNF QRP. Although there may be some overlap in the outcomes captured across the two measures (for example, residents who have a potentially preventable readmission also have an unsuccessful discharge to community) each measure has a distinct purpose, outcome definition, and measure population. For example, the discharge to community measure assesses the rate of successful discharges to the community, defined as discharge to a community setting without post-discharge unplanned readmissions or death, while the potentially preventable readmission measure assesses the rate of readmissions that may be potentially prevented for patients/residents discharged to lower levels of care from the SNF.

Our goal is to develop measures that are meaningful to patients and consumers, and assist them in making informed choices when selecting post-acute providers. Since the goal of PAC for most patients and family members is to be discharged to the community and remain in the community, from a patient/consumer perspective, it is important to assess whether a patient remained in the community after discharge and to separately report discharge to community rates. In addition to assessing the success of community discharges, the inclusion of post-discharge readmission and death outcomes is intended to avoid the potential unintended consequence of inappropriate discharges to the community.

Analysis on our measure development sample has shown that, of SNF patients discharged to the community, approximately 15 percent had an unplanned readmission in the post-discharge observation window. The mean number of days from SNF discharge to readmission was 12.2 with a standard deviation of 9.7; 25 percent of readmissions occurred within 3 days of SNF discharge, and 50 percent within 10 days. Ignoring these post-discharge readmissions occurring soon after discharge to community would fail to reflect our intent with this measure.

Comment: One commenter suggested that the discharge to community measure examine emergency room visits in the post-discharge observation window, in addition to unplanned readmissions. The commenter noted that this addition would impose no additional data collection burden on SNFs or hospitals, since these data are already collected by us.

Response: The discharge to community measure captures patients that are discharged to the community and remain in the community post-discharge. An emergency room visit that does not result in hospitalization would not be considered a failure to remain in the community. Nevertheless, we will assess emergency room visit rates in the post-discharge observation window to monitor for increasing rates, and potential indication of poor quality of care or inappropriate community discharges.

Comment: Some commenters had questions regarding death in the post-discharge window. One commenter requested clarification as to why an unexpected death, such as an accidental death, in the post-discharge observation window would count against a SNF's measure rate on the discharge to community measure. Another commenter recommended that the measure exclude patients who have been discharged to the community and expire within the post-discharge observation window. The commenter stated that the types of patients treated in SNFs varied greatly, and including post-discharge death in the measure could lead to an inaccurate reflection of the quality of care furnished by the SNF.

Response: Including 31-day post-discharge mortality outcomes is intended to identify successful discharges to community, and to avoid the potential unintended consequence of inappropriate community discharges. We have found, through our analyses on our measure development sample, that death in the 31 days following discharge to community is an infrequent event, with only 2.0 percent of SNF Medicare FFS beneficiaries discharged to community dying during that period. In addition, accidental or unrelated deaths in the post-discharge window are expected to be rare and randomly distributed. We do not expect such deaths to disproportionately affect measure rates for specific facilities. Finally, we do not expect facilities to achieve a 0 percent death rate in the measure's post-discharge observation window; however, one focus of the measure is to identify facilities with unexpectedly high rates of death for quality monitoring purposes.

Comment: A few commenters requested clarification on whether patients who are discharged to home under hospice care qualify as a discharge to community for the purposes of the measure. One commenter also requested clarification on how a patient who elects hospice care after SNF discharge but within the post-discharge observation window would be counted in the measure. Two commenters suggested that patients who die on hospice within the post-discharge observation window not be excluded from the discharge to community measures, but instead be considered successful discharges to the community. One commenter noted that dying at home is the preference of the majority of Americans, and nursing homes should not be penalized for helping a person choose where they want their life to end. The other commenter believed that excluding patients on hospice could create an incentive to keep dying individuals in a SNF or discharge them to the hospital.

Response: The discharge to community measure excludes patients discharged to home- or facility-based hospice care. Thus, discharges to hospice are not considered discharges to community, but rather are excluded from the measure calculation. We are are adding an exclusion of patients/residents with a hospice benefit in the post-discharge observation window to the proposed Discharge to Community—PAC SNF QRP measure, in response to

public comments received on this measure proposal, comments received during measure development, and our ongoing analysis and testing.

In response to commenters' concerns about the exclusion of hospice patients/residents, we would like to note that we that we reached the decision to exclude patients/residents discharged to hospice after discussion with our TEP members and hospice clinical experts, comparison of post-discharge death rates for hospice and non-hospice patients/residents, and comparison of discharge planning and goals of care for hospice and non-hospice patients/residents. We concluded that it would be conceptually confusing to include in the discharge to community outcome both patients/residents who are successfully rehabilitated to live in the community for whom death is an undesirable outcome, and patients/residents who are terminally ill, and wish to die in the comfort of their home. The rationale for the added exclusion of patients/residents with a post-discharge hospice benefit aligns with the rationale for exclusion of discharges to hospice.

Comment: One commenter suggested that the measure does not appropriately account for patients who seek other end-of-life care in the community, beyond hospice.

Response: There are no current data sources available that would enable us to identify patients seeking end-of-life care that is separate from hospice services.

Comment: One commenter suggested that we revise the measure name to reflect that it only applies to the Medicare FFS population. The commenter was concerned that, in many states, a large proportion of Medicare beneficiaries served by SNFs are not enrolled in Medicare FFS; thus, the measure may not reflect a SNF's overall discharge to community rate, but rather the discharge to community rate among FFS beneficiaries only.

Response: We will take the commenter's suggestion into consideration.

Comment: Several commenters had concerns that the risk adjustment methodology does not include adjustment for sociodemographic or socioeconomic status. Commenters noted the importance of home and community supports such as caregiver availability, willingness, and ability to support the person in the community, and availability of an established home in determining a beneficiary's ability to be discharged to community and remain in their home or community setting. Commenters believed that sociodemographic and socioeconomic factors were strong predictors of return to the community, and since they were outside a provider's control, they should be accounted for in risk adjustment. One commenter expressed concern that the measure does not adjust for regional differences in community-based needs and supports that result from factors such as geographic variance in availability of affordable housing. Another commenter suggested that the measure account for rurality, since limited alternative services may be available in rural areas, making discharge to community less feasible.

Response: We understand the importance of home and community supports and availability of housing for ensuring a successful discharge to community outcome. The discharge to community measure is a claims-based measure and, currently, there are no standardized data on variables such as living status, family and caregiver supports, or housing availability across across the four PAC settings. We appreciate and will consider the commenter's suggestion to account for potential challenges of discharging patients to the community in rural areas. As we refine the measure in the future, we will consider testing and adding additional relevant data sources and standardized items for risk adjustment of this measure. With regard to the suggestions regarding risk adjustment pertaining to sociodemographic and socioeconomic factors, we refer the readers to section III.D.2.f. for a more detailed discussion of the role of SES/SDS factors in risk adjustment of our measures.

Comment: One commenter raised concerns that the measure does not adjust for factors that are unique to certain specific provider types, such as providers offering dedicated services to specialty residents, for example, those with HIV/AIDS. The commenter noted that providers caring for these populations may encounter greater challenges in discharging patients to the community due to special needs such as affordable and safe housing, mental health and substance abuse counseling, and medication management and supports.

Response: We appreciate the commenters' suggestion that the discharge to community measure should adjust for providers primarily caring for specialty populations that may encounter greater challenges with discharge to community settings. Our risk adjustment model accounts for a comprehensive list of diagnoses and comorbidities, including HIV/AIDS. We will consider testing for an association between providers primarily caring for specialty populations and discharge to community outcomes as we refine this measure.

Comment: One commenter emphasized the relationship between functional gains made by patients during their SNF stay and their ability to discharge to the community. The commenter stated that return to one's previous home represents part of the goal of care; additionally, it is also important that the patient is able to function to the greatest possible extent in the home and community setting, and achieve the highest quality of life possible. The commenter recommended that we delay adopting this measure until it incorporates metrics that assess whether patients achieved their functional and independence goals based on their plan of care and their specific condition.

Many other commenters suggested that we include functional status in the risk adjustment for the discharge to community measure. Commenters noted that the literature demonstrates evidence that higher functional and cognitive status are strong predictors of individuals' ability to live independently, whereas lower functional status was a strong predictor of requiring long-term nursing home placement. Another commenter noted that functional status is associated with increased risk of 30-day all-cause hospital readmissions, and since readmissions and discharge to community are closely related, functional status risk adjustment is also important for this measure. One commenter suggested that the SNF and LTCH measures include risk adjustment that is similar to the risk adjustment for Case-Mix Groups (CMGs) in the IRF setting and Activities of Daily Living in the HHA setting. One commenter interpreted the measure proposal as stating that we will not adjust the quality measures, including the discharge to community measure, to account for functional status of beneficiaries until such data are collected under the IMPACT Act.

Response: We agree that it is important to assess various aspects of patient outcomes that are indicative of successful discharge from the SNF setting. We also agree that functional status may be related to discharge to community outcomes, and that it is important to test functional status risk adjustment when assessing discharge to community outcomes. The discharge to community measure does include functional status risk adjustment in the IRF setting using CMGs from claims, and in the home health setting using Activities of Daily Living from claims.

As mandated by the IMPACT Act, we are moving toward the goal of collecting standardized patient assessment data for functional status across PAC settings. Currently, the SNF Quality Reporting Program includes a process measure related to functional status assessment: 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). Once standardized functional status data become available across settings, it is our intent to use these data to assess patients' functional gains during their PAC stay, and to examine the relationship between functional status, discharge destination, and patients' ability to discharge to community. As we examine these relationships between functional outcomes and discharge to community outcomes in the future, we will assess the feasibility of leveraging these standardized patient assessment data to incorporate functional outcomes into the discharge to community measure. Standardized cross-setting patient assessment data will also allow us to examine interrelationships between the quality and resource use measures in each PAC setting, to understand how these measures are correlated.

Comment: One commenter stated that ventilator use is included as a risk adjuster in the LTCH setting only, but should be used across all settings. This commenter also requested information on the hierarchical logistic regression modeling and variables that will be used for risk adjustment.

Response: We would like to clarify that risk adjustment for ventilator use is included in both LTCH and SNF settings. We investigated the need for risk adjustment for ventilator use in IRFs, but found that less than 0.01 percent of the IRF population (19 patient stays in 2012, and 9 patient stays in 2013) had ventilator use in the IRF. Given the low frequency of ventilator use in IRFs, any associated estimates would not be reliable; thus, ventilator use is not included as a risk adjuster in the IRF setting measure. However, we will continue to assess this risk adjuster for inclusion in the IRF model for this measure.

For details on measure specifications, modeling, and calculations, we refer readers to the Measure Specifications for Measures Adopted in the FY 2017 SNF QRP Final Rule, posted on the CMS SNF QRP Web page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html*.

Comment: Two commenters conveyed concerns about unintended consequences of the discharge to community measure. One commenter was concerned about increased costs to the health care system in instances where patients have difficult transitions to community, have subsequent difficulty accessing SNF care, and experience costlier inpatient care as a consequence. Another commenter had concerns that the discharge to community measure may limit access to specialty services, limit access to care for low-income populations; create perverse incentives for providers; or impact the finances of post-acute care providers based on factors beyond their control. One commenter stated that effective risk adjustment would be important to avoid unintended consequences of decreased access for patients who may need a longer SNF stay.

Response: We appreciate the commenter's concerns regarding potential unintended consequences of the discharge to community measure. We expect that, on average, discharges to community settings rather than institutional settings will result in lower healthcare costs. To avoid potential unintended consequences of inappropriate discharges to the community, this measure examines acute care and LTCH readmissions and death in the 31-day post-discharge observation window; the measure thus incentivizes providers to ensure safe transitions to the community without post-discharge unplanned readmissions. In future modifications of the measure, we will consider looking for IRF, SNF, and nursing facility admissions and readmissions in the 31-day post-discharge window when examining discharge to community outcomes. With regard to the commenter's concern that the measure may result in decreased access for patients who may need a longer SNF stay, we would like to clarify that the measure does not examine the length of a SNF stay and does not incentivize facilities to avoid patients/residents who may need a longer stay in the facility. The measure examines discharge destination from the SNF, irrespective of their length of stay.

As with all our measures, we will monitor for unintended consequences as part of measure monitoring and evaluation to ensure that measures do not reduce quality of care or access for patients, result in disparities for certain patient sub-groups, or adversely affect healthcare spending.

Comment: One commenter conveyed appreciation that the measure would be revised using an ICD–9 to ICD–10 crosswalk.

Response: We thank the commenter for their appreciation of proposed measure updates using the ICD–9 to ICD–10 crosswalk, as stated in the Proposed Measure Specifications for Measures Proposed in the FY 2017 SNF QRP Proposed Rule.

Comment: One commenter encouraged us to provide PAC settings with access to measure performance data as early as possible so providers have time to adequately review these data, and implement strategies to decrease readmissions where necessary.

Response: We intend to provide initial confidential feedback to PAC providers, prior to public reporting of this measure, based on Medicare FFS claims data from discharges in CY 2016.

Comment: Several commenters expressed concern about the lack of NQF endorsement for the measure, and suggested additional measure testing and development. One commenter requested that we provide a timeline for submission of the proposed measures to NQF. Additionally, commenters recommended NQF endorsement prior to implementation or public reporting.

Response: We thank the commenter for their comments regarding NQF endorsement. We would like to clarify that the discharge to community measure has been fully developed and tested. We plan to submit the Discharge to Community—PAC SNF QRP measure to the NQF for consideration for endorsement.

Final Decision: After careful consideration of the public comments, we are finalizing our proposal to adopt the measure, Discharge to Community—PAC SNF QRP as a Medicare FFS claims-based measure for the FY 2018 payment determination and subsequent years, with the added exclusion of residents with a hospice benefit in the 31-day post-discharge observation window. For measure specifications, we refer readers to the Measure Specifications for Measures Adopted in the FY 2017 SNF QRP Final Rule, posted on the CMS SNF QRP Web page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html*.

iii. Measure To Address the IMPACT Act Domain of Resource Use and Other Measures: Potentially Preventable 30-Day Post-Discharge Readmission Measure for Skilled Nursing Facility Quality Reporting Program

Sections 1899B(a)(2)(E)(ii) and 1899B(d)(1)(C) of the Act require the Secretary to specify measures to address the domain of all-condition risk-adjusted potentially preventable hospital readmission rates by SNFs, LTCHs, and IRFs by October 1, 2016, and HHAs by January 1, 2017. We proposed the measure Potentially Preventable 30-Day Post-Discharge Readmission Measure for SNF QRP as a Medicare FFS claims-based measure to meet this requirement for the FY 2018 payment determination and subsequent years.

The measure assesses the facility-level risk-standardized rate of unplanned, potentially preventable hospital readmissions for Medicare FFS beneficiaries in the 30 days post-SNF discharge. The SNF admission must have occurred within up to 30 days of discharge from a prior proximal hospital stay which is defined as an inpatient admission to an acute care hospital (including IPPS, CAH, or a psychiatric hospital). Hospital readmissions include readmissions to a short-stay acute care hospitals or an LTCH, with a diagnosis considered to be unplanned and potentially preventable. This measure is claims-based, requiring no additional data collection or submission burden for SNFs. Because the measure denominator is based on SNF admissions, each Medicare beneficiary may be included in the measure multiple times within the measurement period. Readmissions counted in this measure are identified by examining Medicare FFS claims data for readmissions to either acute care hospitals (IPPS or CAH) or LTCHs that occur during a 30-day window beginning two days after SNF discharge. This measure is conceptualized uniformly across the PAC settings, in terms of the measure definition, the approach to risk adjustment, and the measure calculation. Our approach for defining potentially preventable hospital readmissions is described in more detail below.

Hospital readmissions among the Medicare population, including beneficiaries that utilize PAC, are common, costly, and often preventable.[86] [87] MedPAC and a study by Jencks et al. estimated that 17 to 20 percent of Medicare beneficiaries discharged from the hospital were readmitted within 30 days. MedPAC found that more than 75 percent of 30-day and 15-day readmissions and 84 percent of 7-day readmissions were considered ''potentially preventable.'' [88] In addition, MedPAC calculated that annual Medicare spending on potentially preventable readmissions would be $12 billion for 30-day, $8 billion for 15-day, and $5 billion for 7-day readmissions in 2005.[89] For hospital readmissions from SNFs, MedPAC deemed 76 percent of readmissions as ''potentially avoidable''—associated with $12 billion in Medicare expenditures.[90] Mor et al. analyzed 2006 Medicare claims and SNF assessment data (Minimum Data Set), and reported a 23.5 percent readmission rate from SNFs, associated with $4.3 billion in expenditures.[91] Fewer studies have investigated potentially preventable readmission rates from the remaining post-acute care settings.

We have addressed the high rates of hospital readmissions in the acute care setting, as well as in PAC. For example, we developed the following measure: Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM) (NQF #2510), as well as similar measures for other PAC providers (NQF #2502 for IRFs and NQF #2512 for LTCHs).[92] These measures are endorsed by the NQF, and the NQF endorsed SNF measure (NQF #2510) was adopted into the SNF VBP Program in the FY 2016 SNF final rule (80 FR 46411 through 46419). Note that these NQF endorsed measures assess all-cause unplanned readmissions.

Several general methods and algorithms 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, approaches developed by MedPAC, and proprietary approaches, such as the 3M™ algorithm for Potentially Preventable Readmissions.[93] [94] [95] Recent work led by Kramer et al. for MedPAC identified 13 conditions for which readmissions were deemed as potentially preventable among SNF and IRF populations.[96] [97] Although much of the existing literature addresses hospital readmissions more broadly and potentially avoidable hospitalizations for specific settings like long-term care, these findings are relevant to the development of potentially preventable readmission measures for PAC.[98] [99] [100]

Potentially Preventable Readmission Measure Definition: We conducted a comprehensive environmental scan, analyzed claims data, and obtained input from a TEP to develop a definition and list of conditions for which hospital readmissions are potentially preventable. The Ambulatory Care Sensitive Conditions and Prevention Quality Indicators, developed by AHRQ, served as the starting point in this work. For patients in the 30-day post-PAC

[86] Friedman, B., and Basu, J.: The rate and cost of hospital readmissions for preventable conditions. *Med. Care Res. Rev.* 61(2):225–240, 2004. doi:10.1177/1077558704263799.

[87] Jencks, S.F., Williams, M.V., and Coleman, E.A.: Rehospitalizations among patients in the Medicare Fee-for-Service Program. *N. Engl. J. Med.* 360(14):1418–1428, 2009. doi:10.1016/j.jvs.2009.05.045.

[88] MedPAC: Payment policy for inpatient readmissions, in *Report to the Congress: Promoting Greater Efficiency in Medicare.* Washington, DC, pp. 103–120, 2007. Available from *http://www.medpac.gov/documents/reports/Jun07_EntireReport.pdf.*

[89] ibid.

[90] ibid.

[91] Mor, V., Intrator, O., Feng, Z., et al.: The revolving door of rehospitalization from skilled nursing facilities. *Health Aff.* 29(1):57–64, 2010. doi:10.1377/hlthaff.2009.0629.

[92] National Quality Forum: *All-Cause Admissions and Readmissions Measures.* pp. 1–319, April 2015. Available from *http://www.qualityforum.org/Publications/2015/04/All-Cause_Admissions_and_Readmissions_Measures_-_Final_Report.aspx.*

[93] 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/.*

[94] Agency for Healthcare Quality and Research: *Prevention Quality Indicators Overview.* 2008.

[95] 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.*

[96] Kramer, A., Lin, M., Fish, R., et al.: *Development of Inpatient Rehabilitation Facility Quality Measures: Potentially Avoidable Readmissions, Community Discharge, and Functional Improvement.* pp. 1–42, 2015. Available from *http://www.medpac.gov/documents/contractor-reports/development-of-inpatient-rehabilitation-facility-quality-measures-potentially-avoidable-readmissions-community-discharge-and-functional-improvement.pdf?sfvrsn=0.*

[97] Kramer, A., Lin, M., Fish, R., et al.: *Development of Potentially Avoidable Readmission and Functional Outcome SNF Quality Measures.* pp. 1–75, 2014. Available from *http://www.medpac.gov/documents/contractor-reports/mar14_snfqualitymeasures_contractor.pdf?sfvrsn=0.*

[98] Allaudeen, N., Vidyarthi, A., Maselli, J., et al.: Redefining readmission risk factors for general medicine patients. *J. Hosp. Med.* 6(2):54–60, 2011. doi:10.1002/jhm.805.

[99] Gao, J., Moran, E., Li, Y.-F., et al.: Predicting potentially avoidable hospitalizations. *Med. Care* 52(2):164–171, 2014. doi:10.1097/MLR.0000000000000041.

[100] 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.x.

discharge period, a potentially preventable readmission (PRR) refers to a readmission for which the probability of occurrence could be minimized with adequately planned, explained, and implemented post discharge instructions, including the establishment of appropriate follow-up ambulatory care. Our list of PPR conditions is categorized by 3 clinical rationale groupings:

- Inadequate management of chronic conditions;
- Inadequate management of infections; and
- Inadequate management of other unplanned events.

Additional details regarding the definition for potentially preventable readmissions are available in the document titled, Proposed Measure Specifications for Measures Proposed in the FY 2017 SNF QRP Proposed Rule, available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html*.

This measure focuses on readmissions that are potentially preventable and also unplanned. Similar to the SNF 30-Day All-Cause Readmission Measure (NQF #2510), this measure uses the current version of the CMS Planned Readmission Algorithm as the main component for identifying planned readmissions. A complete description of the CMS Planned Readmission Algorithm, which includes lists of planned diagnoses and procedures, can be found on the CMS Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. In addition to the CMS Planned Readmission Algorithm, this measure incorporates procedures that are considered planned in post-acute care settings, as identified in consultation with TEPs. Full details on the planned readmissions 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 Measure Specifications for Measures Proposed in the FY 2017 SNF QRP Proposed Rule at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html*.

This measure, Potentially Preventable 30-Day Post-Discharge Readmission Measure for Skilled Nursing Facility Quality Reporting Program, assesses potentially preventable readmission rates while accounting for patient demographics, principal diagnosis in the prior hospital stay, comorbidities, and other patient factors. While estimating the predictive power of patient characteristics, the model also estimates a facility-specific effect, common to patients treated in each facility. This measure is calculated for each SNF based on the ratio of the predicted number of risk-adjusted, unplanned, potentially preventable hospital readmissions that occur within 30 days after a SNF discharge, including the estimated facility effect, to the estimated predicted number of risk-adjusted, unplanned inpatient hospital readmissions for the same patients treated at the average SNF. A ratio above 1.0 indicates a higher than expected readmission rate (worse) while a ratio below 1.0 indicates a lower than expected readmission rate (better). This ratio is referred to as the standardized risk ratio (SRR). The SRR is then multiplied by the overall national raw rate of potentially preventable readmissions for all SNF stays. The resulting rate is the risk-standardized readmission rate (RSRR) of potentially preventable readmissions.

An eligible SNF stay is followed until: (1) The 30-day post-discharge period ends; or (2) the patient is readmitted to an acute care hospital (IPPS or CAH) or LTCH. If the readmission is unplanned and potentially preventable, it is counted as a readmission in the measure calculation. If the readmission is planned, the readmission is not counted in the measure rate.

This measure is risk adjusted. The risk adjustment modeling estimates the effects of patient characteristics, comorbidities, and select health care variables on the probability of readmission. More specifically, the risk-adjustment model for SNFs accounts for demographic characteristics (age, sex, original reason for Medicare entitlement), principal diagnosis during the prior proximal hospital stay, body system specific surgical indicators, comorbidities, length of stay during the patient's prior proximal hospital stay, intensive care unit (ICU) utilization, end-stage renal disease status, and number of acute care hospitalizations in the preceding 365 days.

This measure is calculated using 1 calendar year of FFS claims data, to ensure the statistical reliability of this measure for facilities. In addition, we proposed a minimum of 25 eligible stays for public reporting of the measure.

A TEP convened by our measure development contractor provided recommendations on the technical specifications of this measure, including the development of an approach to define potentially preventable hospital readmission for PAC. 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 Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*. We also solicited stakeholder feedback on the development of this measure through a public comment period held from November 2 through December 1, 2015. Comments on the measure varied, with some commenters supportive of the measure, while others either were not in favor of the measure, or suggested potential modifications to the measure specifications, such as including standardized function data. A summary of the public comments is also available on the CMS Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

The MAP encouraged continued development of the measure. Specifically, the MAP stressed the need to promote shared accountability and ensure effective care transitions. More information about the MAP's recommendations for this measure is available at *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC–LTC.aspx*. At the time, the risk-adjustment model was still under development. Following completion of that development work, we were able to test for measure validity and reliability as identified in the measure specifications document provided above. Testing results are within range for similar outcome measures finalized in public reporting and value-based purchasing programs, including the SNFRM (NQF #2510) adopted into the SNF VBP Program in the FY 2016 SNF final rule (80 FR 46411 through 46419).

We reviewed the NQF's consensus endorsed measures and were unable to identify any NQF endorsed measures focused on potentially preventable

hospital readmissions. We are unaware of any other measures for this IMPACT Act domain that have been endorsed or adopted by other consensus organizations. Therefore, we proposed the Potentially Preventable 30-Day Post-Discharge Readmission Measure for SNF QRP, under the Secretary's authority to specify non-NQF-endorsed measures under section 1899B(e)(2)(B) of the Act, for the SNF QRP for the FY 2018 payment determination and subsequent years given the evidence previously discussed above.

We plan to submit the measure to the NQF for consideration of endorsement. We stated in the proposed rule that we intended to provide initial confidential feedback to SNFs, prior to public reporting of this measure, based on 1 calendar year of claims data from discharges in CY 2016. We also stated that we intended to publicly report this measure using claims data from CY 2017.

We invited public comment on our proposal to adopt the measure, Potentially Preventable 30-Day Post-Discharge Readmission Measure for SNF QRP. We received several comments, which are summarized with our responses below.

Comment: MedPAC and several other commenters expressed general support for the proposed Potentially Preventable 30-Day Post-Discharge Readmission Measure for SNF QRP. One commenter noted that the PPR measure would supplement the all-cause readmission measure by creating an incentive for SNFs to focus attention on managing SNF residents that are chronically ill as well as to manage or avoid infections. Some commenters specifically supported the post-PAC discharge readmission window, noting that SNFs should be accountable for safe transitions to the community or next care setting.

Response: We thank commenters for their support of this measure.

Comment: One commenter specifically supported the inclusion of infectious conditions in the ''inadequate management of infections'' and ''inadequate management of other unplanned events'' categories in the measure's definition of potentially preventable hospital readmissions. Another commenter expressed support for the inclusion of chronic conditions and infections as conditions for which readmissions would be considered potentially preventable. Another commenter expressed appreciation for the focus on preventable readmissions, but urged us to continue evaluating and testing the measure to ensure that the codes used for the PPR definition are clinically relevant. One commenter expressed concern over being ''penalized'' for readmissions that are clinically unrelated to a patient's original reason for SNF admission.

Response: We thank commenters for their support of this measure domain and the list of PPR conditions developed for this measure. Though readmissions may be considered potentially preventable even if they may not appear to be clinically related to the patient's original reason for SNF admission, there is substantial evidence that the conditions included in the definition may be preventable with adequately planned, explained, and implemented post-discharge instructions, including the establishment of appropriate follow-up ambulatory care. Furthermore, this measure is based on Medicare FFS claims data, and it may not always be feasible to determine whether a subsequent readmission is or is not clinically related to the reason why the patient was receiving SNF care. We intend to conduct ongoing evaluation and monitoring of this measure.

Comment: Several commenters expressed concern over the cross-setting alignment of the proposed PPR measures. One commenter encouraged us to assess readmission measures across the agency's programs to ensure that they promote collaboration and support readmission reduction efforts. MedPAC commented that the measure definition and risk adjustment should be identical across PAC settings so that potentially preventable readmission rates can be compared across settings. Another commenter expressed concern specifically over the ''nonalignment'' between the IRF and SNF versions of the measure, adding that this may lead to confusion.

Response: The PPR definition (that is, list of conditions for which readmissions would be considered potentially preventable) is aligned for measures with the same readmission window, regardless of PAC setting. Specifically, the post-PAC discharge PPR measures that were developed for each of the PAC settings contain the same list of PPR conditions. Although there are some minor differences in the specifications across the measures (for example, years of data used to calculate the measures to ensure reliability and some of the measure exclusions necessary to attribute responsibility to the individual settings), the IMPACT Act PPR measures are standardized. As described for all IMPACT Act measures in section III.D.2.f., the statistical approach for risk adjustment is also aligned across the measures; however, there is variation in the exact risk adjusters. The risk-adjustment models are empirically driven and differ between measures as a consequence of case mix differences, which is necessary to ensure that the estimates are valid.

Comment: One commenter expressed concern that the post-discharge readmission window provides an opportunity for patient health to decline following discharge due to factors beyond providers' control, including patient behavior, noting these factors vary considerably among patients. The commenter suggested the measure reflect the shared responsibility of all parties involved in a patient's care, such as caregivers and the patients themselves. The commenter also suggested we clarify how patients that expire within the readmission window are handled in the measure.

Response: The focus of the PPR measure is to identify excess PPR rates for the purposes of quality improvement. There is substantial evidence that certain readmissions can be prevented with adequately planned, explained, and implemented post-discharge instructions, including the establishment of appropriate follow-up ambulatory care. We are aware that there are certain patient characteristics that may increase the risk of readmission, and a number of these conditions are accounted for in the risk-adjustment model. We would also like to clarify that patients who expire during the SNF stay are excluded because there is no post-SNF discharge window to observe the outcome. However, we do include patients that expire during the post-SNF discharge readmission window to assess the outcome as it is relevant for all patients discharged from SNFs. This is also consistent with other NQF-endorsed readmission measures.

Comment: Several commenters raised concerns over the risk-adjustment approach for the PPR measures, urging us to incorporate factors such as cognitive and functional status, supply variables, and SES/SDS factors into the measure's risk adjustment. One commenter noted that assessment instruments, such as the MDS, provide data sources for various patient clinical characteristics. Furthermore, the commenter expressed that because the IMPACT Act mandates the standardization of assessment instruments, the IMPACT Act measures should incorporate standardized items as risk adjusters.

Another commenter supported the proposed risk-adjustment methodology commenting that it will provide a valid assessment of quality of care in

preventing unplanned, preventable hospital readmissions.

Response: The risk-adjustment model takes into account medical complexity, as patients with multiple risk factors will rate as having higher risk of readmission. For those cross-setting post-acute measures such as those intended to satisfy the IMPACT Act domains that use the patient assessment-based data elements for risk adjustment, we have either made such items standardized, or intend to do so as feasible. We wish to note that we intend to evaluate the feasibility of including functional and cognitive status when standardized assessment data become available. With regard to the suggestions pertaining to risk adjustment methodologies pertaining to sociodemographic factors we refer the readers to section section III.D.2.f. where we also discuss these topics.

Comment: Some commenters cautioned against potential unintended consequences of the measure, in particular, noting that the measure could incentivize SNFs to delay necessary readmission to the hospital or prolong the SNF stay. One commenter noted that the measure could cause SNFs to be selective about the patients they admit (that is, ''cherry pick'' their patients), and suggested that an appropriate risk adjustment could prevent this.

Response: We intend to conduct ongoing monitoring to assess for potential unintended consequences associated with the implementation of this measure, and we will take these suggestions into account. A major goal of risk adjustment is to ensure that patient case mix is taken into account in order to allow for fair comparisons of facilities. The risk of readmission for patients in poor health is taken into account by the risk-adjustment model used in the calculation of this measure. Given this is a post-SNF discharge measure, SNFs would have no incentive to delay hospital readmissions.

Comment: One commenter suggested that the PPR measure incorporate both inpatient and emergency room (ER) visits because a measure that captures both would be more understandable to consumers. Another expressed concern regarding overlap between the proposed PPR measure and the discharge to community measure, and the implications for quality improvement.

Response: We appreciate the comment suggesting that the measure include inpatient as well as ER visits. However, we wish to clarify that the PPR measure was developed to fulfill the IMPACT Act's statutory requirement for a measure to address the domain of potentially preventable hospital readmissions. We agree that ER or emergency department visits are also an important outcome, but they are not hospital readmissions.

We discuss above the similarities and differences between the PPR and discharge to community measure. Although there are conceptual similarities between the measures, we believe that each measure provides important information for quality improvement purposes and will enable SNFs to target different aspects of care provided.

Comment: One commenter provided comments on the statistical approach used to calculate the measure, recommending that we use the actual readmission rate (that is, observed) as the numerator of the SRR rather than the predicted number of readmissions, or provide evidence to justify this more complicated methodology. The commenter acknowledged the aims of the risk-adjustment model but suggested using the actual instead of the predicted number of readmissions so that the numerator of the SRR is clearer and more actionable for facilities, and is not likely to result in substantial changes to the relative ranking of facilities. The same commenter also indicated support for the current minimum denominator size—25 patients—for public reporting but suggested that a minimum size of 30 would improve the reliability of the measurement.

Response: The statistical approach for this measure, including the use of the predicted to expected readmission rate, is used in several other readmission measures, including the SNFRM (NQF #2510) and other NQF-endorsed readmission measures. Not using this approach would render providers with small numbers of eligible patient stays excessively vulnerable to reported rates driven by the influence of random variation in performance, limiting the value of the public reporting their measure performance. We would also like to note that facilities will be given their observed rates in their reports.

We acknowledge that increasing the minimum denominator size for public reporting of this measure may increase the reliability of the measure, but doing so would prevent a substantial number of facilities from reporting this measure.

Comment: One commenter commented that we should not finalize this measure because the measure was still under development and the MAP did not vote to support it, but instead encouraged continued development. In addition, this commenter said we should submit the measure for NQF endorsement and only propose NQF endorsed measures. Another commenter encouraged additional testing and evaluation of the measure prior to implementation.

Response: We intend to submit this measure to NQF for consideration of endorsement. Although the measure is not currently endorsed, we did conduct additional testing subsequent to the MAP meeting. Based on that testing, we were able to complete the risk adjustment model and evaluate facilities' PPR rates, and we made the results of our analyses available at the time of the proposed rule. We found that testing results were similar to the SNFRM (NQF #2510) and allowed us to conclude that the measure is sufficiently developed, valid and reliable for adoption in the SNF QRP.

Comment: One commenter expressed concern that we used language that suggested all readmissions are preventable and recommends the use of the term ''may be avoidable'' in place of ''should be avoidable'' in describing readmissions. The commenter was concerned that the language used would imply that the goal of the measure is for providers to reach zero percent PPR.

Another commenter expressed concern about the accuracy of claims-based data, but supported the effort to limit the data collection burden placed on providers.

Response: We agree with the commenter that this is a measure of potentially preventable readmissions and that not all readmissions are preventable. We wish to clarify that the PPR rate is not expected to be 0. The goal of the measure is to identify excess PPR rates for the purposes of quality improvement.

With respect to the use of claims data to calculate this measure, multiple studies have been conducted to examine the validity of using Medicare hospital claims to calculate several NQF endorsed quality measures for public reporting.[101] [102] [103] These studies supported the use of claims data as a valid means for risk adjustment and assessing similar outcomes. Additionally, although assessment and other data sources may be valuable for

[101] Bratzler DW, Normand SL, Wang Y, *et al.* An administrative claims model for profiling hospital 30-day mortality rates for pneumonia patients. PLoS One 2011;6(4):e17401.

[102] Keenan PS, Normand SL, Lin Z, *et al.* An administrative claims measure suitable for profiling hospital performance on the basis of 30-day all-cause readmission rates among patients with heart failure. Circulation 2008;1(1):29–37.

[103] Krumholz HM, Wang Y, Mattera JA, *et al.* An administrative claims model suitable for profiling hospital performance based on 30-day mortality rates among patients with heart failure. Circulation 2006;113:1693–1701.

risk adjustment, we are not aware of another data source aside from Medicare claims data that could be used to reliably assess the outcome of potentially preventable hospital readmissions post-SNF discharge.

Final Decision: After careful consideration of the public comments, we are finalizing our proposal to adopt the measure, Potentially Preventable 30-Day Post-Discharge Readmission Measure for SNF QRP beginning with the FY 2018 payment determination. Measure Specifications for Measures Adopted in the FY 2017 SNF QRP Final Rule are available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html*.

g. SNF QRP Quality Measure Finalized for the FY 2020 Payment Determination and Subsequent Years

We proposed to adopt one new quality measure to meet the requirements of the IMPACT Act for the FY 2020 payment determination and subsequent years. The measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP, addresses the IMPACT Act quality domain of Medication Reconciliation.

1. Quality Measure Addressing the IMPACT Act Domain of Medication Reconciliation: Drug Regimen Review Conducted With Follow-Up for Identified Issues—Post Acute Care (PAC) Skilled Nursing Facility Quality Reporting Program

Sections 1899B (a)(2)(E)(i)(III) and 1899B(c)(1)(C) of the Act require the Secretary to specify a quality measure to address the domain of medication reconciliation by October 1, 2018 for IRFs, LTCHs and SNFs; and by January 1, 2017 for HHAs. We proposed to adopt the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PPAC SNF QRP, for the SNF QRP as a resident-assessment based, cross-setting quality measure to meet the IMPACT Act requirements with data collection beginning October 1, 2018 for the FY 2020 payment determinations and subsequent years.

This measure assesses whether PAC providers were responsive to potential or actual clinically significant medication issue(s) when such issues were identified. Specifically, the proposed quality measure reports the percentage of resident stays in which a drug regimen review was conducted at the time of admission and timely follow-up with a physician occurred each time potential clinically significant medication issues were identified throughout that stay. For this proposed quality measure, a drug regimen review is defined as the review of all medications or drugs the patient is taking to identify any potential clinically significant medication issues. This proposed quality measure utilizes both the processes of medication reconciliation and a drug regimen review, in the event an actual or potential medication issue occurred. The measure informs whether the PAC facility identified and addressed each clinically significant medication issue and if the facility responded or addressed the medication issue in a timely manner. Of note, drug regimen review in PAC settings is generally considered to include medication reconciliation and review of the patient's drug regimen to identify potential clinically significant medication issues.[104] (Please note: In the proposed rule, footnote 94 was inadvertently labeled *ibid,* which attributed the reference to the American Geriatric Society. In this final rule, we have corrected the reference and replaced it with the intended one, Institute of Medicine. Preventing Medication Errors. Washington, DC: National Academies Press; 2006.) This measure is applied uniformly across the PAC settings.

Medication reconciliation is a process of reviewing an individual's complete and current medication list. Medication reconciliation is a recognized process for reducing the occurrence of medication discrepancies that may lead to Adverse Drug Events (ADEs).[105] Medication discrepancies occur when there is conflicting information documented in the medical records. The World Health Organization regards medication reconciliation as a standard operating protocol necessary to reduce the potential for ADEs that cause harm to patients. Medication reconciliation is an important patient safety process that addresses medication accuracy during transitions in resident care and in identifying preventable ADEs.[106] The Joint Commission added medication reconciliation to its list of National Patient Safety Goals (2005), suggesting that medication reconciliation is an integral component of medication safety.[107] The Society of Hospital Medicine published a statement in agreement of the Joint Commission's emphasis and value of medication reconciliation as a patient safety goal.[108] There is universal agreement that medication reconciliation directly addresses resident safety issues that can result from medication miscommunication and unavailable or incorrect information.[109] [110] [111]

The performance of timely medication reconciliation is valuable to the process of drug regimen review. Preventing and responding to ADEs is of critical importance as ADEs account for significant increases in health services utilization and costs [112] [113] [114] including subsequent emergency room visits and re-hospitalizations.[115] Annual health care costs from ADEs in the United States are estimated at $3.5 billion, resulting in 7,000 deaths annually.[116]

Medication errors include the duplication of medications, delivery of an incorrect drug, inappropriate drug omissions, or errors in the dosage, route, frequency, and duration of medications. Medication errors are one of the most common types of medical errors and can occur at any point in the process of ordering and delivering a medication. Medication errors have the potential to

[104] Institute of Medicine. Preventing Medication Errors. Washington, DC: National Academies Press; 2006.

[105] Ibid.

[106] Leotsakos A., *et al.* Standardization in patient safety: The WHO High 5s project. Int J Qual Health Care. 2014:26(2):109–116.

[107] The Joint Commission. 2016 Long Term Care: National Patient Safety Goals Medicare/Medicaid Certification-based Option. (NPSG.03.06.01).

[108] Greenwald, J.L., Halasyamani, L., Greene, J., LaCivita, C., *et al.* (2010). Making inpatient medication reconciliation patient centered, clinically relevant and implementable: A consensus statement on key principles and necessary first steps. Journal of Hospital Medicine, 5(8), 477–485.

[109] Leotsakos A., *et al.* Standardization in patient safety: The WHO High 5s project. Int J Qual Health Care. 2014:26(2):109–116.

[110] The Joint Commission. 2016 Long Term Care: National Patient Safety Goals Medicare/Medicaid Certification-based Option. (NPSG.03.06.01).

[111] IHI. Medication Reconciliation to Prevent Adverse Drug Events [Internet]. Cambridge, MA: Institute for Healthcare Improvement; [cited 2016 Jan 11]. Available from: *http://www.ihi.org/topics/adesmedicationreconciliation/Pages/default.aspx*.

[112] Institute of Medicine. Preventing Medication Errors. Washington, DC: National Academies Press; 2006.

[113] Jha AK, Kuperman GJ, Rittenberg E, *et al.* Identifying hospital admissions due to adverse drug events using a computer-based monitor. Pharmacoepidemiol Drug Saf. 2001;10(2):113–119.

[114] Hohl CM, Nosyk B, Kuramoto L, *et al.* Outcomes of emergency department patients presenting with adverse drug events. Ann Emerg Med. 2011;58:270–279.

[115] Kohn LT, Corrigan JM, Donaldson MS. To Err Is Human: Building a Safer Health System Washington, DC: National Academies Press; 1999.

[116] Greenwald, J.L., Halasyamani, L., Greene, J., LaCivita, C., et al. (2010). Making inpatient medication reconciliation patient centered, clinically relevant and implementable: A consensus statement on key principles and necessary first steps. Journal of Hospital Medicine, 5(8), 477–485.

result in an ADE.[117] [118] [119] [120] [121] [122] Inappropriately prescribed medications are also considered a major healthcare concern in the United States for the elderly population, with costs of roughly $7.2 billion annually.[123]

There is strong evidence that medication discrepancies occur during transfers from acute care facilities to post-acute care facilities. Discrepancies occur when there is conflicting information documented in the medical records. Almost one-third of medication discrepancies have the potential to cause patient harm.[124] Medication discrepancies upon admission to SNFs have been reported as occurring at a rate of more than 21 percent. It has been found that at least one medication discrepancy occurred in more than 71 percent of all the SNF admissions.[125] An estimated fifty percent of patients experienced a clinically important medication error after hospital discharge in an analysis of two tertiary care academic hospitals.[126]

Medication reconciliation has been identified as an area for improvement during transfer from the acute care facility to the receiving post-acute care facility. Post-acute care facilities report gaps in medication information between the acute care hospital and the receiving post-acute care setting when performing medication reconciliation.[127] [128] Hospital discharge has been identified as a particularly high risk point in time, with evidence that medication reconciliation identifies high levels of discrepancy.[129] [130] [131] [132] [133] [134] Also, there is evidence that medication reconciliation discrepancies occur throughout the patient stay.[135] [136] For older patients who may have multiple comorbid conditions and thus multiple medications, transitions between acute and post-acute care settings can be further complicated,[137] and medication reconciliation and patient knowledge (medication literacy) can be inadequate post-discharge.[138] The proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP, provides an important component of care coordination for PAC settings and would affect a large proportion of the Medicare population who transfer from hospitals into PAC services each year. For example, in 2013, 1.7 million Medicare FFS beneficiaries had SNF stays, 338,000 beneficiaries had IRF stays, and 122,000 beneficiaries had LTCH stays.[139]

A TEP convened by our measure development contractor provided input on the technical specifications of this proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP, including components of reliability, validity and the feasibility of implementing the measure across PAC settings. The TEP supported the measure's implementation across PAC settings and was supportive of our plans to standardize this measure for cross-setting development. A summary of the TEP proceedings is available on the PAC Quality Initiatives Downloads and Video Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We solicited stakeholder feedback on the development of this measure by means of a public comment period held from September 18 through October 6, 2015. Through public comments submitted by several stakeholders and organizations, we received support for implementation of this measure. The public comment summary report for the measure is available on the CMS Public Comment Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

The NQF-convened MAP met on December 14 and 15, 2015 and provided input on the use of this proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP. The MAP encouraged continued development of the proposed quality measure to meet the mandate added by the IMPACT Act. The MAP agreed with the measure gaps identified by us including medication reconciliation, and stressed that medication reconciliation be present as an ongoing process. More information about the MAPs recommendations for this measure is available at *http://www.qualityforum.org/Publications/2016/02/*

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[135] Bates DW, Cullen DJ, Laird N, Petersen LA, Small SD, *et al.* Incidence of adverse drug events and potential adverse drug events. Implications for prevention. JAMA. 1995:274(1): 29–34.

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MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx.

Since the MAP's review and recommendation of continued development, we have continued to refine this measure consistent with the MAP's recommendations. The measure is consistent with the information submitted to the MAP and support its scientific acceptability for use in quality reporting programs. Therefore, we proposed this measure for implementation in the SNF QRP as required by the IMPACT Act.

We reviewed the NQF's endorsed measures and identified one NQF-endorsed cross-setting quality measure related to medication reconciliation, which applies to the SNF, LTCH, IRF, and HHA settings of care: Care for Older Adults (COA) (NQF #0553). The quality measure, Care for Older Adults (COA) (NQF #0553) assesses the percentage of adults 66 years and older who had a medication review. The Care for Older Adults (COA) (NQF #0553) measure requires at least one medication review conducted by a prescribing practitioner or clinical pharmacist during the measurement year and the presence of a medication list in the medical record. This is in contrast to the proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP, which reports the percentage of resident stays in which a drug regimen review was conducted at the time of admission and that timely follow-up with a physician occurred each time one or more potential clinically significant medication issues were identified throughout that stay.

After careful review of both quality measures, we decided to propose the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP for the following reasons:

- The IMPACT Act requires the implementation of quality measures using patient assessment data that are standardized and interoperable across PAC settings. The quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP, employs three standardized resident-assessment data elements for each of the four PAC settings so that data are standardized, interoperable, and comparable; whereas, the Care for Older Adults (COA), (NQF #0553) quality measure does not contain data elements that are standardized across all four PAC settings.
- The quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP, requires the identification of potential clinically significant medication issues at the beginning, during and at the end of the resident's stay to capture data on each resident's complete PAC stay; whereas, the Care for Older Adults (COA), (NQF #0553) quality measure only requires annual documentation in the form of a medication list in the medical record of the target population.
- The quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP, includes identification of the potential clinically significant medication issues and communication with the physician (or physician designee), as well as resolution of the issue(s) within a rapid timeframe (by midnight of the next calendar day); whereas, the Care for Older Adults (COA), (NQF #0553) quality measure does not include any follow-up or timeframe in which the follow-up would need to occur.
- The quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP, does not have age exclusions; whereas, the Care for Older Adults (COA), (NQF #0553) quality measure limits the measure's population to patients aged 66 and older.
- The quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP, will be reported to SNFs quarterly to facilitate internal quality monitoring and quality improvement in areas such as resident safety, care coordination and resident satisfaction; whereas, the Care for Older Adults (COA), (NQF #0553) quality measure would not enable quarterly quality updates, and thus data comparisons within and across PAC providers would be difficult due to the limited data and scope of the data collected.

Therefore, based on the evidence discussed above, we proposed to adopt the quality measure entitled, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP, for the SNF QRP for FY 2020 payment determination and subsequent years. We plan to submit the quality measure to the NQF for consideration for endorsement.

The calculation of the proposed quality measure would be based on the data collection of three standardized items to be included in the MDS. The collection of data by means of the standardized items would be obtained at admission and discharge. For more information about the data submission required for this measure, please see section V.B.9. of the FY 2017 SNF PPS proposed rule (81 FR 24270 through 24273).

The standardized items used to calculate this proposed quality measure do not duplicate existing items currently used for data collection within the MDS. The measure denominator is the number of resident stays with a discharge or expired assessment during the reporting period. The measure numerator is the number of stays in the denominator where the medical record contains documentation of a drug regimen review conducted at: (1) Admission; and (2) discharge with a look back through the entire resident stay, with all potential clinically significant medication issues identified during the course of care and followed-up with a physician or physician designee by midnight of the next calendar day. This measure is not risk adjusted. For technical information about this measure including information about the measure calculation and discussion pertaining to the standardized items used to calculate this measure, refer to the document titled, Proposed Measure Specifications for Measures Proposed in the FY 2017 SNF QRP Proposed Rule available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html.*

Data for the proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP, would be collected using the MDS with submission through the Quality Improvement Evaluation System (QIES) Assessment Submission and Processing (ASAP) system.

We invited public comment on our proposal to adopt the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP, for the SNF QRP. The comments we received on this topic, with their responses, appear below.

Comment: Several commenters, including MedPAC, expressed support for the quality measure. Further, several commenters expressed appreciation to us for proposing a quality measure to address the IMPACT Act domain, Medication Reconciliation, acknowledging the importance of medication reconciliation for addressing resident safety issues. Several commenters emphasized the importance of preventing and responding to Adverse Drug Events (ADEs) to reduce health services utilization and associated healthcare costs and emphasized that medication

reconciliation is fundamental to resident safety during care transitions.

Response: We appreciate the commenters' support for the quality measure and the recognition of the importance of medication reconciliation as addressed in the measure. We agree that medication reconciliation is an important patient safety process for addressing medication accuracy during transitions in patient care and identifying preventable Adverse Drug Events (ADEs), which may lead to reduced health services utilization and associated costs.

Comment: We received several comments regarding concerns about whether the measure has continued to be refined since the NQF-convened MAP meeting in December 2015. Many commenters noted that the MAP recommended ''continued development'' for the measure and requested evidence of robust testing of the measure to support measure validity. Several commenters requested that we test this measure prior to implementing it as part of the quality reporting system. One commenter further expressed that testing would enable us to more fully understand the benefits and limitations of the measure and its implication for providers and patients. Several commenters expressed concern that the measure was not NQF endorsed.

Response: Since the time of the NQF-convened MAP, with our measure contractor, we tested this measure in a pilot test involving twelve post-acute care facilities (IRF, SNF, LTCH), representing variation across geographic location, size, profit status, and clinical records system. Two clinicians in each facility collected data on a sample of 10 to 20 patients for a total of 298 records (147 qualifying pairs). Analysis of agreement between coders within each participating facility indicated a 71 percent agreement for item DRR–01 [140] Drug Regimen Review (admission); 69 percent agreement for item DRR–02 [141] Medication Follow-up (admission); and 61 percent agreement for DRR–03 [142] Medication Intervention (During Stay and Discharge). Overall, pilot testing enabled us to verify feasibility of the measure. Furthermore, measure development included convening a technical expert panel (TEP) to provide input on the technical specifications of this proposed quality measure, including components of reliability, validity and the feasibility of implementing the measure across PAC settings. The TEP included SNF stakeholders and supported the measure's implementation across PAC settings and was supportive of our plans to standardize this measure for cross-setting development. A summary of the TEP proceedings is available on the PAC Quality Initiatives Downloads and Videos Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

As noted above, we plan to conduct further testing on this measure once we have started collecting data from the PAC settings. Analysis of this data will allow us to evaluate whether the measure satisfies NQF endorsement criteria (for example, measure performance). Once we have completed this additional measure performance testing, we plan to submit the measure to NQF for endorsement.

Comment: We received several comments about the lack of a specific definition of clinically significant medication issues for the measure. Several commenters were concerned that the phrase could be interpreted differently by the many providers involved in a resident's treatment, and that this could result in a challenge to collect reliable and accurate data for this quality measure. Several commenters requested that we provide additional guidance regarding this definition. One commenter suggested that it was premature for us to provide clarifying language because a related proposed rule regarding Discharge Planning (Reform of Requirements for Long-Term Care Facilities, 80 FR 42168) has not been finalized. One commenter further conveyed that, without further guidance on the definition of clinically significant, there are likely to be variations in measure performance that are not based on differences in care, but rather on differences in data collection.

Response: For this measure, potential clinically significant medication issues are defined as those issues that, in the clinician's professional judgment, warrant interventions, such as alerting the physician and/or others, and the timely completion of any recommended actions (by midnight of the next calendar day) so as to avoid and mitigate any untoward or adverse outcomes. The definition of ''clinically significant'' in this measure was conceptualized during the measure development process. For purposes of the measure, the decision regarding whether or not a medication issue is ''clinically significant'' will need to be made on a case-by-case basis, but we also intend to provide additional guidance and training on this issue.

Comment: We received several comments related to the State Operations Manual (SOM) § 483.60(c). One commenter requested that we provide further guidance on how the measure relates to the ''medication regimen review'' within the SOM. Many commenters recommended that the definitions of potentially clinically significant medication issues and drug regimen review align with similar definitions in the SOM. One commenter further requested that we allow the existing SNF SOM required reviews to fulfill the requirements of the measure. One commenter further noted that the definitions contained in the measure are not as clinically detailed (as the SOM), are not PAC setting inclusive, and do not acknowledge the need for a multiple disciplinary team. The commenter also noted that the SOM uses the term ''medication'' rather than ''drug'' and offers that ''medication'' is a more appropriate title to the measure. One commenter conveyed a need for clarification in how the measure will interface with the current SNF requirements for drug regimen review. One commenter expressed concern that the requirements of the measure potentially conflict with the requirements CMS SNF State Operations Manual.

Response: We acknowledge the commenters' request to align other regulatory requirements involving medication regimen review with the measure such as the State Operations Manual § 483.60(c). We would like to note that during the development of this measure, the definitions as detailed in the SOM were taken into consideration. We do not believe that the measure's use of terminology of ''clinically significant'' overrides the guidance as outlined in the SOM. Further, we wish to clarify that the specification of the measure does not preclude the activities of drug regimen reviews that are consistent with the SOM. We would like to reiterate that this measure was developed to assess whether PAC providers were responsive to potential or actual clinically significant medication issue(s) when such issues were identified and was not developed for regulatory purposes for Skilled Nursing Facilities to be in compliance with the requirements of the 42 CFR part 483. In particular, the SOM

[140] DRR pilot items DRR–01, DRR–02 and DRR–03 are equivalent to the proposed rule DRR PAC instrument items N. 2001, N. 2003 and N. 2005.

[141] DRR pilot items DRR–01, DRR–02 and DRR–03 are equivalent to the proposed rule DRR PAC instrument items N. 2001, N. 2003 and N. 2005.

[142] DRR pilot items DRR–01, DRR–02 and DRR–03 are equivalent to the proposed rule DRR PAC instrument items N. 2001, N. 2003 and N. 2005.

Appendix PP—Guidance to Surveyors for Long Term Care Facilities, under § 483.60(c) Drug Regimen Review, references pharmacy services requirements where: (1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist; and (2) The pharmacist must report any irregularities to the attending physician, and the director of nursing, and these reports must be acted upon. The measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP reports the percentage of resident stays in which a drug regimen review was conducted at the time of admission, and timely follow-up with a physician occurred each time potential clinically significant medication issues were identified throughout that stay.

Comment: Several commenters were concerned that the measure does not meet the medication reconciliation domain of the IMPACT Act. In particular, these commenters believe that the proposed quality measure goes beyond the statutory mandate by incorporating drug regimen (medication) review into the measure. Commenters supported measure development related to the concepts of drug regimen review and medication reconciliation in reducing unnecessary rehospitalizations, preventable adverse events, and improving health care outcomes, but maintained that the services provided as part of drug regimen review are distinctly different from the services provided as part of medication reconciliation, and that they are completed by different members of the care team. One commenter conveyed that the measure has not been proven to be relevant to medication reconciliation.

Response: We disagree with the commenters' suggestion that the measure does not meet the requirements of the IMPACT Act. Medication reconciliation and drug regimen review are interrelated activities; while medication reconciliation is a process that identifies the most accurate and current list of medications, particularly during transitions of care, it also includes the evaluation of the name, dosage, frequency, and route. Drug regimen review is a process that necessitates and includes the review of all medications for additional purposes such as the identification of potential adverse effects. The process of drug regimen review includes medication reconciliation at the time of resident transitions and throughout the resident's stay. Therefore, we believe that medication reconciliation and drug regimen review are processes that are appropriate to combine in a single measure for purposes of the SNF QRP.

Comment: We received several comments regarding the time frame for the measure and resulting burden. Several commenters noted that requiring SNFs to notify the physician within one day was unreasonable. One commenter was concerned that the requirement that a physician be contacted within a day was too prescriptive, given that it may take more than a day for a physician to return a call, and suggested that we adopt a more reasonable standard. Further, another commenter suggested that this timeline created a mandate that many SNFs simply won't be able to meet. One commenter acknowledged that medication issues need to be resolved with urgency, but conveyed that the timeframe requirements of the measure are not feasible, citing limitations with the prescriber's and the hospitalist's availability to respond to issues and limited access to information technology that supports the prompt resolution of issues. Another commenter also noted that while clinically significant medical issues are required to be reported in a timely process, the word timely has not been adequately defined. One commenter suggested that we abandon the measure and instead verify that medication reconciliation is provided upon admission. Another commenter suggested that we clarify whether physician follow up is only required for clinically significant issues, rather than each time the drug regimen review is conducted.

Several commenters conveyed concern that the time frame of the measure (for example, following up by midnight of the next calendar day) will create challenges for rural SNFs without an in-house pharmacy or physicians, and that the measure will increase operational and financial challenges for long-term care providers. A few commenters asked us to consider reforms to mitigate the burden for providers located in rural areas. Another commenter conveyed that additional questions on the MDS would result in additional staff cost and effort. One commenter noted that many SNFs have not implemented electronic medical records, which will increase the burden associated with collecting this information. One commenter recommended that we work with stakeholders to develop a policy that aligns with the resident's best interest and accounts for the complex post-acute care setting.

Response: We appreciate the challenges that SNFs face when they have to coordinate resident care with a treatment team that may include physicians, non-physician practitioners, pharmacists and others, and also appreciate that some of these treatment team members might not work full-time at the SNF. However, we chose to set the intervention timeline as midnight of the next calendar day because we believe this timeline is consistent with current standard clinical practice where a clinically significant medication issue arises. We believe that high quality care should be provided wherever resident services are administered, including small and rural facilities, and that these activities, in addition to any regulatory requirements, ensure such high quality care is provided and patient harm avoided.

Comment: We received several comments related to the role of pharmacists in drug regimen review. One commenter expressed concern that the measure would require frequent consultant pharmacist visits to the SNF without providing more funding to cover additional expenses. Many commenters suggested that we redefine the measure to allow the SNF to determine which licensed professional provides the medication reconciliation. These commenters recommended that we recognize the essential role that pharmacists play in providing services to beneficiaries. One commenter submitted a study that noted the monetary savings that drug regimen review by pharmacists have provided to post-acute care residential facilities. Several commenters expressed that pharmacists should receive compensation for service they provide around this measure. One commenter encouraged us to consider ways in which to provide incentives to LTC pharmacies for the savings and improved care.

Response: We recognize the essential role that pharmacists, as well as other members of the SNF treatment team, play in furnishing services to Medicare beneficiaries. This measure does not supersede or conflict with current CMS guidance or regulations related to drug regimen review. The measure also does not specify what clinical professional is required to perform these activities.

Comment: We received several comments pertaining to the scope of the measure. One commenter conveyed that the CMS definition of Medication Reconciliation in a measure for hospitals differs from the definition for purposes of the proposed SNF QRP measure. One commenter conveyed opposition to the measure, expressing that the measure calculation proposes to capture a number of action steps within this single measure. Many commenters

expressed concerns that the measure may not accurately capture SNF performance, given all the work that the SNF and pharmacy undertake to ensure that medication-related issues are addressed prior to dispensing medication.

Response: The Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP measure evaluates medication reconciliation in conjunction with drug regimen review in the post acute care setting, which distinguishes it from solely medication reconciliation that is conducted in the hospital which we believe the commenter is referring to. We believe it is appropriate that the measure captures multiple action steps in a single measure as drug regimen review is a multifaceted process that should take place throughout the resident's stay.

Comment: We received a comment suggesting that we inaccurately represented that an article by American Geriatric Society suggests (and therefore aides our position) that drug regimen review includes a medication reconciliation and review of the patient's drug regimen to identify potential issues.

Response: The commenter is correct regarding an inaccurate reference. We inadvertently attributed reference to the American Geriatric Society in our discussion. Therefore, we have corrected the reference and replaced it with the intended one (Institute of Medicine. Preventing Medication Errors. Washington, DC: National Academies Press; 2006).

Comment: One commenter supported the need for medication reconciliation, but had concerns about factors outside the facility's control. The commenter conveyed the challenge of medication reconciliation across the continuum, conveying the importance of a discharge summary from the prior care setting that includes a thorough medication list, by indication, in avoiding therapeutic duplication. The commenter suggested that we consider the need for increased collaboration with hospitals to address this issue. Other commenters, including MedPAC, suggested that we develop a measure that evaluates whether PAC providers are sending medication lists home or to the next level of care. These commenters suggested that requiring providers to transfer medication lists may improve monitoring of the patient's condition, which may help prevent readmissions and unintended medical harm. Another commenter recommended that we add a medication management measure to fully address patients' medication management routine needs in order to prepare patients for discharge to PAC settings or the community.

Response: We appreciate the comments about the importance of collaboration across the continuum of care, as well as the value of a detailed discharge summary from the prior level of care. We believe that all providers should strive to ensure accurate, sufficient, and efficient patient-centered care during their care transitions across the continuum, including medication oversight. Thus while we may implement quality measures that address gaps in quality, such as information exchange during care transitions, ultimately providers must act to ensure that such coordination is taking place.

We appreciate the commenter's comment and interest in future quality measure development, including measures related to sending a medication list at discharge and adding a medication management measure. As a requirement of this measure and as with common clinical practice, PAC facilities are expected to document information pertaining to the process of drug regimen review, which includes medication reconciliation, in the resident's discharge medical record. However, we will take the commenters recommendations into consideration as we continue to develop additional quality measures under the domain of Medication Reconciliation.

Comment: One commenter encouraged us to make the reporting of the measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP, available to SNFs in real time through the CASPER Quality Measures report in QIES ASAP system.

Response: We thank the commenter for their suggestion. We anticipate making this measure information available to SNFs in the CASPER Quality Measures reports beginning approximately in October, 2020. Confidential SNF feedback on this measure will be made available to SNFs in October, 2019.

Comment: We received a comment about the role of registered nurses in the medication reconciliation process. The commenter recognized the critical importance of medication reconciliation and cited research demonstrating that registered nurses (RNs) are more likely to identify medication discrepancies in nursing facilities than licensed practical nurses (LPNs); the commenter encouraged us, in the Conditions of Participation for Skilled Nursing Facilities (SNFs) and Nursing Facilities (NFs), to require that facilities employ RNs 24 hours per day.

Response: We thank the commenter for recognizing the importance of medication reconciliation and the role of registered nurses in the medication reconciliation process.

Comment: We received a comment about materials that were posted on the CMS Public Comment Web site for a public comment period held from September 18 through October 6, 2015. The comment specifically included specific questions regarding the language used in the ''Importance'' section of the Measure Justification Form, which requests the measure developer quote verbatim currently published clinical practice guidelines. The commenter noted the absence of an ''Outcome 1,'' which is defined as functional status, in the quoted material. Additionally, the commenter expressed concern about specific targets within the goal of reducing polypharmacy and about guidelines for calculating creatinine clearance levels and about the Cockcroft Gault Score. Finally, the commenter noted that it is clinically unrealistic to have an expected outcome of ''No adverse drug reactions, no drugs ordered to treat side effects or adverse reaction.''

Response: We thank the commenter for their comments but wish to clarify that the document they reference, the Measure Justification Form, was posted for a prior public comment period that was not part of the proposed rule. We also wish to clarify that language that was commented on was derived directly from published clinical practice guidelines and not by CMS.

Final Decision: After consideration of the public comments, we are finalizing our proposal to adopt the measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP measure for the SNF QRP for the FY 2020 payment determination and subsequent years, as described in the Measure Specifications for Measures Adopted in the FY 2017 SNF QRP final rule, available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html*.

h. SNF QRP Quality Measures and Measure Concepts Under Consideration for Future Years

We invited comment on the importance, relevance, appropriateness, and applicability for each of the quality measures in Table 13 for future years in

the SNF QRP. We are developing a measure related to the IMPACT Act domain, accurately communicating the existence of and providing for the transfer of health information and care preferences of an individual to the individual, family caregiver of the individual, and providers of services furnishing items and services to the individual, when the individual transitions. We are considering the possibility of adding quality measures that rely on the patient's perspective; that is, measures that include patient-reported experience of care and health status data. For this purpose, we are considering a measure focused on pain and four measures focused on function that rely on the collection of patient-reported data. Finally, we are considering a measure related to health and well-being, Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine, and a measure related to patient safety, Percent of SNF Residents Who Newly Received an Antipsychotic Medication.

TABLE 13—SNF QRP QUALITY MEASURES UNDER CONSIDERATION FOR FUTURE YEARS

IMPACT Act Domain	Accurately communicating the existence of and providing for the transfer of health information and care preferences of an individual to the individual, family caregiver of the individual, and providers of services furnishing items and services to the individual, when the individual transitions.
IMPACT Act Measure	• Transfer of health information and care preferences when an individual transitions.
NQS Priority	Patient- and Caregiver-Centered Care.
Measures	• Percent of Residents Who Self-Report Moderate to Severe Pain • Application of the Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633) • Application of the Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634) • Application of the Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635) • Application of the Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636).
NQS Priority	Health and Well-Being.
Measure	• Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine.
NQS Priority	Patient Safety.
Measure	• Percent of SNF Residents Who Newly Received an Antipsychotic Medication.

The comments we received on this topic, with their responses, appear below.

Comment: We received several comments supporting the inclusion of measures regarding the transfer of health information and care preferences. One commenter encouraged the inclusion of measures that capture the role of family caregivers in supporting care transitions, quality outcomes, and individual care preferences. Another commenter recommended pilot testing measures regarding transfer of health information and preferences; while another suggested a measure that would incentivize the adoption of health IT around the domain requirement to support the electronic transmission of health information and care preferences.

Response: We thank the commenters for their comments and agree that the transfer of health information across PAC settings is important to capture. As we move through the development of this measure concept, we will consider the inclusion of the role of family caregivers in supporting care transitions, quality outcomes, and individual care preferences. In addition, we will take into consideration the commenters' recommendations pertaining to the pilot testing for these measure concepts.

Comment: We received comments that were broadly supportive of patient- and caregiver-reported measures and agreed that they are meaningful to patients and their families.

Response: We thank the commenters for their support of patient-reported measures under consideration for future implementation in the SNF QRP and agree with the importance of patient- and caregiver-centered measures such as these.

Comment: Several commenters supported the potential future use of the four self-reported function measures. One commenter supported risk adjustment of these measures and the focus on patient-centered outcomes. Another supported the use of the four self-reported function measures applied from the IRF setting and emphasized the importance of alignment across PAC settings and encouraged measure testing in the SNF setting prior to implementation. Another commenter recommended that SNF residents should be excluded from measures related to change in function if there is no expectation of functional improvement.

Several commenters suggested the development of function measures addressing cognition. One commenter remarked on the limited number of items in the MDS related to communication, cognition, and swallowing and noted that these three domains stand as major obstacles to validly determine the status, needs, and outcomes of individuals with neurological disorders. The commenter encouraged us to adopt a specific screening tool, the Montreal Cognitive Assessment (MoCA), or similar screening tools and assessment tools (that is, CARE–C) to best meet the needs of Medicare beneficiaries and the intent of the IMPACT Act.

Another commenter recommended that we consider community-based measures of function, examining patient outcomes after they are discharged from a PAC setting. One commenter encouraged the development of an outcome measure to meet the IMPACT Act domain of functional status, suggesting the NH Compare measure, Percent of Residents Whose Need for Help with Activities of Daily Living has Increased (Long Stay).

Response: We thank the commenters for their support of the four self-reported function measures under consideration for future implementation in the SNF QRP. We also appreciate commenters' suggestions regarding the development and specification of these measures as well as additional measure concepts or areas related to function that we should consider. We agree that the implementation of outcome measures of function in the SNF QRP is a priority. We also agree that future measure development should include other areas of function, such as communication, cognition, and swallowing. We will continue to engage stakeholders in future measure development. We will take these suggested quality measure concepts and recommendations regarding measure specifications into consideration in our ongoing measure development and testing efforts.

Comment: We received several comments regarding pain management and prevention. One commenter suggested that we consider HCAHPS measures related to pain control, while another commenter suggested such a measure should reflect a patient-centered approach to pain management instead of level and frequency of pain symptoms. We also received a comment encouraging the use of the CAHPS NH survey to examine resident and family members' experience of care.

Response: We will take these suggested quality measure concepts and recommendations regarding measure specifications into consideration in our ongoing measure development and testing efforts.

Comment: We received several comments supporting a future seasonal influenza vaccination measure. Several commenters encouraged us to consider other immunization measures for the SNF QRP, including a pneumococcal vaccine measure. One commenter encouraged consideration of the cost of delivering these services as they may have financial implications for SNFs.

Response: We thank the commenters for their support of a future seasonal influenza vaccination measure. Cost burden for providers is always a consideration as we develop and implement new measures. We appreciate the commenters' feedback on potential measure development areas related to immunization. We will take their recommendations into consideration in our measure development and testing efforts, as well as in our ongoing efforts to identify and propose appropriate measures for the SNF QRP in the future.

Comment: We received several comments supporting the inclusion of the antipsychotic quality measure (listed on the Nursing Home Compare Web site) in the SNF QRP. One commenter supported the measure but cautioned against adapting the pre-existing, non-NQF-endorsed antipsychotic measures currently used in nursing homes, indicating that these process measures do not provide a linkage to clinical outcomes or intermediate outcomes. Commenters also emphasized the need for the measures to account for situations where continued or newly prescribed antipsychotics would be clinically appropriate.

Response: We appreciate commenters' feedback on this potential measure development area. We will take their recommendations into consideration in our measure development and testing efforts, as well as in our ongoing efforts to identify and propose appropriate measures for the SNF QRP in the future.

Comment: Commenters suggested additional measures and measure concepts for us to consider for future implementation in the SNF QRP, including workforce-related measures and measures assessing resident experience of care, engagement, and shared decision-making. Several commenters recommended that CMS consider incorporating various Nursing Home Compare measures into the SNF QRP.

Response: We thank commenters for their suggestions regarding areas for potential future measure development. We will take their recommendations into consideration in our measure development and testing efforts, as well as in our ongoing efforts to identify and propose appropriate measures for the SNF QRP in the future.

i. Form, Manner, and Timing of Quality Data Submission

i. Participation/Timing for New SNFs

In the FY 2016 SNF PPS final rule (80 FR 46455), we established the requirements associated with the timing of data submission, beginning with the submission of data required for the FY 2018 payment determination, for new SNFs. We finalized that a new SNF would be required to begin reporting data on any quality measures finalized for that program year by no later than the first day of the calendar quarter subsequent to 30 days after the date on its CMS Certification Number (CCN) notification letter. For example, for the FY 2018 payment determinations, if a SNF received its CCN on August 28, 2016, and 30 days are added (August 28 + 30 days = September 27), the SNF would be required to submit data for residents who are admitted beginning on October 1, 2016. We did not propose any new policies related to the participation and timing for new SNFs.

ii. Finalized Data Collection Timelines and Requirements for the FY 2018 Payment Determination and Subsequent Years

In the FY 2016 SNF PPS final rule (80 FR 46457), for the FY 2018 payment determination, we finalized that SNFs submit data on the three finalized quality measures for residents who are admitted to the SNF on and after October 1, 2016, and discharged from the SNF up to and including December 31, 2016, using the data submission method and schedule that we proposed in this section. We also finalized that we would collect that single quarter of data for FY 2018 to remain consistent with the usual October release schedule for the MDS, to give SNFs a sufficient amount of time to update their systems so that they can comply with the new data reporting requirements, and to give CMS a sufficient amount of time to determine compliance for the FY 2018 program. The proposed use of one quarter of data for the initial year of quality reporting is consistent with the approach we used to implement a number of other QRPs, including the LTCH, IRF, and Hospice QRPs.

We also finalized that, following the close of the reporting quarter, October 1, 2016, through December 31, 2016, for the FY 2018 payment determination, SNFs would have an additional 5.5 months to correct and/or submit their quality data and we finalized that the final deadline for submitting data for the FY 2018 payment determination would be May 15, 2017 (80 FR 46457). The statement that SNFs would have an additional 5.5 months was incorrect in that the time between the close of the quarter on December 31, 2016 and May 15, 2017 is 4.5 months, not 5.5 months. Therefore, we proposed that SNFs will have 4.5 months, from January 1, 2017 through May 15, 2017, following the data submission period of October 1, 2016 through December 31, 2016, in which to complete their data submissions and make corrections to their data where necessary.

TABLE 14—FINALIZED MEASURES, DATA COLLECTION SOURCE, DATA COLLECTION PERIOD AND DATA SUBMISSION DEADLINES AFFECTING THE FY 2018 PAYMENT DETERMINATION

Quality measure	Data collection source	Data collection period	Data submission deadline for FY 2018 payment determination
NQF # 0678: Percent of Patients or Residents with Pressure Ulcers that are New or Worsened.	MDS	10/01/16–12/31/16	May 15, 2017.
NQF # 0674: Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay).	MDS	10/01/16–12/31/16	May 15, 2017.

TABLE 14—FINALIZED MEASURES, DATA COLLECTION SOURCE, DATA COLLECTION PERIOD AND DATA SUBMISSION DEADLINES AFFECTING THE FY 2018 PAYMENT DETERMINATION—Continued

Quality measure	Data collection source	Data collection period	Data submission deadline for FY 2018 payment determination
NQF # 2631: Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function.	MDS	10/01/16–12/31/16	May 15, 2017.

We invited public comments on our proposal to correct the time frame for SNFs to correct and/or submit their quality data used for the FY 2018 payment determination to consist of 4.5 months rather than the 5.5 months stated in the FY 2016 SNF PPS final rule (80 FR 46457). We received no comments on this proposed correction.

Final decision: We are finalizing as proposed that for the FY 2018 payment determination, SNFs will have 4.5 months following the end of the reporting quarter to complete their data submissions and make corrections to their data where necessary.

iii. Data Collection Timelines and Requirements for the FY 2019 Payment Determinations and Subsequent Years

In the FY 2016 SNF PPS final rule (80 FR 46457), we finalized that, for the FY 2019 payment determination, we would collect data from the 2nd through 4th quarters of FY 2017 (that is, data for residents who are admitted from January 1st and discharged up to and including September 30th) to determine whether a SNF has met its quality reporting requirements for that FY. In the FY 2016 SNF PPS final rule we also finalized that beginning with the FY 2020 payment determination, we would move to a full year of fiscal year (FY) data collection. We intend to propose the FY 2019 payment determination quality reporting data submission deadlines in future rulemaking.

In the FY 2016 SNF PPS final rule (80 FR 46457), we also finalized that we would collect FY 2018 data in a manner that would remain consistent with the usual October release schedule for the MDS. However, to align with the data reporting cycles in other quality reporting programs, in contrast to fiscal year data collection that we finalized last year, we are now proposing to move to calendar year (CY) reporting following the initial reporting of data from October 1, 2016, through December 31, 2016, as finalized in the FY 2016 SNF PPS final rule (80 FR 46457), for the FY 2018 payment determination.

More specifically, we proposed to follow a CY schedule for measure and data submission requirements that includes quarterly deadlines following each quarter of data submission, beginning with data reporting for the FY 2019 payment determinations. Each quarterly deadline will occur approximately 4.5 months after the end of a given calendar quarter as outlined below in Table 15. This timeframe will give SNFs enough time to submit corrections to the assessment data, as discussed below. Thus, if finalized, the FY 2019 payment determination would be based on 12 calendar months of data reporting beginning on January 1, 2017, and ending on December 31, 2017 (that is, data from January 1, 2017, up to and including December 31, 2017.) This approach would enable CMS to move to a full 12 months of data reporting immediately following the first 3 months of reporting (October 1, 2016 through December 31, 2016 for the FY 2018 payment determination) rather than an interim year which uses only 9 months of data, and a subsequent 12 months of FY data reporting following the initial reporting for the FY 2018 payment determination.

Our proposal to implement, for the FY 2019 payment determination and all subsequent years for assessment-based data submitted via the MDS, calendar year, quarterly data collection periods followed by data submission deadlines is consistent with the approach taken by the LTCH QRP and the IRF QRP, which are based on CY data and for which each data collection quarterly period is followed by a 4.5 month time frame that allows for the continued submission and correction of data until a deadline has been reached for that quarter of data. At that point, the data submitted becomes a frozen ''snapshot'' of data for both public reporting purposes and for the purposes of determining compliance in meeting the data reporting thresholds.

TABLE 15—PROPOSED DATA COLLECTION PERIOD AND DATA SUBMISSION DEADLINES AFFECTING THE FY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Quality measure	Data collection source	Data collection/submission quarterly reporting period *	Quarterly review and correction periods and data submission quarterly deadlines for FY 2019 payment determination **
NQF # 0678: Percent of Patients or Residents with Pressure Ulcers that are New or Worsened. NQF # 0674: Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) NQF #2631: Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function	MDS	CY 2017 Q1—1/1/2017–3/31/2017. CY 2017 Q2—4/1/2017–6/30/17. CY 2017 Q3—7/1/2017–9/30/2017. CY 2017 Q4—10/1/2017–12/31/2017.	CY 2017 Q1 Deadline: August 15, 2017. CY 2017 Q2 Deadline: November 15, 2017. CY 2017 Q3 Deadline: February 15, 2018. CY 2017 Q4 Deadline: May 15, 2018.

* Data collection/submission will follow a similar quarterly reporting period schedule for subsequent CYs.
** Data review and correction periods and data submission deadlines will follow a similar quarterly schedule for subsequent CYs.

We invited public comments on our proposal to adopt calendar year data collection time frames, following the initial 3-month reporting period from October 1, 2016, to December 31, 2016, for all measures finalized for adoption

into the SNF QRP. The comments we received on this topic, with their responses, appear below.

Comment: We received several comments supporting our proposal to move to a CY reporting schedule to align with the LTCH and IRF QRPs.

Response: We appreciate the commenters' support of our proposal to move to a calendar year reporting schedule, which is consistent with the approach we also use for the LTCH and IRF QRPs. We seek to align requirements across QRPs whenever possible.

Comment: We received one comment supporting the continuation of the October release schedule for updates to the MDS and the alignment of data collection with that October release schedule.

Response: We appreciate the commenters' support of our alignment of the beginning of the initial data collection period for new measures with the October release schedule for the MDS and moving to CY reporting following the initial data collection period.

Further, we proposed that beginning with FY 2019 payment determination, assessment-based measures finalized for adoption into the SNF QRP will follow a CY schedule of data reporting, quarterly review and correction periods, and data submission deadlines as provided in Tables 15 and 16 for all subsequent payment determination years unless otherwise specified:

TABLE 16—PROPOSED DATA COLLECTION PERIOD AND DATA SUBMISSION DEADLINES AFFECTING THE FY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

CY data collection quarter	Data collection/submission quarterly reporting period	Quarterly review and correction periods and data submission deadlines for payment determination
Quarter 1	January 1–March 31	April 1–August 15.
Quarter 2	April 1–June 30	July 1–November 15.
Quarter 3	July 1–September 30	October 1–February 15.
Quarter 4	October 1–December 31	January 1–May 15.

We invited public comments on the proposed data collection period and data submission deadlines for all assessment-based measures finalized for adoption into the SNF QRP beginning with the FY 2019 payment determination, specifically, on our use of CY reporting with data submission deadlines following a period of approximately 4.5 months after each quarterly data collection period to enable the correction of such data, as outlined in Table 16. We received no additional comments on this proposed general schedule.

Final decision: We are finalizing our proposed data collection period and data submission deadlines for all assessment-based measures finalized for adoption into the SNF QRP beginning with FY 2019 payment determination, as outlined in Tables 15 and 16.

iv. Timeline and Data Submission Mechanisms for Claims-Based Measures for the FY 2018 Payment Determination and Subsequent Years

The Medicare Spending per Beneficiary—PAC SNF QRP, Discharge to Community—PAC SNF QRP, and Potentially Preventable Potentially Preventable 30-Day Post-Discharge Readmission Measure for SNF QRP measures are Medicare FFS claims-based measures. Because claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes, no additional information collection will be required from SNFs. As discussed in section V.B.6. of the FY 2017 SNF PPS proposed rule (81 FR 24257 through 24267), for the Medicare Spending per Beneficiary—PAC SNF QRP Measure, the Discharge to Community—PAC SNF QRP measure and the Potentially Preventable 30-Day Post-Discharge Readmission Measure for SNF QRP, we proposed to use 1 year of claims data beginning with CY 2016 claims data to inform confidential feedback reports for SNFs, and CY 2017 claims data for public reporting.

We invited public comments on this proposal. We did not receive any comments specifically related to this proposal.

Final Decision: We are finalizing the timeline and data submission mechanisms for claims-based measures proposed for the FY 2018 payment determination and subsequent years as proposed in Tables 15 and 16.

v. Timeline and Data Submission Mechanisms for the FY 2020 Payment Determination and Subsequent Years for New SNF QRP Assessment-Based Quality Measure

We proposed that SNFs would submit data on the Drug Regimen Review measure by completing data elements to be included in the MDS and then submitting the MDS to CMS through the Quality Improvement and Evaluation System (QIES), Assessment Submission and Processing System (ASAP) system beginning October 1, 2018. For more information on SNF QRP reporting through the QIES ASAP system, refer to the ''Related Links'' section at the bottom of *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/index.html?redirect=/NursingHomeQualityInits/30_NHQIMDS30TechnicalInformation.asp#TopOfPage.*

We invited public comments on our proposed SNF QRP data collection requirements for the Drug Regimen Review measure for the FY 2020 payment determination and subsequent years. We did not receive any comments related to this topic.

For the FY 2020 payment determination, we proposed that SNFs submit data on the proposed assessment-based quality measure for residents who are admitted to the SNF on and after October 1, 2018, and discharged from SNF Part A covered stays (that is, both residents discharged from Part A covered stays and physically discharged) up to and including December 31, 2018, using the data submission schedule that we proposed in this section.

We proposed to collect a single quarter of data for the FY 2020 payment determination to remain consistent with the usual October release schedule for the MDS, to give SNFs a sufficient amount of time to update their systems so that they can comply with the new data reporting requirements, and to give CMS a sufficient amount of time to determine compliance for the FY 2020 program. The proposed use of one quarter of data for the initial year of assessment data reporting in the SNF QRP is consistent with the approach we used previously for the SNF QRP and in other QRPs, including the LTCH, IRF, and Hospice QRPs in which we have finalized the use of fewer than 12 months of data.

We also proposed that following the close of the reporting quarter, October 1, 2018, through December 31, 2018, for the FY 2020 payment determination, SNFs would have an additional 4.5 months to correct and/or submit their quality data and that the final deadline for submitting data for the FY 2020 payment determination would be May 15, 2019. We further proposed that for the FY 2021 payment determination and subsequent years, we will collect data using the CY reporting cycle as previously proposed in section V.B.9.c. of the FY 2017 SNF PPS proposed rule (81 FR 24271 through 24272).

TABLE 17—PROPOSED NEW SNF QRP ASSESSMENT-BASED QUALITY MEASURES DATA COLLECTION PERIOD AND DATA SUBMISSION DEADLINES AFFECTING THE FY 2020 PAYMENT DETERMINATION

Quality measure	Data collection source	Data collection/ submission reporting period	Data submission deadline for FY 2020 payment determination
Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP.	MDS	10/01/18–12/31/18	May 15, 2019.

We invited public comment on the proposed new SNF QRP assessment-based quality measure data collection period and data submission deadline affecting the FY 2020 payment determination. We did not receive comments related to this topic.

Final Decision: We are finalizing as proposed the timeline and data submission mechanism for the FY 2020 payment determination for the new assessment-based quality as provided in Table 17.

For this measure, we also proposed to follow a CY schedule for measure and data submission requirements that includes quarterly deadlines following each quarter of data submission, beginning with data reporting for the FY 2021 payment determinations. As previously discussed, each quarterly deadline will occur approximately 4.5 months after the end of a given calendar quarter as outlined in Table 18. Thus, if finalized, the FY 2021 payment determination would be based on 12 calendar months of data reporting beginning January 1, 2019, and ending December 31, 2019. Table 18 provides the data submission and collection method, data collection period and data submission timelines for the assessment-based quality measure affecting the FY 2021 payment determination and subsequent years.

TABLE 18—PROPOSED NEW SNF QRP ASSESSMENT-BASED QUALITY MEASURE DATA COLLECTION PERIOD AND DATA SUBMISSION DEADLINE AFFECTING FY 2021 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Quality measure	Data collection source	Data collection/ submission quarterly reporting period *	Data submission quarterly deadlines for FY 2021 payment determination **
Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP.	MDS	CY 19 Q1, 1/1/2019–3/31/2019	CY 2019 Q1 Deadline: August 15, 2019.
		CY 19 Q2, 4/1/2019–6/30/19 ...	CY 2019 Q2 Deadline: November 15, 2019.
		CY 19 Q3, 7/1/2019–9/30/2019	CY 2019 Q3 Deadline: February 15, 2020.
		CY 19 Q4, 10/1/2019–12/31/2019.	CY 2019 Q4 Deadline: May 15, 2020.

* Data collection/submission will follow a similar quarterly reporting period schedule for subsequent CYs.
** Data review and correction periods and data submission deadlines will follow a similar quarterly schedule for subsequent CYs.

We invited public comment on the SNF QRP assessment-based quality measure data collection period and data submission deadline affecting the FY 2021 payment determination and subsequent years for the new assessment-based measure. We did not receive comments related to this topic.

Final Decision: We are finalizing as proposed the timeline and data submission mechanism for the FY 2021 payment determination and subsequent years for the new SNF QRP assessment-based quality measure as outlined in Table 18.

j. SNF QRP Data Completion Thresholds for the FY 2018 Payment Determination and Subsequent Years

We refer readers to the FY 2016 SNF PPS final rule (80 FR 46458) for our finalized policies regarding data completion thresholds for the FY 2018 payment determination and subsequent years. We finalized that, beginning with the FY 2018 payment determination, SNFs must report all of the data necessary to calculate the proposed quality measures on at least 80 percent of the MDS assessments that they submit. We also finalized that, for the FY 2018 SNF QRP, any SNF that does not meet the proposed requirement that 80 percent of all MDS assessments submitted contain 100 percent of all data items necessary to calculate the SNF QRP measures would be subject to a reduction of 2 percentage points to its FY 2018 market basket percentage. We finalized that a SNF has reported all of the data necessary to calculate the measures if the data actually can be used for purposes of calculating the quality measures, as opposed to, for example, the use of a dash [-], to indicate that the SNF was unable to perform a pressure ulcer assessment. We wish to clarify that the provision we

finalized will affect FY 2018 payment determinations and subsequent years and is dependent upon the successful achievement of the completion threshold of the data used to calculate the measures we finalize. We did not propose any changes to these policies. While we did not solicit comments specifically regarding the data completion threshold for the SNF QRP, we did receive one comment related to this topic.

Comment: One commenter suggested that the 80 percent data completion threshold finalized the SNF PPS FY 2016 final rule is set too low and requested that, for the FY 2018 payment determination, the data completion threshold be increased to at least ninety percent.

Response: We intend to reevaluate this threshold over time and will propose to modify it, if warranted, based on our analysis.

k. SNF QRP Data Validation Requirements for the FY 2018 Payment Determination and Subsequent Years

We refer readers to the FY 2016 SNF PPS final rule (80 FR 46458 through 46459) for a summary of our approach to the development of data validation process for the SNF QRP. At this time, we are continuing to explore data validation methodology that will limit the amount of burden and cost to SNFs, while allowing us to establish estimations of the accuracy of SNF QRP data. We did not propose any further details pertaining to the data validation process for the SNF QRP, but we plan to do so in future rulemaking cycles. While we did not solicit comments specifically regarding data validation requirements for the SNF QRP, we received several comments related to this topic.

Comment: Several commenters agreed that validation of quality measure data is important in IMPACT Act implementation. One commenter recommended that we utilize pure data checks to identify both inconsistencies between QRP measures and MDS items and that data from these audits should be provided as part of SNF feedback reports to improve data accuracy. This commenter also suggested that we audit suspicious data patterns using trained MDS experts and present a list of validation checks to providers and MDS vendors to help improve data accuracy and expedite the process. Another commenter suggested revising and testing revisions to the survey protocol to review resident assessments and instituting penalties for violating resident assessment requirements.

Response: We thank the commenters for their input on policies that we should consider pertaining to data validation and accuracy analysis. We appreciate the commenters' suggestions to ensure data accuracy such as a combination of pure data checks to identify inconsistencies. We encourage providers to engage in available opportunities to improve the accuracy of their data. These suggestions will be taken into consideration as we develop the data validation methodologies for the SNF QRP.

l. SNF QRP Submission Exception and Extension Requirements for the FY 2018 Payment Determination and Subsequent Years

We refer readers to the FY 2016 SNF PPS final rule (80 FR 46459 through 46460) for our finalized policies regarding submission exception and extension requirements for the FY 2018 payment determination and subsequent years. We did not propose any changes to these policies.

m. SNF QRP Reconsideration and Appeals Procedures for the FY 2018 Payment Determination and Subsequent Years

We refer the reader to the FY 2016 SNF PPS final rule (80 FR 46460 through 46461) for a summary of our finalized reconsideration and appeals procedures for the SNF QRP for FY 2018 payment determination and subsequent years. We did not propose any changes to these procedures.

n. Public Display of Quality Measure Data for the SNF QRP & Procedures for the Opportunity To Review and Correct Data and Information

Section 1899B(g) of the Act requires the Secretary to establish procedures for public reporting of SNFs' performance, including the performance of individual SNFs, on quality measures specified under paragraph (c)(1) and resource use and other measures specified under paragraph (d)(1) of the Act (collectively, IMPACT Act measures) beginning not later than 2 years after the applicable specified application date under section 1899B(a)(2)(E) of the Act. Under section 1899B(g)(2) of the Act, the procedures must ensure, including through a process consistent with the process applied under section 1886(b)(3)(B)(viii)(VII) of the Act, which refers to public display and review requirements in the Hospital Inpatient Quality Reporting Program (HIQR), that each SNF has the opportunity to review and submit corrections to its data and information that are to be made public prior to the information being made public. In future rulemaking, we intend to propose a policy to publicly display performance information for individual SNFs on IMPACT Act measures, as required under the Act.

We proposed in the FY 2017 SNF PPS proposed rule to implement procedures that would allow individual SNFs to review and correct their data and information on IMPACT Act measures that are to be made public before those measure data are made public.

For assessment-based measures, we proposed a process by which we would provide each SNF with a confidential feedback report that would allow the SNF to review its performance on such measures and, during a review and correction period, to review and correct the data the SNF submitted to CMS via the CMS Quality Improvement and Evaluation System (QIES) Assessment Submission and Processing (ASAP) system for each such measure. In addition, during the review and correction period, the SNF would be able to request correction of any errors in the assessment-based measure rate calculations.

We proposed that these confidential feedback reports would be available to each SNF using the Certification and Survey Provider Enhanced Reporting (CASPER) System. We refer to these reports as the SNF Quality Measure (QM) Reports. We proposed to provide monthly updates to the data contained in these reports that pertain to assessment-based data, as the data become available. We proposed to provide the reports so that providers would be able to view their data and information at both the facility- and resident-level for quality measures. The CASPER facility-level QM Reports may contain information such as the numerator, denominator, facility rate, and national rate. The CASPER patient-level QM Reports may contain individual patient information which will provide information related to which patients were included in the quality measures to identify any potential errors. In addition, we would make other reports available in the CASPER System, such as MDS data submission reports and provider validation reports, which would disclose SNFs' data submission status, providing details on all items submitted for a selected assessment and the status of records submitted. Additional information regarding the content and availability of these confidential feedback reports would be provided on an ongoing basis at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-*

Instruments/NursingHomeQualityInits/SNF-Quality-Reporting.html.

As proposed in section III.D.2.i.ii. of the FY 2017 SNF PPS Proposed Rule (81 FR 24270), SNFs would have approximately 4.5 months after the reporting quarter to correct any errors that appear on the CASPER-generated QM reports pertaining to their assessment-based data used to calculate the assessment-based measures. During the time of data submission for a given quarterly reporting period and up until the quarterly submission deadline, SNFs could review and perform corrections to errors in the assessment data used to calculate the measures and could request correction of measure calculations. However, once the quarterly submission deadline occurs, the data is ''frozen'' and calculated for public reporting; providers can no longer submit any corrections. We would encourage SNFs to submit timely assessment data during a given quarterly reporting period and review their data and information early during the review and correction period so that they can identify errors and resubmit data before the data submission deadline.

As noted in this section, the data would be populated into the confidential feedback reports, and we intend to update the reports monthly with all data that have been submitted and are available. We believe that a proposed data submission and review period, consisting of the reporting quarter plus approximately 4.5 months, is sufficient time for SNFs to submit, review and, where necessary, correct their data and information. These proposed time frames and deadlines for review and correction of assessment-based measures and data satisfy the statutory requirement that SNFs be provided the opportunity to review and correct their data and information that is to be made public and are consistent with the informal process hospitals follow in the Hospital Inpatient Quality Reporting (IQR) Program.

We proposed that, in addition to the data collection/submission quarterly reporting periods that are followed by data review and correction periods and submission deadlines, we would give SNFs a 30-day preview period prior to public display during which SNFs may preview the performance information on their measures that will be made public. We proposed to provide a preview report also using the CASPER System with which SNFs are familiar. The CASPER preview reports would inform providers of their performance on each measure which will be publicly reported. The CASPER preview reports for the reporting quarter will be available after the 4.5-month review and correction period and its data submission deadline, and the reports are refreshed on a quarterly basis for those measures publicly reported quarterly and annually for those measures publicly reported annually. We proposed to give SNFs 30 days to review this information, beginning from the date on which they can access the preview report. Corrections to the underlying data would not be permitted during this time; however, SNFs may contest incorrect measure calculations during the 30-day preview period. We proposed that if CMS determines that the measure, as it is displayed in the preview report, contains a calculation error, CMS could suppress the data on the public reporting Web site, recalculate the measure and publish it at the time of the next scheduled public display date. This process would be consistent with that followed in the Hospital IQR Program. If finalized, we intend to utilize a subregulatory mechanism, such as our SNF QRP Web site, to explain the process for how and when providers may ask for a correction to their measure calculations.

We invited public comment on these proposals. The comments we received on this topic, with their responses, appear below.

Comment: Several commenters, including MedPAC, supported public reporting of the cross-setting quality measures.

Response: We appreciate the support from MedPAC and several other commenters for public reporting of quality measures across post-acute care settings. We will continue to move forward with cross-setting measure development and public reporting of these measures to meet the mandate of the IMPACT Act.

Comment: One commenter was concerned about measure methodology associated with public reporting. The commenter stated that a year or more between the report date and penalties would not be meaningful or effective in changing behaviors.

Response: We appreciate the concern raised regarding the measure methodology associated with public reporting and the time delay between the performance period and public display of the quality measure results. We assume commenter's use of the term ''measure methodology'' to refer to how the quality measure is calculated. We first want to clarify that there are no penalties associated with quality measure performance. The quality measures for public display reflect basic fundamental processes or outcomes of providing good quality care. SNFs should have internal processes established to monitor and improve their care. Additionally, through the Certification and Survey Provider Enhanced Reports (CASPER) system, providers are able to review their data and performance results via reports that are available to them well in advance of public display of the quality measures for the purposes of ongoing quality improvement. We discuss such reports in greater detail below and such reports will enable providers to review their data on an ongoing basis so that they can utilize this information to improve their quality of care.

Comment: One commenter was concerned that the review and correction process may not provide SNFs enough information to validate measure values.

Response: We appreciate the commenter's concern regarding the review and correct process. In addition to the CASPER QM and Review and Correct Reports as described earlier in the proposed rule, SNFs have opportunities to review their information and validate their data for measure calculation using other reports such as data submission reports available through CASPER which gives providers information on fatal errors and warning messages related to data submission. For example, various data submission reports provide details regarding assessment items submitted for a selected MDS 3.0 assessment and others summarize errors encountered in assessments submitted during a specified period. We believe these CASPER reports will provide SNFs with sufficient information to validate measure values.

In addition to assessment-based measures, we have also proposed claims-based measures for the SNF QRP. Section 1899B(g)(2) of the Act requires prepublication provider review and correction procedures that are consistent with those followed in the Hospital IQR Program. For claims-based measures used in the Hospital IQR Program, we provide hospitals 30 days to preview their claims-based measures and data in a preview report containing aggregate hospital-level data. We proposed to adopt a similar process for the SNF QRP.

Prior to the public display of our claims-based measures, in alignment with the Hospital IQR, HAC and Hospital VBP Programs, we proposed to make available through the CASPER system a confidential preview report that will contain information pertaining to claims-based measure rate calculations, for example, facility and national rates. Such data and

information would be for feedback purposes only and could not be corrected. This information would be accompanied by additional confidential information based on the most recent administrative data available at the time we extract the claims data for purposes of calculating the rates. Because the claims-based measures are calculated on an annual basis, these confidential CASPER QM reports for claims-based measures would be refreshed annually. SNFs would have 30 days from the date the preview report is made available in which to review this information. The 30-day preview period is the only time when SNFs would be able to see claims-based measures before they are publicly displayed. SNFs will not be able to make corrections to underlying claims data during this preview period, nor will they be able to add new claims to the data extract. However, SNFs may request that we correct our measure calculation if the SNF believes it is incorrect during the 30 day preview period. We proposed that if we agree that the measure, as it is displayed in the preview report, contains a calculation error, we would suppress the data on the public reporting Web site, recalculate the measure, and publish it at the time of the next scheduled public display date. This process would be consistent with that followed in the Hospital IQR Program. If finalized, we intend to utilize a subregulatory mechanism, such as our SNF QRP Web site, to explain the process for how and when providers may contest their measure calculations.

The proposed claims-based measures—Medicare Spending per Beneficiary—PAC SNF QRP Measure; Discharge to Community—PAC SNF QRP and Potentially Preventable 30 Day Post-Discharge Readmission Measure for SNF QRP—use Medicare administrative data from hospitalizations for Medicare FFS beneficiaries. Public reporting of data will be based on one CY of data. We proposed to create data extracts using claims data for these claims based measures, at least 90 days after the last discharge date in the applicable period (12 calendar months preceding), which we will use for the calculations. For example, if the last discharge date in the applicable period for a measure is December 31, 2017, for data collection January 1, 2017, through December 31, 2017, we would create the data extract on approximately March 31, 2018, at the earliest, and use that data to calculate the claims-based measures for that applicable period. Since SNFs would not be able to submit corrections to the underlying claims snapshot or add claims (for those measures that use SNF claims) to this data set at the conclusion of the at least 90-day period following the last date of discharge used in the applicable period, at that time we would consider SNF claims data to be complete for purposes of calculating the claims-based measures.

We proposed that beginning with data that will be publicly displayed in 2018, claims-based measures will be calculated using claims data with at least a 90 day run off period after the last discharge date in the applicable period, at which time we would create a data extract or snapshot of the available claims data to use for the measure calculations. This timeframe allows us to balance the need to provide timely program information to SNFs with the need to calculate the claims-based measures using as complete a data set as possible. As noted, under this proposed procedure, during the 30-day preview period, SNFs would not be able to submit corrections to the underlying claims data or add new claims to the data extract. This is for two reasons. First, for certain measures, the claims data used to calculate the measure is derived not from the SNF's claims, but from the claims of another provider. For example, the measure Potentially Preventable 30-Day Post-Discharge Readmission Measure for SNF QRP uses claims data submitted by the hospital to which the patient was readmitted. The claims are not those of the SNF and, therefore, the SNF could not make corrections to them. Second, even where the claims used to calculate the measures are those of the SNF, it would not be not possible to correct the data after it is extracted for the measures calculation. This is because it is necessary to take a static ''snapshot'' of the claims to perform the necessary measure calculations.

We seek to have as complete a data set as possible. We recognize that the proposed at least 90-day ''run-out'' period when we would take the data extract to calculate the claims-based measures is less than the Medicare program's current timely claims filing policy, under which providers have up to one year from the date of discharge to submit claims. We considered a number of factors in determining that the proposed at least 90-day run-out period is appropriate to calculate the claims-based measures. After the data extract is created, it takes several months to incorporate other data needed for the calculations (particularly in the case of risk-adjusted or episode-based measures). We then need to generate and check the calculations. Because several months lead time is necessary after acquiring the data to generate the claims-based calculations, if we were to delay our data extraction point to 12 months after the last date of the last discharge in the applicable period, we would not be able to deliver the calculations to SNFs sooner than 18 to 24 months after the last discharge. We believe this would create an unacceptably long delay, both for SNFs and for us to deliver timely calculations to SNFs for quality improvement.

We invited public comment on these proposals. The comments we received on this topic, with their responses, appear below.

Comment: Several commenters recommended we provide real time reporting for assessment-based measures and every six months reporting for claims-based measures.

Response: SNFs will have an opportunity to review and utilize their data using confidential reports provided through the Certification and Survey Provider Enhanced Reports (CASPER) system as close to real time as is feasible. We intend to provide SNF *Review and Correct* reports that will allow providers to review information on assessment-based measures and anticipate the reports will be updated at least monthly. The decision to update claims-based measures on an annual basis was to ensure that the amount of data received during the reporting period was sufficient to generate reliable measure rates. However, we will look into the feasibility of providing SNFs with information more frequently.

Comment: One commenter was concerned with the 90-day run-out period for the claims-based measures because claims not filed within this period may negatively impact measure rates.

Response: We wish to clarify that we proposed for the claims-based measures to be calculated using claims data with at least a 90 day run off period after the last discharge date in the applicable period. We established this as the minimum run off period so as to use the most recently available data when calculating the claims-based measures. We developed this proposal to balance the need to provide timely program information to SNFs with the need to calculate the claims-based measures using as complete a data set as possible.

Final Decision: After careful consideration of public comments, we are finalizing these proposals as proposed.

o. Mechanism for Providing Feedback Reports to SNFs

Section 1899B(f) of the Act requires the Secretary to provide confidential

feedback reports to post-acute care providers on their performance for the measures specified under paragraphs (c)(1) and (d)(1), beginning 1 year after the specified application date that applies to such measures and PAC providers. As discussed earlier, the reports we proposed to provide to SNFs to review their data and information would be confidential feedback reports that would enable SNFs to review their performance on the measures required under the SNF QRP. We proposed that these confidential feedback reports would be available to each SNF using the CASPER System. Data contained within these CASPER reports would be updated, as previously described, on a monthly basis as the data become available except for claims-based measures which can only be previewed on an annual basis.

We intend to provide detailed procedures to SNFs on how to obtain their confidential feedback CASPER reports on the SNF QRP Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-Quality-Reporting.html.* We proposed to use the CMS Quality Improvement and Evaluation System (QIES) Assessment Submission and Processing (ASAP) system to provide quality measure reports in a manner consistent with how providers obtain such reports to date. The QIES ASAP system is a confidential and secure system with access granted to providers, or their designees.

We sought public comment on this proposal to satisfy the requirement to provide confidential feedback reports to SNFs. The comments we received on this topic, with their responses, appear below.

Comment: One commenter supported our plan to make the feedback reports available in QIES ASAP through CASPER.

Response: We appreciate the commenter's support for providing feedback reports through CASPER.

Comment: Several commenters recommended that we conduct a ''dry run'' in which providers receive confidential preview reports prior to publicly reporting new SNF QRP measures so that providers can become familiar with the methodology, understand the measure results, know how well they are performing, and have an opportunity to give us feedback on potential technical issues with the measures.

Response: We appreciate that implementation activities such as dry runs are valuable prior to measure implementation to ensure the usability of a measure and educate providers. We intend to offer SNFs information and outreach training related to their measures so that they become familiar with the measure's methodology and understand how to interpret the confidential preview reports, which they will receive prior to the public reporting of new SNF QRP measures. SNFs will also receive additional confidential reports such as the SNF facility and resident level QM Reports and Review and Correct reports which we are developing. The Review and Correct Report will display all of the reporting quarters so that SNFs can identify errors in their data prior to and up until the submission deadline (freeze date) of a given quarter. The *Review and Correct* Report will provide updates regarding our data with a cumulative rate that will reflect publicly reported performance. We believe that these various reports will provide an indication on how well the SNF is performing as well as opportunities to provide us feedback on technical issues with the measures. The SNF *Review and Correct* Reports will be available beginning in the spring of 2017 and will be issued prior to the public reporting of SNF QRP measures. We refer readers to the SNF QRP Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-Quality-Reporting.html* for further information, where we will address the process of accessing reports. We will continue to engage stakeholders and ask for recommendations to take into consideration for future public reporting development for the SNF QRP.

Final Decision: After careful consideration of public comments, we are finalizing our policies for providing confidential feedback reports to SNFs as proposed.

3. SNF Payment Models Research

In the FY 2017 SNF PPS proposed rule (81 FR 24275 through 24276), we provided an update on the progress we have made in the SNF Payment Models Research project. Specifically, we discussed the two prior Technical Expert Panels (TEPs) hosted by Acumen, LLC, the contractor conducting this research. On June 15, 2016, during the comment period associated with the FY 2017 SNF PPS proposed rule, Acumen hosted a third TEP which brought together many of the concepts and developments from the prior TEPs and analysis. We received a great deal of support from TEP panelists, as well as some excellent feedback on ways to improve the research going forward. As noted in the FY 2017 SNF PPS proposed rule, materials associated with these TEPs are available on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html.*

In the FY 2017 SNF PPS proposed rule, we requested comments on the SNF PMR project. The comments we received on this topic, with responses, appear below.

Comment: Many commenters supported the goals of the research effort, specifically to develop a replacement for the existing SNF PPS that reimburses providers based on resident characteristics and not service provision. Some commenters stated that we should consider adding certain elements into the new payment system, such as a high cost outlier payment, separate payment for non-therapy ancillaries, and shifting from a per diem payment to a stay-based or episode-based payment schedule. One commenter stated that we should consider incorporating an episode-based payment model specifically for speech-language pathology services. A few commenters stated that the reformed payment system should consider a resident's socioeconomic status. Finally, some of these commenters asked that we try to align the new PPS model with other existing or future post-acute care payment models.

Response: We appreciate the support for this project, and will consider the suggestions made by commenters. However, we would note that, in order to develop a revised payment model that is implementable without requiring additional statutory authority, we have decided to only pursue those options which would be authorized within existing statutory constraints. Among other things, we believe this precludes the possibility of an outlier policy or non-per diem payment.

Comment: A few commenters expressed concern regarding the timeline for reform of the existing SNF PPS, with one commenter expressing frustration that we have not yet implemented a revised SNF PPS. These commenters stated that we should implement reform as soon as possible.

Response: We appreciate these commenters' concerns regarding the timing for implementing reform, but would note that reform of a system which covers such a wide range of services and such a diverse population of beneficiaries requires time to be completed correctly. We are moving as expeditiously as possible, ensuring that we allow sufficient time for requesting and considering public comments.

Comment: A few commenters expressed concerns regarding the data being used for the research. One commenter stated that we should not use any data from the Staff Time and Resource Intensity Verification, or STRIVE, project. A few commenters stated that SNF cost report data may not represent a viable source of data upon which to base a revised SNF PPS. One commenter expressed concern regarding the potential use of ADL information collected on the MDS as a source of nursing resource information, as the number of medications a resident is taking would not be taken into account. Finally, a few commenters stated that we should refrain from implementing a revised SNF PPS until new resident data, such as that required by the IMPACT Act, is available for analysis.

Response: We appreciate the concerns raised by these commenters and will pass along these concerns to our contractor performing the research so that it can take them into account as the research continues to evolve.

Comment: One commenter provided comments on information the commenter received participating in a TEP associated with the research project. Specifically, the commenter expressed concern regarding the possibility of combining physical and occupational therapy together under a single rate component. The commenter also made reference to the possibility of an additional TEP in Fall 2016.

Response: We appreciate this commenter's thoughts on the TEP materials, as well as their participation on the panel itself. We will pass these comments on to our contractor performing the research to ensure that this, and other comments made by the commenter during the panel, are taken into account. With regard to the possibility of another TEP in Fall 2016, we have discussed plans with the contractor to host an additional TEP in Fall 2016.

We appreciate all of the comments received on this topic and look forward to providing additional details on the CMS Web site and in future rulemaking. We invite the public to provide comments outside of the rulemaking process by contacting us at *SNFTherapyPayments@cms.hhs.gov*.

IV. Collection of Information Requirements

Section III.D.2.f. of this preamble sets out three claims-based measures that we are adopting for the SNF QRP beginning with the FY 2018 payment year: (1) Medicare Spending per Beneficiary—PAC SNF QRP; (2) Discharge to Community—PAC SNF QRP; and (3) Potentially Preventable 30-Day Post-Discharge Readmission Measure for SNF QRP. Because they are claims-based, the measures can be calculated using data that are already reported to the Medicare program for payment purposes. Consequently, we believe there will be no additional burden on SNFs in connection with the the reporting of data needed to calculate these measures.

We did not receive any public comments on this topic in response to the FY 2017 SNF PPS proposed rule.

For the FY 2020 payment determination and subsequent years, we are adopting for the SNF QRP an assessment-based measure entitled Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC SNF QRP. The data for this measure will be collected and reported using the MDS (version effective October 1, 2018). While the reporting of data on quality measures is an information collection, we believe that the burden associated with modifications to the MDS fall under the PRA exception (provided in section 1899B(m) of the IMPACT Act of 2014) because they are required to achieve the standardization of patient assessment data. The requirement and burden will, however, be submitted to OMB for review and approval when the modifications to the MDS or other applicable PAC assessment instruments have achieved standardization and are no longer exempt from the requirements under section 1899B(m).

We estimate the additional elements for the new assessment measure will take 7.5 minutes of nursing/clinical staff time to report data on admission and 2.5 minutes of nursing/clinical staff time to report data on discharge, for a total of 10 minutes. We estimate that the additional MDS–RAI items will be completed by Registered Nurses (RN) for approximately 75 percent of the time required and Pharmacists for approximately 25 percent of the time required. Individual providers determine the staffing resources necessary. We estimate 2,101,370 discharges from 16,484 SNFs annually, with an additional burden of 10 minutes. This would equate to 350,228 total hours or 21.25 hours per SNF. We believe this work will be completed by RNs (75 percent) and Pharmacists (25 percent). We obtained mean hourly wages for these staff from the U.S. Bureau of Labor Statistics' (BLS) May 2015 National Occupational Employment and Wage Estimates (*http://www.bls.gov/oes/current/oes_nat.htm*), to account for overhead and fringe benefits, we have doubled the mean hourly wage. Per the National Occupational Employment and Wage Estimates, the mean hourly wage for a RN (BLS occupation code: 29–1141) is $34.14/hr. However, to account for overhead and fringe benefits, we have double the mean hourly wage, making it $68.28/hr for an RN. The mean hourly wage for a pharmacist (BLS occupation code: 29–1051) is $57.34/hr. To account for overhead and fringe benefits, we have double the mean hourly wage, making it $114.68/hr for a pharmacist. Given these wages and time estimates, the total cost related to the four measures is estimated at $1,697.17 per SNF annually, or $27,976,212.64 [(262,671 hr × $68.28/hr) + (87,557 hr × $114.68/hr)] for all SNFs annually. These values have been updated from the FY 2017 SNF PPS proposed rule to reflect the more recent 2015 wage estimates. While we are setting out burden, the requirements and associated estimates will not be submitted to OMB for approval under Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) since the burden estimates are either claims-based or associated with the exemption under section 1899B(m) of the IMPACT Act of 2014. We are setting out the burden as a courtesy to advise interested parties of the time and costs. These figures are not in the RIA section of this rule.

We received the following comment in response to the FY 2017 SNF PPS proposed rule.

Comment: One commenter agreed that standardization and associated collection of this MDS-based measure is PRA exempt. However, the commenter suggested that the estimate provided by CMS in the proposed rule is insufficient.

Response: For burden associated with this FY 2017 SNF PPS final rule, we considered the comment while planning to implement new items on the MDS. The comment was general in that it did not identify the estimate of concern nor did it identify what the correct estimate should be. While considering the comment, we revised our hourly wage estimate to account for more recent BLS wage data. Otherwise, our final estimate is unchanged from what was proposed.

As described in further detail in section III.D.1.b. of this final rule, we are adopting the SNFPPR measure for the SNF VBP Program. Like the SNFRM (NQF #2510), which was adopted for the SNF VBP Program in the FY 2016 SNF PPS final rule (80 FR 46419), the SNFPPR measure is also claims-based. Because claims-based measures are calculated based on claims that are already submitted to the Medicare program for payment purposes, there is no additional burden associated with

data collection or submission for the SNFPPR measure. Thus there is no additional reporting burden associated with the SNFPPR measure.

We did not receive any public comments on this topic in response to the FY 2017 SNF PPS proposed rule.

Comments on any of the aforementioned collection of information claims must be received by the OMB desk officer by August 29, 2016.

To be assured consideration, comments and recommendations must be received via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, *Fax Number:* (202) 395–5806 *OR*, *Email: OIRA_submission@omb.eop.gov*.

V. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA, September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA, March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated an economically significant rule, under section 3(f)(1) of Executive Order 12866. Accordingly, we have prepared a regulatory impact analysis (RIA) as further discussed below, and the rule has been reviewed by OMB.

2. Statement of Need

This final rule updates the SNF prospective payment rates for FY 2017 as required under section 1888(e)(4)(E) of the Act. It also responds to section 1888(e)(4)(H) of the Act, which requires the Secretary to provide for publication in the **Federal Register** before the August 1 that precedes the start of each FY, the unadjusted federal per diem rates, the case-mix classification system, and the factors to be applied in making the area wage adjustment. As these statutory provisions prescribe a detailed methodology for calculating and disseminating payment rates under the SNF PPS, we do not have the discretion to adopt an alternative approach.

3. Overall Impacts

This final rule sets forth updates of the SNF PPS rates contained in the SNF PPS final rule for FY 2016 (80 FR 46390). Based on the above, we estimate that the aggregate impact would be an increase of $920 million in payments to SNFs, resulting from the SNF market basket update to the payment rates, as adjusted by the MFP adjustment. The impact analysis of this final rule represents the projected effects of the changes in the SNF PPS from FY 2016 to FY 2017. Although the best data available are utilized, there is no attempt to predict behavioral responses to these changes or to make adjustments for future changes in such variables as days or case-mix.

Certain events may occur to limit the scope or accuracy of our impact analysis, as this analysis is future-oriented and, thus, very susceptible to forecasting errors due to certain events that may occur within the assessed impact time period. Some examples of possible events may include newly-legislated general Medicare program funding changes by the Congress or changes specifically related to SNFs. In addition, changes to the Medicare program may continue to be made as a result of previously-enacted legislation or new statutory provisions. Although these changes may not be specific to the SNF PPS, the nature of the Medicare program is such that the changes may interact and, thus, the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon SNFs.

In accordance with sections 1888(e)(4)(E) and 1888(e)(5) of the Act, we update the FY 2016 payment rates by a factor equal to the market basket percentage change adjusted by the MFP adjustment to determine the payment rates for FY 2017. As discussed previously, for FY 2012 and each subsequent FY, as required by section 1888(e)(5)(B) of the Act, as amended by section 3401(b) of the Affordable Care Act, the market basket percentage is reduced by the MFP adjustment. The special AIDS add-on established by section 511 of the MMA remains in effect until such date as the Secretary certifies that there is an appropriate adjustment in the case mix. We have not provided a separate impact analysis for the MMA provision. Our latest estimates indicate that there are fewer than 4,800 beneficiaries who qualify for the add-on payment for residents with AIDS. The impact to Medicare is included in the total column of Table 19. In updating the SNF PPS rates for FY 2017, we made a number of standard annual revisions and clarifications mentioned elsewhere in this final rule (for example, the update to the wage and market basket indexes used for adjusting the federal rates).

The annual update set forth in this final rule applies to SNF PPS payments in FY 2017. Accordingly, the analysis that follows only describes the impact of this single year. In accordance with the requirements of the Act, we will publish a notice or rule for each subsequent FY that will provide for an update to the SNF PPS payment rates and include an associated impact analysis.

4. Detailed Economic Analysis

The FY 2017 SNF PPS payment impacts appear in Table 19. Using the most recently available data, in this case FY 2015, we apply the current FY 2016 wage index and labor-related share value to the number of payment days to simulate FY 2016 payments. Then, using the same FY 2015 data, we apply the FY 2017 wage index and labor-related share value to simulate FY 2017 payments. We tabulate the resulting payments according to the classifications in Table 19 (for example, facility type, geographic region, facility ownership), and compare the simulated FY 2016 payments to the simulated FY 2017 payments to determine the overall impact. In Section III.B.2 and III.B.4 of this final rule, we discussed an error in calculating the FY 2017 wage index budget neutrality factor in the FY 2017 SNF PPS proposed rule and how this error affected the impact table in the FY 2017 SNF PPS proposed rule (81 FR 24278). Specifically, we stated that in calculating the proposed wage index budget neutrality factor, we inadvertently neglected to update the wage index data used in the calculation with the most recently available FY 2017 data. As we discussed in section III.B.2. and III.B.4. of this final rule, this same error (the use of non-updated wage index data) which resulted in an incorrect calculation of the proposed wage index budget neutrality factor also resulted in inaccurate wage index impacts in Table 19 of the FY 2017 SNF PPS proposed rule. We have corrected this error, and Table 19 of this final rule includes corrected impact values based

on updated FY 2017 wage index data. The breakdown of the various categories of data in the table follows:

- The first column shows the breakdown of all SNFs by urban or rural status, hospital-based or freestanding status, census region, and ownership.
- The first row of figures describes the estimated effects of the various changes on all facilities. The next six rows show the effects on facilities split by hospital-based, freestanding, urban, and rural categories. The next nineteen rows show the effects on facilities by urban versus rural status by census region. The last three rows show the effects on facilities by ownership (that is, government, profit, and non-profit status).
- The second column shows the number of facilities in the impact database.
- The third column shows the effect of the annual update to the wage index. This represents the effect of using the most recent wage data available. The total impact of this change is zero percent; however, there are distributional effects of the change.
- The fourth column shows the effect of all of the changes on the FY 2017 payments. The update of 2.4 percent (consisting of the market basket increase of 2.7 percentage points, reduced by the 0.3 percentage point MFP adjustment) is constant for all providers and, though not shown individually, is included in the total column. It is projected that aggregate payments will increase by 2.4 percent, assuming facilities do not change their care delivery and billing practices in response.

As illustrated in Table 19, the combined effects of all of the changes vary by specific types of providers and by location. For example, due to changes finalized in this rule, providers in the urban Outlying region would experience a 1.7 percent increase in FY 2017 total payments.

TABLE 19—PROJECTED IMPACT TO THE SNF PPS FOR FY 2017

	Number of facilities FY 2017	Update wage data (percent)	Total change (percent)
Group:			
Total	15,445	0.0	2.4
Urban	10,946	0.0	2.4
Rural	4,499	0.3	2.7
Hospital based urban	467	−0.2	2.2
Freestanding urban	10,479	0.0	2.4
Hospital based rural	320	0.5	2.9
Freestanding rural	4,179	0.3	2.7
Urban by region:			
New England	797	−0.8	1.6
Middle Atlantic	1,481	−0.1	2.3
South Atlantic	1,862	−0.2	2.2
East North Central	2,095	−0.1	2.3
East South Central	547	−0.1	2.3
West North Central	907	−0.2	2.2
West South Central	1,323	0.3	2.7
Mountain	509	−0.1	2.3
Pacific	1,420	0.6	3.0
Outlying	5	−0.6	1.7
Rural by region:			
New England	139	0.1	2.5
Middle Atlantic	221	0.4	2.8
South Atlantic	507	−0.2	2.2
East North Central	933	0.2	2.6
East South Central	530	0.4	2.8
West North Central	1,087	0.5	2.9
West South Central	745	0.6	3.0
Mountain	233	0.7	3.2
Pacific	104	−0.4	2.0
Ownership:			
Government	1,051	0.1	2.5
Profit	10,766	0.0	2.4
Non-profit	3,628	−0.1	2.3

Note: The Total column includes the 2.7 percent market basket increase, reduced by the 0.3 percentage point MFP adjustment. Additionally, we found no SNFs in rural outlying areas.

5. Alternatives Considered

As described in this section, we estimate that the aggregate impact for FY 2017 under the SNF PPS would be an increase of $920 million in payments to SNFs, resulting from the SNF market basket update to the payment rates, as adjusted by the MFP adjustment.

Section 1888(e) of the Act establishes the SNF PPS for the payment of Medicare SNF services for cost reporting periods beginning on or after July 1, 1998. This section of the statute prescribes a detailed formula for calculating payment rates under the SNF PPS and does not provide for the use of any alternative methodology. It specifies that the base year cost data to be used for computing the SNF PPS payment rates must be from FY 1995 (October 1, 1994, through September 30, 1995). In accordance with the statute, we also incorporated a number of elements into the SNF PPS (for example, case-mix classification methodology, a market basket index, a wage index, and the urban and rural distinction used in the development or adjustment of the federal rates). Further, section 1888(e)(4)(H) of the Act specifically requires us to disseminate the payment rates for each new FY through the **Federal Register** and to do so before the

August 1 that precedes the start of the new FY. Accordingly, we are not pursuing alternatives for the payment methodology as discussed previously.

6. Accounting Statement

As required by OMB Circular A–4 (available online at *www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/a-4.pdf*), in Table 20, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule. Table 20 provides our best estimate of the possible changes in Medicare payments under the SNF PPS as a result of the policies in this final rule, based on the data for 15,427 SNFs in our database. All expenditures are classified as transfers to Medicare providers (that is, SNFs).

TABLE 20—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM THE 2016 SNF PPS FISCAL YEAR TO THE 2017 SNF PPS FISCAL YEAR

Category	Transfers
Annualized Monetized Transfers.	$920 million.*
From Whom To Whom?.	Federal Government to SNF Medicare Providers.

*The net increase of $920 million in transfer payments is a result of the MFP-adjusted market basket increase of $920 million.

7. Conclusion

This final rule sets forth updates of the SNF PPS rates contained in the SNF PPS final rule for FY 2016 (80 FR 46390). Based on the above, we estimate the overall estimated payments for SNFs in FY 2017 are projected to increase by $920 million, or 2.4 percent, compared with those in FY 2016. We estimate that in FY 2017 under RUG–IV, SNFs in urban and rural areas would experience, on average, a 2.4 and 2.7 percent increase, respectively, in estimated payments compared with FY 2016. Providers in the rural Mountain region would experience the largest estimated increase in payments of approximately 3.2 percent. Providers in the urban New England region would experience the smallest estimated increase in payments of 1.6 percent.

8. Effects of the Requirements for the SNF VBP and SNF QRP Program

The requirements set forth for the SNF VBP and SNF QRP Program in this final rule would not impact SNFs in FY 2017; therefore, we are not including a regulatory impact analysis for the SNF VBP and SNF QRP Program in this final rule.

B. Regulatory Flexibility Act Analysis

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, non-profit organizations, and small governmental jurisdictions. Most SNFs and most other providers and suppliers are small entities, either by reason of their non-profit status or by having revenues of $27.5 million or less in any 1 year. We utilized the revenues of individual SNF providers (from recent Medicare Cost Reports) to classify a small business, and not the revenue of a larger firm with which they may be affiliated. As a result, we estimate approximately 91 percent of SNFs are considered small businesses according to the Small Business Administration's latest size standards (NAICS 623110), with total revenues of $27.5 million or less in any 1 year. (For details, see the Small Business Administration's Web site at *http://www.sba.gov/category/navigation-structure/contracting/contracting-officials/eligibility-size-standards*). In addition, approximately 25 percent of SNFs classified as small entities are non-profit organizations. Finally, individuals and states are not included in the definition of a small entity.

This final rule sets forth updates of the SNF PPS rates contained in the SNF PPS final rule for FY 2016 (80 FR 46390). Based on the above, we estimate that the aggregate impact would be an increase of $920 million in payments to SNFs, resulting from the SNF market basket update to the payment rates, as adjusted by the MFP adjustment. While it is projected in Table 19 that most providers would experience a net increase in payments, we note that some individual providers within the same region or group may experience different impacts on payments than others due to the distributional impact of the FY 2017 wage indexes and the degree of Medicare utilization.

Guidance issued by the Department of Health and Human Services on the proper assessment of the impact on small entities in rulemakings utilizes a cost or revenue impact of 3 to 5 percent as a significance threshold under the RFA. According to MedPAC, Medicare covers approximately 12 percent of total patient days in freestanding facilities and 21 percent of facility revenue (Report to the Congress: Medicare Payment Policy, March 2016, available at *http://medpac.gov/documents/reports/chapter-7-skilled-nursing-facility-services-(march-2016-report).pdf*). As a result, for most facilities, when all payers are included in the revenue stream, the overall impact on total revenues should be substantially less than those impacts presented in Table 19. As indicated in Table 19, the effect on facilities is projected to be an aggregate positive impact of 2.4 percent. As the overall impact on the industry as a whole, and thus on small entities specifically, is less than the 3 to 5 percent threshold discussed previously, the Secretary has determined that this final rule would not have a significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an MSA and has fewer than 100 beds. This final rule would affect small rural hospitals that (1) furnish SNF services under a swing-bed agreement or (2) have a hospital-based SNF. We anticipate that the impact on small rural hospitals would be similar to the impact on SNF providers overall. Moreover, as noted in previous SNF PPS final rules (most recently the one for FY 2016 (80 FR 46476)), the category of small rural hospitals would be included within the analysis of the impact of this final rule on small entities in general. As indicated in Table 19, the effect on facilities is projected to be an aggregate positive impact of 2.4 percent. As the overall impact on the industry as a whole is less than the 3 to 5 percent threshold discussed above, the Secretary has determined that this final rule would not have a significant impact on a substantial number of small rural hospitals.

C. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2016, that threshold is approximately $146 million. This final rule does not include any mandate on state, local, or tribal governments in the aggregate, or by the private sector, of $146 million.

D. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. This final rule would have no substantial direct effect on state and local governments, preempt state law, or otherwise have federalism implications.

E. Congressional Review Act

This final rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq*.) and has been transmitted to the Congress and the Comptroller General for review.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

Dated: July 18, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: July 25, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

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Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 412

Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2017; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 412

[CMS–1647–F]

RIN 0938–AS78

Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2017

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule will update the prospective payment rates for inpatient rehabilitation facilities (IRFs) for federal fiscal year (FY) 2017 as required by the statute. As required by section 1886(j)(5) of the Act, this rule includes the classification and weighting factors for the IRF prospective payment system's (IRF PPS's) case-mix groups and a description of the methodologies and data used in computing the prospective payment rates for FY 2017. This final rule also revises and updates quality measures and reporting requirements under the IRF quality reporting program (QRP).

DATES:

Effective Dates: These regulations are effective on October 1, 2016.

Applicability Dates: The updated IRF prospective payment rates are applicable for IRF discharges occurring on or after October 1, 2016, and on or before September 30, 2017 (FY 2017). The updated quality measures and reporting requirements under the IRF QRP are effective for IRF discharges occurring on or after October 1, 2016.

FOR FURTHER INFORMATION CONTACT: Gwendolyn Johnson, (410) 786–6954, for general information. Catie Kraemer, (410) 786–0179, for information about the wage index. Christine Grose, (410) 786-1362, for information about the quality reporting program. Kadie Derby, (410) 786–0468, or Susanne Seagrave, (410) 786–0044, for information about the payment policies and payment rates.

SUPPLEMENTARY INFORMATION: The IRF PPS Addenda along with other supporting documents and tables referenced in this final rule are available through the Internet on the CMS Web site at *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/*.

Executive Summary

A. Purpose

This final rule updates the prospective payment rates for IRFs for FY 2017 (that is, for discharges occurring on or after October 1, 2016, and on or before September 30, 2017) as required under section 1886(j)(3)(C) of the Social Security Act (the Act). As required by section 1886(j)(5) of the Act, this rule includes the classification and weighting factors for the IRF PPS's case-mix groups and a description of the methodologies and data used in computing the prospective payment rates for FY 2017. This final rule also finalizes revisions and updates to the quality measures and reporting requirements under the IRF QRP.

B. Summary of Major Provisions

In this final rule, we use the methods described in the FY 2016 IRF PPS final rule (80 FR 47036) to update the federal prospective payment rates for FY 2017 using updated FY 2015 IRF claims and the most recent available IRF cost report data, which is FY 2014 IRF cost report data. We are also finalizing revisions and updates to the quality measures and reporting requirements under the IRF QRP.

C. Summary of Impacts

Provision description	Transfers
FY 2017 IRF PPS payment rate update	The overall economic impact of this final rule is an estimated $145 million in increased payments from the Federal government to IRFs during FY 2017.
Provision description	**Costs**
New quality reporting program requirements	The total costs in FY 2017 for IRFs as a result of the new quality reporting requirements are estimated to be $5,231,398.17.

To assist readers in referencing sections contained in this document, we are providing the following Table of Contents.

Table of Contents

Acronyms, Abbreviations, and Short Forms

Because of the many terms to which we refer by acronym, abbreviation, or short form in this final rule, we are listing the acronyms, abbreviation, and short forms used and their corresponding terms in alphabetical order.

The Act The Social Security Act
ADC Average Daily Census
ADE Adverse Drug Events
The Affordable Care Act Patient Protection and Affordable Care Act (Pub. L. 111–148, enacted on March 23, 2010)
AHRQ Agency for Healthcare Research and Quality
APU Annual Payment Update
ASAP Assessment Submission and Processing
ASCA The Administrative Simplification Compliance Act of 2002 (Pub. L. 107–105, enacted on December 27, 2002)
ASPE Office of the Assistant Secretary for Planning and Evaluation
BLS U.S. Bureau of Labor Statistics
BMI Body Mass Index
CAH Critical Access Hospitals
CASPER Certification and Survey Provider Enhanced Reports
CAUTI Catheter-Associated Urinary Tract Infection
CBSA Core-Based Statistical Area
CCR Cost-to-Charge Ratio
CDC The Centers for Disease Control and Prevention
CDI *Clostridium difficile* Infection
CFR Code of Federal Regulations
CMG Case-Mix Group
CMS Centers for Medicare & Medicaid Services
COA Care for Older Adults
CY Calendar year
DSH Disproportionate Share Hospital
DSH PP Disproportionate Share Patient Percentage
DRG Diagnosis-Related Group
eCQMs Electronically Specified Clinical Quality Measures
ESRD End-Stage Renal Disease
FFS Fee-for-Service
FR Federal Register
FY Federal Fiscal Year
GEMS General Equivalence Mapping
GPCI Geographic Practice Cost Index
HAI Healthcare Associated Infection
HCC Hierarchical Condition Category
HHA Home Health Agencies
HCP Home Care Personnel
HHS U.S. Department of Health & Human Services
HIPAA Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191, enacted on August 21, 1996)
Hospital VBP Hospital Value-Based Purchasing Program (also HVBP)
ICD–9–CM International Classification of Diseases, 9th Revision, Clinical Modification
ICD–10–CM International Classification of Diseases, 10th Revision, Clinical Modification
IGC Impairment Group Code
IGI IHS Global Insight
IMPACT Act Improving Medicare Post-Acute Care Transformation Act of 2014 (Pub. L. 113–185, enacted on October 6, 2014)
IME Indirect Medical Education
IPF Inpatient Psychiatric Facility
IPPS Inpatient prospective payment system
IQR Inpatient Quality Reporting Program
IRF Inpatient Rehabilitation Facility
IRF–PAI Inpatient Rehabilitation Facility-Patient Assessment Instrument
IRF PPS Inpatient Rehabilitation Facility Prospective Payment System
IRF QRP Inpatient Rehabilitation Facility Quality Reporting Program
IRVEN Inpatient Rehabilitation Validation and Entry
LIP Low-Income Percentage
IVS Influenza Vaccination Season
LTCH Long-Term Care Hospital
MA (Medicare Part C) Medicare Advantage
MAC Medicare Administrative Contractor
MAP Measures Application Partnership
MedPAC Medicare Payment Advisory Commission
MFP Multifactor Productivity
MMSEA Medicare, Medicaid, and SCHIP Extension Act of 2007 (Pub. L. 110–173, enacted on December 29, 2007)
MRSA Methicillin-Resistant *Staphylococcus aureus*
MSPB Medicare Spending per Beneficiary
MUC Measures under Consideration
NHSN National Healthcare Safety Network
NQF National Quality Forum
OMB Office of Management and Budget
ONC Office of the National Coordinator for Health Information Technology
OPPS/ASC Outpatient Prospective Payment System/Ambulatory Surgical Center
PAC Post-Acute Care
PAC/LTC Post-Acute Care/Long-Term Care
PAI Patient Assessment Instrument
PPR Potentially Preventable Readmissions
PPS Prospective Payment System
PRA Paperwork Reduction Act of 1995 (Pub. L. 104–13, enacted on May 22, 1995)
QIES Quality Improvement Evaluation System
QM Quality Measure
QRP Quality Reporting Program
RIA Regulatory Impact Analysis
RIC Rehabilitation Impairment Category
RFA Regulatory Flexibility Act (Pub. L. 96–354, enacted on September 19, 1980)
RN Registered Nurse
RPL Rehabilitation, Psychiatric, and Long-Term Care market basket
RSRR Risk-standardized readmission rate
SIR Standardized Infection Ratio
SNF Skilled Nursing Facilities
SRR Standardized Risk Ratio
SSI Supplemental Security Income
TEP Technical Expert Panel

I. Background

A. Historical Overview of the IRF PPS

Section 1886(j) of the Act provides for the implementation of a per-discharge prospective payment system (PPS) for inpatient rehabilitation hospitals and inpatient rehabilitation units of a hospital (collectively, hereinafter referred to as IRFs). Payments under the IRF PPS encompass inpatient operating and capital costs of furnishing covered rehabilitation services (that is, routine, ancillary, and capital costs), but not direct graduate medical education costs, costs of approved nursing and allied health education activities, bad debts, and other services or items outside the scope of the IRF PPS. Although a complete discussion of the IRF PPS provisions appears in the original FY 2002 IRF PPS final rule (66 FR 41316) and the FY 2006 IRF PPS final rule (70 FR 47880), we are providing below a general description of the IRF PPS for FYs 2002 through 2016.

Under the IRF PPS from FY 2002 through FY 2005 the federal prospective payment rates were computed across 100 distinct case-mix groups (CMGs), as described in the FY 2002 IRF PPS final rule (66 FR 41316). We constructed 95 CMGs using rehabilitation impairment categories (RICs), functional status (both motor and cognitive), and age (in some cases, cognitive status and age may not be a factor in defining a CMG). In addition, we constructed five special CMGs to account for very short stays and for patients who expire in the IRF.

For each of the CMGs, we developed relative weighting factors to account for a patient's clinical characteristics and expected resource needs. Thus, the weighting factors accounted for the relative difference in resource use across all CMGs. Within each CMG, we created tiers based on the estimated effects that certain comorbidities would have on resource use.

We established the federal PPS rates using a standardized payment conversion factor (formerly referred to

as the budget-neutral conversion factor). For a detailed discussion of the budget-neutral conversion factor, please refer to our FY 2004 IRF PPS final rule (68 FR 45684 through 45685). In the FY 2006 IRF PPS final rule (70 FR 47880), we discussed in detail the methodology for determining the standard payment conversion factor.

We applied the relative weighting factors to the standard payment conversion factor to compute the unadjusted federal prospective payment rates under the IRF PPS from FYs 2002 through 2005. Within the structure of the payment system, we then made adjustments to account for interrupted stays, transfers, short stays, and deaths. Finally, we applied the applicable adjustments to account for geographic variations in wages (wage index), the percentage of low-income patients, location in a rural area (if applicable), and outlier payments (if applicable) to the IRFs' unadjusted federal prospective payment rates.

For cost reporting periods that began on or after January 1, 2002, and before October 1, 2002, we determined the final prospective payment amounts using the transition methodology prescribed in section 1886(j)(1) of the Act. Under this provision, IRFs transitioning into the PPS were paid a blend of the federal IRF PPS rate and the payment that the IRFs would have received had the IRF PPS not been implemented. This provision also allowed IRFs to elect to bypass this blended payment and immediately be paid 100 percent of the federal IRF PPS rate. The transition methodology expired as of cost reporting periods beginning on or after October 1, 2002 (FY 2003), and payments for all IRFs now consist of 100 percent of the federal IRF PPS rate.

We established a CMS Web site as a primary information resource for the IRF PPS which is available at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/index.html*. The Web site may be accessed to download or view publications, software, data specifications, educational materials, and other information pertinent to the IRF PPS.

Section 1886(j) of the Act confers broad statutory authority upon the Secretary to propose refinements to the IRF PPS. In the FY 2006 IRF PPS final rule (70 FR 47880) and in correcting amendments to the FY 2006 IRF PPS final rule (70 FR 57166) that we published on September 30, 2005, we finalized a number of refinements to the IRF PPS case-mix classification system (the CMGs and the corresponding relative weights) and the case-level and facility-level adjustments. These refinements included the adoption of the Office of Management and Budget's (OMB) Core-Based Statistical Area (CBSA) market definitions, modifications to the CMGs, tier comorbidities, and CMG relative weights, implementation of a new teaching status adjustment for IRFs, revision and rebasing of the market basket index used to update IRF payments, and updates to the rural, low-income percentage (LIP), and high-cost outlier adjustments. Beginning with the FY 2006 IRF PPS final rule (70 FR 47908 through 47917), the market basket index used to update IRF payments was a market basket reflecting the operating and capital cost structures for freestanding IRFs, freestanding inpatient psychiatric facilities (IPFs), and long-term care hospitals (LTCHs) (hereinafter referred to as the rehabilitation, psychiatric, and long-term care (RPL) market basket). Any reference to the FY 2006 IRF PPS final rule in this final rule also includes the provisions effective in the correcting amendments. For a detailed discussion of the final key policy changes for FY 2006, please refer to the FY 2006 IRF PPS final rule (70 FR 47880 and 70 FR 57166).

In the FY 2007 IRF PPS final rule (71 FR 48354), we further refined the IRF PPS case-mix classification system (the CMG relative weights) and the case-level adjustments, to ensure that IRF PPS payments would continue to reflect as accurately as possible the costs of care. For a detailed discussion of the FY 2007 policy revisions, please refer to the FY 2007 IRF PPS final rule (71 FR 48354).

In the FY 2008 IRF PPS final rule (72 FR 44284), we updated the federal prospective payment rates and the outlier threshold, revised the IRF wage index policy, and clarified how we determine high-cost outlier payments for transfer cases. For more information on the policy changes implemented for FY 2008, please refer to the FY 2008 IRF PPS final rule (72 FR 44284), in which we published the final FY 2008 IRF federal prospective payment rates. After publication of the FY 2008 IRF PPS final rule (72 FR 44284), section 115 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (Pub. L. 110–173, enacted on December 29, 2007) (MMSEA), amended section 1886(j)(3)(C) of the Act to apply a zero percent increase factor for FYs 2008 and 2009, effective for IRF discharges occurring on or after April 1, 2008. Section 1886(j)(3)(C) of the Act required the Secretary to develop an increase factor to update the IRF federal prospective payment rates for each FY. Based on the legislative change to the increase factor, we revised the FY 2008 federal prospective payment rates for IRF discharges occurring on or after April 1, 2008. Thus, the final FY 2008 IRF federal prospective payment rates that were published in the FY 2008 IRF PPS final rule (72 FR 44284) were effective for discharges occurring on or after October 1, 2007, and on or before March 31, 2008; and the revised FY 2008 IRF federal prospective payment rates were effective for discharges occurring on or after April 1, 2008, and on or before September 30, 2008. The revised FY 2008 federal prospective payment rates are available on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html*.

In the FY 2009 IRF PPS final rule (73 FR 46370), we updated the CMG relative weights, the average length of stay values, and the outlier threshold; clarified IRF wage index policies regarding the treatment of ''New England deemed'' counties and multi-campus hospitals; and revised the regulation text in response to section 115 of the MMSEA to set the IRF compliance percentage at 60 percent (the ''60 percent rule'') and continue the practice of including comorbidities in the calculation of compliance percentages. We also applied a zero percent market basket increase factor for FY 2009 in accordance with section 115 of the MMSEA. For more information on the policy changes implemented for FY 2009, please refer to the FY 2009 IRF PPS final rule (73 FR 46370), in which we published the final FY 2009 IRF federal prospective payment rates.

In the FY 2010 IRF PPS final rule (74 FR 39762) and in correcting amendments to the FY 2010 IRF PPS final rule (74 FR 50712) that we published on October 1, 2009, we updated the federal prospective payment rates, the CMG relative weights, the average length of stay values, the rural, LIP, teaching status adjustment factors, and the outlier threshold; implemented new IRF coverage requirements for determining whether an IRF claim is reasonable and necessary; and revised the regulation text to require IRFs to submit patient assessments on Medicare Advantage (MA) (formerly called Medicare Part C) patients for use in the 60 percent rule calculations. Any reference to the FY 2010 IRF PPS final rule in this final rule also includes the provisions effective in the correcting amendments. For more information on the policy changes implemented for FY 2010, please refer

to the FY 2010 IRF PPS final rule (74 FR 39762 and 74 FR 50712), in which we published the final FY 2010 IRF federal prospective payment rates.

After publication of the FY 2010 IRF PPS final rule (74 FR 39762), section 3401(d) of the Patient Protection and Affordable Care Act (Pub. L. 111–148, enacted on March 23, 2010), as amended by section 10319 of the same Act and by section 1105 of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, enacted on March 30, 2010) (collectively, hereinafter referred to as ''The Affordable Care Act''), amended section 1886(j)(3)(C) of the Act and added section 1886(j)(3)(D) of the Act. Section 1886(j)(3)(C) of the Act requires the Secretary to estimate a multifactor productivity adjustment to the market basket increase factor, and to apply other adjustments as defined by the Act. The productivity adjustment applies to FYs from 2012 forward. The other adjustments apply to FYs 2010 to 2019.

Sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(i) of the Act defined the adjustments that were to be applied to the market basket increase factors in FYs 2010 and 2011. Under these provisions, the Secretary was required to reduce the market basket increase factor in FY 2010 by a 0.25 percentage point adjustment. Notwithstanding this provision, in accordance with section 3401(p) of the Affordable Care Act, the adjusted FY 2010 rate was only to be applied to discharges occurring on or after April 1, 2010. Based on the self-implementing legislative changes to section 1886(j)(3) of the Act, we adjusted the FY 2010 federal prospective payment rates as required, and applied these rates to IRF discharges occurring on or after April 1, 2010, and on or before September 30, 2010. Thus, the final FY 2010 IRF federal prospective payment rates that were published in the FY 2010 IRF PPS final rule (74 FR 39762) were used for discharges occurring on or after October 1, 2009, and on or before March 31, 2010, and the adjusted FY 2010 IRF federal prospective payment rates applied to discharges occurring on or after April 1, 2010, and on or before September 30, 2010. The adjusted FY 2010 federal prospective payment rates are available on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html*.

In addition, sections 1886(j)(3)(C) and (D) of the Act also affected the FY 2010 IRF outlier threshold amount because they required an adjustment to the FY 2010 RPL market basket increase factor, which changed the standard payment conversion factor for FY 2010. Specifically, the original FY 2010 IRF outlier threshold amount was determined based on the original estimated FY 2010 RPL market basket increase factor of 2.5 percent and the standard payment conversion factor of $13,661. However, as adjusted, the IRF prospective payments are based on the adjusted RPL market basket increase factor of 2.25 percent and the revised standard payment conversion factor of $13,627. To maintain estimated outlier payments for FY 2010 equal to the established standard of 3 percent of total estimated IRF PPS payments for FY 2010, we revised the IRF outlier threshold amount for FY 2010 for discharges occurring on or after April 1, 2010, and on or before September 30, 2010. The revised IRF outlier threshold amount for FY 2010 was $10,721.

Sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(i) of the Act also required the Secretary to reduce the market basket increase factor in FY 2011 by a 0.25 percentage point adjustment. The FY 2011 IRF PPS notice (75 FR 42836) and the correcting amendments to the FY 2011 IRF PPS notice (75 FR 70013) described the required adjustments to the FY 2011 and FY 2010 IRF PPS federal prospective payment rates and outlier threshold amount for IRF discharges occurring on or after April 1, 2010, and on or before September 30, 2011. It also updated the FY 2011 federal prospective payment rates, the CMG relative weights, and the average length of stay values. Any reference to the FY 2011 IRF PPS notice in this final rule also includes the provisions effective in the correcting amendments. For more information on the FY 2010 and FY 2011 adjustments or the updates for FY 2011, please refer to the FY 2011 IRF PPS notice (75 FR 42836 and 75 FR 70013).

In the FY 2012 IRF PPS final rule (76 FR 47836), we updated the IRF federal prospective payment rates, rebased and revised the RPL market basket, and established a new quality reporting program for IRFs in accordance with section 1886(j)(7) of the Act. We also revised regulation text for the purpose of updating and providing greater clarity. For more information on the policy changes implemented for FY 2012, please refer to the FY 2012 IRF PPS final rule (76 FR 47836), in which we published the final FY 2012 IRF federal prospective payment rates.

The FY 2013 IRF PPS notice (77 FR 44618) described the required adjustments to the FY 2013 federal prospective payment rates and outlier threshold amount for IRF discharges occurring on or after October 1, 2012, and on or before September 30, 2013. It also updated the FY 2013 federal prospective payment rates, the CMG relative weights, and the average length of stay values. For more information on the updates for FY 2013, please refer to the FY 2013 IRF PPS notice (77 FR 44618).

In the FY 2014 IRF PPS final rule (78 FR 47860), we updated the federal prospective payment rates, the CMG relative weights, and the outlier threshold amount. We also updated the facility-level adjustment factors using an enhanced estimation methodology, revised the list of diagnosis codes that count toward an IRF's 60 percent rule compliance calculation to determine ''presumptive compliance,'' revised sections of the Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF–PAI), revised requirements for acute care hospitals that have IRF units, clarified the IRF regulation text regarding limitation of review, updated references to previously changed sections in the regulations text, and revised and updated quality measures and reporting requirements under the IRF quality reporting program. For more information on the policy changes implemented for FY 2014, please refer to the FY 2014 IRF PPS final rule (78 FR 47860), in which we published the final FY 2014 IRF federal prospective payment rates.

In the FY 2015 IRF PPS final rule (79 FR 45872), we updated the federal prospective payment rates, the CMG relative weights, and the outlier threshold amount. We also further revised the list of diagnosis codes that count toward an IRF's 60 percent rule compliance calculation to determine ''presumptive compliance,'' revised sections of the IRF–PAI, and revised and updated quality measures and reporting requirements under the IRF quality reporting program. For more information on the policy changes implemented for FY 2015, please refer to the FY 2015 IRF PPS final rule (79 FR 45872) and the FY 2015 IRF PPS correction notice (79 FR 59121).

In the FY 2016 IRF PPS final rule (80 FR 47036), we updated the federal prospective payment rates, the CMG relative weights, and the outlier threshold amount. We also adopted an IRF-specific market basket that reflects the cost structures of only IRF providers, a blended one-year transition wage index based on the adoption of new OMB area delineations, a 3-year phase-out of the rural adjustment for certain IRFs due to the new OMB area delineations, and revisions and updates to the IRF QRP. For more information on the policy changes implemented for

FY 2016, please refer to the FY 2016 IRF PPS final rule (80 FR 47036).

B. Provisions of the Affordable Care Act Affecting the IRF PPS in FY 2012 and Beyond

The Affordable Care Act included several provisions that affect the IRF PPS in FYs 2012 and beyond. In addition to what was previously discussed, section 3401(d) of the Affordable Care Act also added section 1886(j)(3)(C)(ii)(I) (providing for a ''productivity adjustment'' for fiscal year 2012 and each subsequent fiscal year). The productivity adjustment for FY 2017 is discussed in section VI.B. of this final rule. Section 3401(d) of the Affordable Care Act requires an additional 0.75 percentage point adjustment to the IRF increase factor for each of FYs 2017, 2018, and 2019. The applicable adjustment for FY 2017 is discussed in section VI.B. of this final rule. Section 1886(j)(3)(C)(ii)(II) of the Act notes that the application of these adjustments to the market basket update may result in an update that is less than 0.0 for a fiscal year and in payment rates for a fiscal year being less than such payment rates for the preceding fiscal year. Section 3004(b) of the Affordable Care Act also addressed the IRF PPS program. It reassigned the previously designated section 1886(j)(7) of the Act to section 1886(j)(8) and inserted a new section 1886(j)(7), which contains requirements for the Secretary to establish a quality reporting program for IRFs. Under that program, data must be submitted in a form and manner and at a time specified by the Secretary. Beginning in FY 2014, section 1886(j)(7)(A)(i) of the Act requires the application of a 2 percentage point reduction of the applicable market basket increase factor for IRFs that fail to comply with the quality data submission requirements. Application of the 2 percentage point reduction may result in an update that is less than 0.0 for a fiscal year and in payment rates for a fiscal year being less than such payment rates for the preceding fiscal year. Reporting-based reductions to the market basket increase factor will not be cumulative; they will only apply for the FY involved.

Under section 1886(j)(7)(D)(i) and (ii) of the Act, the Secretary is generally required to select quality measures for the IRF quality reporting program from those that have been endorsed by the consensus-based entity which holds a performance measurement contract under section 1890(a) of the Act. This contract is currently held by the National Quality Forum (NQF). So long as due consideration is given to measures that have been endorsed or adopted by a consensus-based organization, section 1886(j)(7)(D)(ii) of the Act authorizes the Secretary to select non-endorsed measures for specified areas or medical topics when there are no feasible or practical endorsed measure(s).

Section 1886(j)(7)(E) of the Act requires the Secretary to establish procedures for making the IRF PPS quality reporting data available to the public. In so doing, the Secretary must ensure that IRFs have the opportunity to review any such data prior to its release to the public.

C. Operational Overview of the Current IRF PPS

As described in the FY 2002 IRF PPS final rule, upon the admission and discharge of a Medicare Part A Fee-for-Service (FFS) patient, the IRF is required to complete the appropriate sections of a patient assessment instrument (PAI), designated as the IRF–PAI. In addition, beginning with IRF discharges occurring on or after October 1, 2009, the IRF is also required to complete the appropriate sections of the IRF–PAI upon the admission and discharge of each Medicare Advantage (MA) (formerly called Medicare Part C) patient, as described in the FY 2010 IRF PPS final rule. All required data must be electronically encoded into the IRF–PAI software product. Generally, the software product includes patient classification programming called the Grouper software. The Grouper software uses specific IRF–PAI data elements to classify (or group) patients into distinct CMGs and account for the existence of any relevant comorbidities.

The Grouper software produces a 5-character CMG number. The first character is an alphabetic character that indicates the comorbidity tier. The last 4 characters are numeric characters that represent the distinct CMG number. Free downloads of the Inpatient Rehabilitation Validation and Entry (IRVEN) software product, including the Grouper software, are available on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Software.html*.

Once a Medicare FFS Part A patient is discharged, the IRF submits a Medicare claim as a Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191, enacted on August 21, 1996) (HIPAA) compliant electronic claim or, if the Administrative Simplification Compliance Act of 2002 (Pub. L. 107–105, enacted on December 27, 2002) (ASCA) permits, a paper claim (a UB–04 or a CMS–1450 as appropriate) using the five-character CMG number and sends it to the appropriate Medicare Administrative Contractor (MAC). In addition, once a Medicare Advantage patient is discharged, in accordance with the Medicare Claims Processing Manual, chapter 3, section 20.3 (Pub. 100–04), hospitals (including IRFs) must submit an informational-only bill (Type of Bill (TOB) 111), which includes Condition Code 04 to their MAC. This will ensure that the Medicare Advantage days are included in the hospital's Supplemental Security Income (SSI) ratio (used in calculating the IRF low-income percentage adjustment) for fiscal year 2007 and beyond. Claims submitted to Medicare must comply with both ASCA and HIPAA.

Section 3 of the ASCA amends section 1862(a) of the Act by adding paragraph (22), which requires the Medicare program, subject to section 1862(h) of the Act, to deny payment under Part A or Part B for any expenses for items or services ''for which a claim is submitted other than in an electronic form specified by the Secretary.'' Section 1862(h) of the Act, in turn, provides that the Secretary shall waive such denial in situations in which there is no method available for the submission of claims in an electronic form or the entity submitting the claim is a small provider. In addition, the Secretary also has the authority to waive such denial ''in such unusual cases as the Secretary finds appropriate.'' For more information, see the ''Medicare Program; Electronic Submission of Medicare Claims'' final rule (70 FR 71008). Our instructions for the limited number of Medicare claims submitted on paper are available at *http://www.cms.gov/manuals/downloads/clm104c25.pdf*.

Section 3 of the ASCA operates in the context of the administrative simplification provisions of HIPAA, which include, among others, the requirements for transaction standards and code sets codified in 45 CFR, parts 160 and 162, subparts A and I through R (generally known as the Transactions Rule). The Transactions Rule requires covered entities, including covered health care providers, to conduct covered electronic transactions according to the applicable transaction standards. (See the CMS program claim memoranda at *http://www.cms.gov/ElectronicBillingEDITrans/* and listed in the addenda to the Medicare Intermediary Manual, Part 3, section 3600).

The MAC processes the claim through its software system. This software system includes pricing programming called the ''Pricer'' software. The Pricer

software uses the CMG number, along with other specific claim data elements and provider-specific data, to adjust the IRF's prospective payment for interrupted stays, transfers, short stays, and deaths, and then applies the applicable adjustments to account for the IRF's wage index, percentage of low-income patients, rural location, and outlier payments. For discharges occurring on or after October 1, 2005, the IRF PPS payment also reflects the teaching status adjustment that became effective as of FY 2006, as discussed in the FY 2006 IRF PPS final rule (70 FR 47880).

D. Advancing Health Information Exchange

The Department of Health & Human Services (HHS) has a number of initiatives designed to encourage and support the adoption of health information technology and to promote nationwide health information exchange to improve health care. As discussed in the August 2013 Statement ''Principles and Strategies for Accelerating Health Information Exchange'' (available at *http://www.healthit.gov/sites/default/files/advancinghieprinciples_strategy.pdf*). HHS believes that all individuals, their families, their healthcare and social service providers, and payers should have consistent and timely access to health information in a standardized format that can be securely exchanged between the patient, providers, and others involved in the individual's care. Health IT that facilitates the secure, efficient, and effective sharing and use of health-related information when and where it is needed is an important tool for settings across the continuum of care, including inpatient rehabilitation facilities. The effective adoption and use of health information exchange and health IT tools will be essential as IRFs seek to improve quality and lower costs through value-based care.

The Office of the National Coordinator for Health Information Technology (ONC) has released a document entitled ''Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap'' (available at *https://https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf*). In the near term, the Roadmap focuses on actions that will enable individuals and providers across the care continuum to send, receive, find, and use a common set of electronic clinical information at the nationwide level by the end of 2017. The Roadmap's goals also align with the Improving Medicare Post-Acute Care Transformation Act of 2014 (Pub. L. 113–185, enacted on October 6, 2014) (IMPACT Act), which requires assessment data to be standardized and interoperable to allow for exchange of the data.

The Roadmap identifies four critical pathways that health IT stakeholders should focus on now in order to create a foundation for long-term success: (1) Improve technical standards and implementation guidance for priority data domains and associated elements; (2) rapidly shift and align federal, state, and commercial payment policies from FFS to value-based models to stimulate the demand for interoperability; (3) clarify and align federal and state privacy and security requirements that enable interoperability; and (4) align and promote the use of consistent policies and business practices that support interoperability, in coordination with stakeholders. In addition, ONC has released the final version of the 2016 Interoperability Standards Advisory (available at *https://www.healthit.gov/standards-advisory/2016*), which provides a list of the best available standards and implementation specifications to enable priority health information exchange functions. Providers, payers, and vendors are encouraged to take these ''best available standards'' into account as they implement interoperable health information exchange across the continuum of care, including care settings such as inpatient rehabilitation facilities.

We encourage stakeholders to utilize health information exchange and certified health IT to effectively and efficiently help providers improve internal care delivery practices, engage patients in their care, support management of care across the continuum, enable the reporting of electronically specified clinical quality measures (eCQMs), and improve efficiencies and reduce unnecessary costs. As adoption of certified health IT increases and interoperability standards continue to mature, HHS will seek to reinforce standards through relevant policies and programs. We received one comment on health information exchange, which is summarized below.

Comment: A commenter stated that the rule focuses only on providers, vendors, and institutions, not individuals and that sharing information requires standardized data exchange. The commenter suggested that CMS add a system-wide measure to assess whether robust data standards, policies, and governance infrastructure exists to support widespread industry and individual participation.

Response: We agree with the commenter that all individuals, families, and healthcare providers should have consistent and timely access to health information, in accordance with applicable law, in a standardized format that can be securely exchanged to support the health and wellness of individuals and shared decision-making. We agree nationwide interoperability across the care continuum will require stakeholders to agree to and follow a common set of standards, services, policies and practices that facilitates the exchange and use of interoperable health information. ONC recently requested comment on system-wide measures of interoperability required under the Medicare Access and CHIP Reauthorization Act of 2015 (81 FR 20651, *https://federalregister.gov/a/2016–08134*).

II. Summary of Provisions of the Proposed Rule

In the FY 2017 IRF PPS proposed rule (81 FR 24178), we proposed to update the IRF federal prospective payment rates for FY 2017 and to revise and update quality measures and reporting requirements under the IRF QRP.

The proposed updates to the IRF federal prospective payment rates for FY 2017 were as follows:

- Update the FY 2017 IRF PPS relative weights and average length of stay values using the most current and complete Medicare claims and cost report data in a budget-neutral manner, as discussed in section III of the FY 2017 IRF PPS proposed rule (81 FR 24178, 24184 through 24187).
- Describe the continued use of FY 2014 facility-level adjustment factors as discussed in section IV of the FY 2017 IRF PPS proposed rule (81 FR 24178 at 24187).
- Update the FY 2017 IRF PPS payment rates by the proposed market basket increase factor, based upon the most current data available, with a 0.75 percentage point reduction as required by sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(v) of the Act and a proposed productivity adjustment required by section 1886(j)(3)(C)(ii)(I) of the Act, as described in section V of the FY 2017 IRF PPS proposed rule (81 FR 24178, 24187 through 24189).
- Update the FY 2017 IRF PPS payment rates by the FY 2017 wage index and the labor-related share in a budget-neutral manner, as discussed in section V of the FY 2017 IRF PPS proposed rule (81 FR 24178, 24189 through 24190).

- Describe the calculation of the IRF standard payment conversion factor for FY 2017, as discussed in section V of the FY 2017 IRF PPS proposed rule (81 FR 24178, 24190 through 24192).
- Update the outlier threshold amount for FY 2017, as discussed in section VI of the FY 2017 IRF PPS proposed rule (81 FR 24178, at 24193).
- Update the cost-to-charge ratio (CCR) ceiling and urban/rural average CCRs for FY 2017, as discussed in section VI of the FY 2017 IRF PPS proposed rule (81 FR 24178, 24193 through 24194).
- Describe proposed revisions and updates to quality measures and reporting requirements under the quality reporting program for IRFs in accordance with section 1886(j)(7) of the Act, as discussed in section VII of the FY 2017 IRF PPS proposed rule (81 FR 24194 through 24220).

III. Analysis and Responses to Public Comments

We received 61 timely responses from the public, many of which contained multiple comments on the FY 2017 IRF PPS proposed rule (81 FR 24178). We received comments from various trade associations, inpatient rehabilitation facilities, individual physicians, therapists, clinicians, health care industry organizations, and health care consulting firms. The following sections, arranged by subject area, include a summary of the public comments that we received, and our responses.

IV. Update to the Case-Mix Group (CMG) Relative Weights and Average Length of Stay Values for FY 2017

As specified in § 412.620(b)(1), we calculate a relative weight for each CMG that is proportional to the resources needed by an average inpatient rehabilitation case in that CMG. For example, cases in a CMG with a relative weight of 2, on average, will cost twice as much as cases in a CMG with a relative weight of 1. Relative weights account for the variance in cost per discharge due to the variance in resource utilization among the payment groups, and their use helps to ensure that IRF PPS payments support beneficiary access to care, as well as provider efficiency.

In the FY 2017 IRF PPS proposed rule (81 FR 24178, 24184 through 24187), we proposed to update the CMG relative weights and average length of stay values for FY 2017. As required by statute, we always use the most recent available data to update the CMG relative weights and average lengths of stay. For FY 2017, we proposed to use the FY 2015 IRF claims and FY 2014 IRF cost report data. These data are the most current and complete data available at this time.

We note that, as we typically do, we updated our data between the FY 2017 IRF PPS proposed and final rules to ensure that we use the most recent available data in calculating IRF PPS payments. This updated data reflects a more complete set of claims for FY 2015 and additional cost report data for FY 2014.

In the FY 2017 IRF PPS proposed rule, we proposed to apply these data using the same methodologies that we have used to update the CMG relative weights and average length of stay values each fiscal year since we implemented an update to the methodology to use the more detailed CCR data from the cost reports of IRF subprovider units of primary acute care hospitals, instead of CCR data from the associated primary care hospitals, to calculate IRFs' average costs per case, as discussed in the FY 2009 IRF PPS final rule (73 FR 46372). In calculating the CMG relative weights, we use a hospital-specific relative value method to estimate operating (routine and ancillary services) and capital costs of IRFs. The process used to calculate the CMG relative weights for this final rule is as follows:

Step 1. We estimate the effects that comorbidities have on costs.

Step 2. We adjust the cost of each Medicare discharge (case) to reflect the effects found in the first step.

Step 3. We use the adjusted costs from the second step to calculate CMG relative weights, using the hospital-specific relative value method.

Step 4. We normalize the FY 2017 CMG relative weights to the same average CMG relative weight from the CMG relative weights implemented in the FY 2016 IRF PPS final rule (80 FR 47036).

Consistent with the methodology that we have used to update the IRF classification system in each instance in the past, we proposed to update the CMG relative weights for FY 2017 in such a way that total estimated aggregate payments to IRFs for FY 2017 are the same with or without the changes (that is, in a budget-neutral manner) by applying a budget neutrality factor to the standard payment amount. To calculate the appropriate budget neutrality factor for use in updating the FY 2017 CMG relative weights, we use the following steps:

Step 1. Calculate the estimated total amount of IRF PPS payments for FY 2017 (with no changes to the CMG relative weights).

Step 2. Calculate the estimated total amount of IRF PPS payments for FY 2017 by applying the changes to the CMG relative weights (as discussed in this final rule).

Step 3. Divide the amount calculated in step 1 by the amount calculated in step 2 to determine the budget neutrality factor (0.9992) that would maintain the same total estimated aggregate payments in FY 2017 with and without the changes to the CMG relative weights.

Step 4. Apply the budget neutrality factor (0.9992) to the FY 2016 IRF PPS standard payment amount after the application of the budget-neutral wage adjustment factor.

In section VI.E. of this final rule, we discuss the proposed use of the existing methodology to calculate the standard payment conversion factor for FY 2017.

In Table 1, ''Relative Weights and Average Length of Stay Values for Case-Mix Groups,'' we present the CMGs, the comorbidity tiers, the corresponding relative weights, and the average length of stay values for each CMG and tier for FY 2017. The average length of stay for each CMG is used to determine when an IRF discharge meets the definition of a short-stay transfer, which results in a per diem case level adjustment.

TABLE 1: Relative Weights and Average Length of Stay Values for Case-Mix Groups

CMG	CMG Description (M=motor, C=cognitive, A=age)	Relative Weight				Average Length of Stay			
		Tier 1	Tier 2	Tier 3	None	Tier 1	Tier 2	Tier 3	None
0101	Stroke M>51.05	0.7992	0.7117	0.6511	0.6215	8	9	9	8
0102	Stroke M>44.45 and M<51.05 and C>18.5	1.0130	0.9020	0.8252	0.7877	11	12	10	10
0103	Stroke M>44.45 and M<51.05 and C<18.5	1.1836	1.0540	0.9642	0.9204	11	13	12	12
0104	Stroke M>38.85 and M<44.45	1.2598	1.1218	1.0263	0.9796	12	12	12	12
0105	Stroke M>34.25 and M<38.85	1.4572	1.2976	1.1871	1.1331	14	15	14	14
0106	Stroke M>30.05 and M<34.25	1.6296	1.4511	1.3275	1.2671	16	16	15	15
0107	Stroke M>26.15 and M<30.05	1.8187	1.6195	1.4815	1.4142	17	19	17	17
0108	Stroke M<26.15 and A>84.5	2.2893	2.0386	1.8649	1.7801	21	22	21	20
0109	Stroke M>22.35 and M<26.15 and A<84.5	2.0584	1.8329	1.6768	1.6005	19	20	18	19
0110	Stroke M<22.35 and A<84.5	2.7320	2.4327	2.2255	2.1243	29	27	24	24
0201	Traumatic brain injury M>53.35 and C>23.5	0.7753	0.6341	0.5715	0.5343	8	8	8	7
0202	Traumatic brain injury M>44.25 and M<53.35 and C>23.5	1.0945	0.8951	0.8067	0.7542	12	10	9	10
0203	Traumatic brain injury M>44.25 and C<23.5	1.2173	0.9955	0.8973	0.8388	11	12	11	11

CMG	CMG Description (M=motor, C=cognitive, A=age)	Relative Weight				Average Length of Stay			
0204	Traumatic brain injury M>40.65 and M<44.25	1.3455	1.1003	0.9918	0.9272	16	13	12	11
0205	Traumatic brain injury M>28.75 and M<40.65	1.6224	1.3269	1.1959	1.1181	14	15	14	13
0206	Traumatic brain injury M>22.05 and M<28.75	1.9239	1.5734	1.4182	1.3258	19	18	16	15
0207	Traumatic brain injury M<22.05	2.5284	2.0678	1.8637	1.7424	31	23	20	19
0301	Non-traumatic brain injury M>41.05	1.1424	0.9432	0.8571	0.8002	10	11	10	10
0302	Non-traumatic brain injury M>35.05 and M<41.05	1.4063	1.1610	1.0551	0.9850	13	13	12	12
0303	Non-traumatic brain injury M>26.15 and M<35.05	1.6490	1.3614	1.2372	1.1550	15	15	14	14
0304	Non-traumatic brain injury M<26.15	2.1336	1.7614	1.6007	1.4944	21	20	17	16
0401	Traumatic spinal cord injury M>48.45	0.9799	0.8616	0.7947	0.7213	11	11	10	9
0402	Traumatic spinal cord injury M>30.35 and M<48.45	1.4052	1.2357	1.1396	1.0344	14	14	14	13
0403	Traumatic spinal cord injury M>16.05 and M<30.35	2.2165	1.9492	1.7976	1.6316	20	21	20	19
0404	Traumatic spinal cord injury M<16.05 and A>63.5	3.8702	3.4033	3.1387	2.8489	46	37	34	31

CMG	CMG Description (M=motor, C=cognitive, A=age)	Relative Weight				Average Length of Stay			
0405	Traumatic spinal cord injury M<16.05 and A<63.5	3.4395	3.0246	2.7894	2.5319	49	33	28	28
0501	Non-traumatic spinal cord injury M>51.35	0.8524	0.6715	0.6395	0.5751	9	8	7	8
0502	Non-traumatic spinal cord injury M>40.15 and M<51.35	1.1600	0.9139	0.8703	0.7827	11	11	10	10
0503	Non-traumatic spinal cord injury M>31.25 and M<40.15	1.4557	1.1469	1.0921	0.9822	14	13	13	12
0504	Non-traumatic spinal cord injury M>29.25 and M<31.25	1.7087	1.3462	1.2819	1.1529	19	16	14	14
0505	Non-traumatic spinal cord injury M>23.75 and M<29.25	1.9607	1.5447	1.4709	1.3229	20	17	17	16
0506	Non-traumatic spinal cord injury M<23.75	2.7151	2.1391	2.0369	1.8320	28	24	22	21
0601	Neurological M>47.75	1.0352	0.8205	0.7577	0.6939	10	9	9	9
0602	Neurological M>37.35 and M<47.75	1.3322	1.0560	0.9751	0.8930	12	12	11	11
0603	Neurological M>25.85 and M<37.35	1.6411	1.3008	1.2012	1.1001	14	14	13	13
0604	Neurological M<25.85	2.1752	1.7241	1.5922	1.4581	20	18	17	16
0701	Fracture of lower extremity M>42.15	0.9991	0.8136	0.7767	0.7052	10	9	9	9

CMG	CMG Description (M=motor, C=cognitive, A=age)	Relative Weight				Average Length of Stay			
0702	Fracture of lower extremity M>34.15 and M<42.15	1.2759	1.0390	0.9919	0.9006	12	12	12	11
0703	Fracture of lower extremity M>28.15 and M<34.15	1.5383	1.2527	1.1958	1.0858	15	14	14	13
0704	Fracture of lower extremity M<28.15	1.9943	1.6240	1.5503	1.4076	18	18	17	16
0801	Replacement of lower extremity joint M>49.55	0.7983	0.6443	0.5958	0.5476	8	8	7	7
0802	Replacement of lower extremity joint M>37.05 and M<49.55	1.0333	0.8340	0.7713	0.7089	11	10	9	9
0803	Replacement of lower extremity joint M>28.65 and M<37.05 and A>83.5	1.3823	1.1156	1.0317	0.9482	13	13	12	12
0804	Replacement of lower extremity joint M>28.65 and M<37.05 and A<83.5	1.2445	1.0044	0.9289	0.8537	12	12	11	10
0805	Replacement of lower extremity joint M>22.05 and M<28.65	1.4806	1.1949	1.1051	1.0157	15	13	12	12
0806	Replacement of lower extremity joint M<22.05	1.7987	1.4517	1.3425	1.2339	16	16	15	14
0901	Other orthopedic M>44.75	0.9839	0.7940	0.7356	0.6693	11	10	9	8

CMG	CMG Description (M=motor, C=cognitive, A=age)	Relative Weight				Average Length of Stay			
0902	Other orthopedic M>34.35 and M<44.75	1.2583	1.0155	0.9408	0.8560	12	12	11	10
0903	Other orthopedic M>24.15 and M<34.35	1.5810	1.2760	1.1821	1.0755	15	15	13	13
0904	Other orthopedic M<24.15	2.0014	1.6153	1.4965	1.3615	18	18	16	16
1001	Amputation, lower extremity M>47.65	1.0715	0.9448	0.8199	0.7400	11	11	10	9
1002	Amputation, lower extremity M>36.25 and M<47.65	1.3906	1.2261	1.0641	0.9604	14	15	12	12
1003	Amputation, lower extremity M<36.25	1.9639	1.7317	1.5029	1.3564	18	19	17	16
1101	Amputation, non-lower extremity M>36.35	1.3222	1.1985	0.9739	0.8842	12	12	10	11
1102	Amputation, non-lower extremity M<36.35	1.8953	1.7181	1.3961	1.2676	17	16	16	14
1201	Osteoarthritis M>37.65	1.0379	1.0241	0.9306	0.8231	10	11	11	10
1202	Osteoarthritis M>30.75 and M<37.65	1.2061	1.1900	1.0813	0.9564	12	13	12	11
1203	Osteoarthritis M<30.75	1.5370	1.5165	1.3780	1.2188	14	17	15	14
1301	Rheumatoid, other arthritis M>36.35	1.1939	0.9393	0.8690	0.8007	13	10	10	10
1302	Rheumatoid, other arthritis M>26.15 and M<36.35	1.6397	1.2900	1.1935	1.0997	14	15	13	13
1303	Rheumatoid, other arthritis M<26.15	2.0215	1.5904	1.4715	1.3558	16	20	15	15

CMG	CMG Description (M=motor, C=cognitive, A=age)	Relative Weight				Average Length of Stay			
1401	Cardiac M>48.85	0.8666	0.7324	0.6639	0.6025	9	7	8	8
1402	Cardiac M>38.55 and M<48.85	1.1810	0.9981	0.9047	0.8211	11	11	11	10
1403	Cardiac M>31.15 and M<38.55	1.4079	1.1899	1.0785	0.9788	13	13	12	11
1404	Cardiac M<31.15	1.7805	1.5048	1.3640	1.2379	17	16	15	14
1501	Pulmonary M>49.25	1.0089	0.8543	0.7888	0.7436	10	9	9	8
1502	Pulmonary M>39.05 and M<49.25	1.2746	1.0793	0.9966	0.9394	11	11	11	10
1503	Pulmonary M>29.15 and M<39.05	1.5543	1.3162	1.2153	1.1456	15	14	12	12
1504	Pulmonary M<29.15	1.9370	1.6402	1.5145	1.4276	19	17	15	14
1601	Pain syndrome M>37.15	0.9889	0.8933	0.8321	0.7677	9	9	10	9
1602	Pain syndrome M>26.75 and M<37.15	1.2901	1.1654	1.0855	1.0015	12	13	12	12
1603	Pain syndrome M<26.75	1.6155	1.4592	1.3592	1.2540	13	17	15	14
1701	Major multiple trauma without brain or spinal cord injury M>39.25	1.1345	0.9258	0.8520	0.7671	16	10	10	10
1702	Major multiple trauma without brain or spinal cord injury M>31.05 and M<39.25	1.4253	1.1631	1.0704	0.9637	13	14	13	12

CMG	CMG Description (M=motor, C=cognitive, A=age)	Relative Weight				Average Length of Stay			
1703	Major multiple trauma without brain or spinal cord injury M>25.55 and M<31.05	1.6987	1.3862	1.2758	1.1486	16	15	15	14
1704	Major multiple trauma without brain or spinal cord injury M<25.55	2.1821	1.7806	1.6387	1.4753	22	19	18	17
1801	Major multiple trauma with brain or spinal cord injury M>40.85	1.2932	1.0595	0.9203	0.8254	14	13	12	10
1802	Major multiple trauma with brain or spinal cord injury M>23.05 and M<40.85	1.8234	1.4939	1.2976	1.1639	17	17	15	14
1803	Major multiple trauma with brain or spinal cord injury M<23.05	2.8692	2.3507	2.0419	1.8314	31	27	21	20
1901	Guillian Barre M>35.95	1.2267	1.0516	0.9270	0.9134	14	13	11	11
1902	Guillian Barre M>18.05 and M<35.95	2.2288	1.9106	1.6843	1.6595	20	22	19	19
1903	Guillian Barre M<18.05	3.6684	3.1447	2.7722	2.7315	52	31	32	30
2001	Miscellaneous M>49.15	0.9225	0.7562	0.6942	0.6285	9	9	8	8
2002	Miscellaneous M>38.75 and M<49.15	1.2097	0.9916	0.9104	0.8241	12	11	11	10
2003	Miscellaneous M>27.85 and M<38.75	1.5124	1.2397	1.1381	1.0303	14	14	13	12
2004	Miscellaneous M<27.85	1.9412	1.5912	1.4608	1.3224	19	17	16	15
2101	Burns M>0	1.6899	1.6899	1.5061	1.3813	24	18	16	17

CMG	CMG Description (M=motor, C=cognitive, A=age)	Relative Weight				Average Length of Stay			
5001	Short-stay cases, length of stay is 3 days or fewer				0.1585				2
5101	Expired, orthopedic, length of stay is 13 days or fewer				0.6785				7
5102	Expired, orthopedic, length of stay is 14 days or more				1.6606				16
5103	Expired, not orthopedic, length of stay is 15 days or fewer				0.8002				8
5104	Expired, not orthopedic, length of stay is 16 days or more				2.1200				21

Generally, updates to the CMG relative weights result in some increases and some decreases to the CMG relative weight values. Table 2 shows how we estimate that the application of the revisions for FY 2017 would affect particular CMG relative weight values, which would affect the overall distribution of payments within CMGs and tiers. Note that, because we proposed to implement the CMG relative weight revisions in a budget-neutral manner (as previously described), total estimated aggregate payments to IRFs for FY 2017 would not be affected as a result of the proposed CMG relative weight revisions. However, the proposed revisions would affect the distribution of payments within CMGs and tiers.

TABLE 2—DISTRIBUTIONAL EFFECTS OF THE CHANGES TO THE CMG RELATIVE WEIGHTS

[FY 2016 values compared with FY 2017 values]

Percentage change	Number of cases affected	Percentage of cases affected (percent)
Increased by 15% or more	0	0.0
Increased by between 5% and 15%	540	0.1
Changed by less than 5%	395,897	99.7
Decreased by between 5% and 15%	761	0.2
Decreased by 15% or more	41	0.0

As Table 2 shows, 99.7 percent of all IRF cases are in CMGs and tiers that would experience less than a 5 percent change (either increase or decrease) in the CMG relative weight value as a result of the revisions for FY 2017. The largest estimated increase in the CMG relative weight values that affects the largest number of IRF discharges would be a 0.7 percent change in the CMG relative weight value for CMG 0604—Neurological, with a motor score less than 25.85—in the ''no comorbidity'' tier. In the FY 2015 claims data, 8,572 IRF discharges (2.2 percent of all IRF discharges) were classified into this CMG and tier.

The largest decrease in a CMG relative weight value affecting the largest number of IRF cases would be a 1.4 percent decrease in the CMG relative weight for CMG 0110—Stroke, with a motor score less than 22.35 and age less than 84.5—in the ''no comorbidity'' tier. In the FY 2015 IRF claims data, this change would have affected 13,739 cases (3.5 percent of all IRF cases).

The proposed changes in the average length of stay values for FY 2017, compared with the FY 2016 average length of stay values, are small and do not show any particular trends in IRF length of stay patterns.

We received 3 comments on the proposed update to the CMG relative weights and average length of stay values for FY 2017, which are summarized below.

Comment: Commenters, while supportive of the methodology used to calculate the weights, requested that we provide more detail about the use of the CCR data in the CMG relative weight calculations. Additionally, the commenters requested that we outline the methodology used to calculate the average length of stay values in the FY 2017 IRF PPS proposed rule.

Response: As we discussed, most recently, in the FY 2016 IRF PPS final rule (80 FR 47036, 47045), a key variable used to calculate the CMG relative weights is a facility's average cost per case, which is obtained by averaging the estimated cost per case for every patient discharged from the facility in a given fiscal year. To obtain the estimated cost per case for a given IRF patient, we start by pulling the appropriate charges from the Medicare claim for that patient. Then, we calculate the appropriate CCRs from the Medicare cost report submitted by the facility. The CCRs are then multiplied by the charges from the Medicare claim to obtain the estimated IRF cost for the case. This variable is used as the dependent variable in the regression analysis to estimate the CMG relative weights.

As we also discussed in the FY 2016 IRF PPS final rule (80 FR 47036, 47045), the methodology for calculating the average length of stay values is available for download from the IRF PPS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Research.html*.

Final Decision: After careful consideration of the public comments, we are finalizing our proposal to update the CMG relative weight and average length of stay values for FY 2017, as shown in Table 1 of this final rule. These updates are effective October 1, 2016.

V. Facility-Level Adjustment Factors

Section 1886(j)(3)(A)(v) of the Act confers broad authority upon the Secretary to adjust the per unit payment rate by such factors as the Secretary determines are necessary to properly reflect variations in necessary costs of treatment among rehabilitation facilities. Under this authority, we currently adjust the federal prospective payment amount associated with a CMG to account for facility-level characteristics such as an IRF's LIP, teaching status, and location in a rural area, if applicable, as described in § 412.624(e).

Based on the substantive changes to the facility-level adjustment factors that were adopted in the FY 2014 final rule (78 FR 47860, 47868 through 47872), in the FY 2015 final rule (79 FR 45872, 45882 through 45883), we froze the facility-level adjustment factors at the FY 2014 levels for FY 2015 and all subsequent years (unless and until we propose to update them again through future notice-and-comment rulemaking). For FY 2017, we will continue to hold the adjustment factors at the FY 2014 levels as we continue to monitor the most current IRF claims data available and continue to evaluate and monitor the effects of the FY 2014 changes.

VI. FY 2017 IRF PPS Payment Update

A. Background

Section 1886(j)(3)(C) of the Act requires the Secretary to establish an increase factor that reflects changes over time in the prices of an appropriate mix of goods and services included in the covered IRF services, which is referred to as a market basket index. According to section 1886(j)(3)(A)(i) of the Act, the increase factor shall be used to update the IRF federal prospective payment rates for each FY. Section 1886(j)(3)(C)(ii)(I) of the Act requires the application of a productivity adjustment, as described below. In addition, sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(v) of the Act require the application of a 0.75 percentage point reduction to the market basket increase factor for FY 2017. Thus, in the FY 2017 IRF PPS proposed rule (81 FR 24178, 24187 through 24188), we proposed to update the IRF PPS payments for FY 2017 by a market basket increase factor as required by section 1886(j)(3)(C) of the Act, with a productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act, and a 0.75 percentage point reduction as required by sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(v) of the Act.

For FY 2015, IRF PPS payments were updated using the 2008-based RPL market basket. Beginning with the FY 2016 IRF PPS, we created and adopted a stand-alone IRF market basket, which was referred to as the 2012-based IRF market basket, reflecting the operating and capital cost structures for freestanding IRFs and hospital-based IRFs. The general structure of the 2012-based IRF market basket is similar to the 2008-based RPL market basket; however, we made several notable changes. In developing the 2012-based IRF market basket, we derived cost weights from Medicare cost report data for both freestanding and hospital-based IRFs (the 2008-based RPL market basket was based on freestanding data only), incorporated the 2007 Input-Output data from the Bureau of Economic Analysis (the 2008-based RPL market basket was based on the 2002 Input-Output data); used new price proxy blends for two cost categories (Fuel, Oil, and Gasoline and Medical Instruments); added one additional cost category (Installation, Maintenance, and Repair), which was previously included in the residual All Other Services: Labor-Related cost category of the 2008-based RPL market basket; and eliminated three cost categories (Apparel, Machinery & Equipment, and Postage). The FY 2016 IRF PPS final rule (80 FR 47046 through 47068) contains a complete discussion of the development of the 2012-based IRF market basket.

B. FY 2017 Market Basket Update and Productivity Adjustment

For FY 2017, we proposed to use the same methodology described in the FY 2016 IRF PPS final rule (80 FR 47066) to compute the FY 2017 market basket increase factor to update the IRF PPS base payment rate. Consistent with historical practice, we proposed to estimate the market basket update for the IRF PPS based on IHS Global Insight's forecast using the most recent available data. IHS Global Insight (IGI), Inc. is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the components of the market baskets and multifactor productivity (MFP).

Based on IGI's first quarter 2016 forecast with historical data through the fourth quarter of 2015, we proposed that the projected 2012-based IRF market basket increase factor for FY 2017 would be 2.7 percent. We also proposed that if more recent data were subsequently available (for example, a more recent estimate of the market basket update), we would use such data to determine the FY 2017 update in the final rule. Incorporating the most recent data available, based on IGI's second quarter 2016 forecast with historical data through the first quarter of 2016, the projected 2012-based IRF market basket increase factor for FY 2017 is 2.7 percent.

According to section 1886(j)(3)(C)(i) of the Act, the Secretary shall establish an increase factor based on an appropriate percentage increase in a market basket of goods and services. Section 1886(j)(3)(C)(ii) of the Act then requires that, after establishing the increase factor for a FY, the Secretary shall reduce such increase factor for FY 2012 and each subsequent FY, by the

productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act sets forth the definition of this productivity adjustment. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business MFP (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period) (the ''MFP adjustment''). The BLS publishes the official measure of private nonfarm business MFP. Please see *http://www.bls.gov/mfp* for the BLS historical published MFP data. A complete description of the MFP projection methodology is available on the CMS Web site at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html*.

Using IGI's first quarter 2016 forecast, the proposed MFP adjustment for FY 2017 (the 10-year moving average of MFP for the period ending FY 2017) was 0.5 percent. We proposed that if more recent data were subsequently available, we would use such data to determine the FY 2017 MFP adjustment in the final rule. Incorporating the most recent data available, based on IGI's second quarter 2016 forecast with historical data through the first quarter of 2016, the projected MFP adjustment for FY 2017 is 0.3 percent.

Thus, in accordance with section 1886(j)(3)(C) of the Act, we proposed to base the FY 2017 market basket update, which is used to determine the applicable percentage increase for the IRF payments, on the most recent estimate of the 2012-based IRF market basket. We proposed to then reduce this percentage increase by the most up-to-date estimate of the MFP adjustment for FY 2017. Following application of the MFP, we proposed to further reduce the applicable percentage increase by 0.75 percentage point, as required by sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(v) of the Act. Therefore, the estimate of the FY 2017 IRF update for the proposed rule was 1.45 percent (2.7 percent market basket update, less 0.5 percentage point MFP adjustment, less 0.75 percentage point legislative adjustment). Incorporating the most recent data, the current estimate of the FY 2017 IRF update is 1.65 percent (2.7 percent market basket update, less 0.3 percentage point MFP adjustment, less 0.75 percentage point legislative adjustment).

For FY 2017, the Medicare Payment Advisory Commission (MedPAC) recommends that a 0-percent update be applied to IRF PPS payment rates. As discussed, and in accordance with sections 1886(j)(3)(C) and 1886(j)(3)(D) of the Act, the Secretary proposed to update the IRF PPS payment rates for FY 2017 by an adjusted market basket increase factor of 1.45 percent, as section 1886(j)(3)(C) of the Act does not provide the Secretary with the authority to apply a different update factor to IRF PPS payment rates for FY 2017. As noted above, incorporating the most recent data, the current estimate of the FY 2017 IRF update is 1.65 percent.

We received 10 comments on the proposed market basket increase update and productivity adjustment, which are summarized below.

Comment: One commenter (MedPAC) stated that it understood that CMS is required to implement this statutory payment update; however, MedPAC noted that after reviewing many factors—including indicators of beneficiary access to rehabilitative services, the supply of providers, and Medicare margins—it determined that Medicare's current payment rates for IRFs appear to be adequate and therefore recommended no update to IRF payment rates for FY 2017. MedPAC appreciated that CMS cited its recommendation, even while noting that the Secretary does not have the authority to deviate from statutorily mandated updates.

Response: As discussed, and in accordance with sections 1886(j)(3)(C) and 1886(j)(3)(D) of the Act, the Secretary is updating IRF PPS payment rates for FY 2017 by an adjusted market basket increase factor of 1.65 percent, as section 1886(j)(3)(C) of the Act does not provide the Secretary with the authority to apply a different update factor to IRF PPS payment rates for FY 2017.

Comment: Several commenters requested that, with respect to the productivity adjustment, CMS remain cognizant of the intensive labor, time and costs required by state and/or federal regulations to which IRFs are bound. These commenters stated that these requirements may be barriers to IRFs achieving further gains in productivity efficiencies. Further, some commenters stated that successful rehabilitation outcomes require an intense labor component, including the interaction of the full multidisciplinary treatment team, which includes physicians, nurses, physical and occupational therapists, speech language pathologists as well as social workers, psychologists and others. In addition, these commenters indicated that some states have regulations mandating increased professional staffing ratios between health care providers and patients. A few commenters claimed that, since CMS has stated its policy is that the majority of patient therapy should be one-on-one, which is highly labor-intensive, then CMS should not mandate further efficiencies such as productivity adjustments while simultaneously implementing new regulations or interpreting existing regulations in ways that preclude IRFs from adopting clinically appropriate innovations that would allow for greater efficiencies. These commenters requested that the 0.5 percentage point productivity adjustment be ''reversed.'' In addition, several commenters requested that CMS be mindful of the additional labor costs and quality improvement activities that IRFs will incur as a result of the additional items required in version 1.4 of the IRF PAI beginning on October 1, 2016 as well as the IRF PAI proposed changes relating to the drug regimen measure for which data would start to be collected on October 1, 2018.

Response: Section 1886(j)(3)(C)(ii)(I) of the Act requires the application of a productivity adjustment that must be applied to the IRF PPS market basket update. The statute does not provide the Secretary with the authority to ''reverse'' the productivity adjustment or apply a different adjustment. We will continue to monitor the impact of the payment updates, including the effects of the productivity adjustment, on IRF provider margins as well as beneficiary access to care.

Comment: One commenter recommended that CMS use the latest data available in estimating the market basket in the final rule.

Response: We agree with the commenter's recommendation, and it is consistent with the proposed rule language stating that the final IRF PPS payment update will be based on the most recent forecast of the market basket update and productivity adjustment. As noted above, the most recent estimate of the 2012-based IRF market basket is based on IGI's second quarter 2016 forecast with historical data through the first quarter of 2016.

Final Decision: Based on careful consideration of the comments, we are finalizing the FY 2017 market basket update for IRF payments of 1.65 percent (2.7 percent market basket update, less 0.3 percentage point MFP adjustment, less 0.75 percentage point legislative adjustment), which is based on the most recent forecasts of the 2012-based IRF market basket update and the MFP adjustment.

C. Labor-Related Share for FY 2017

Section 1886(j)(6) of the Act specifies that the Secretary is to adjust the proportion (as estimated by the Secretary from time to time) of rehabilitation facilities' costs which are attributable to wages and wage-related costs of the prospective payment rates computed under section 1886(j)(3) for area differences in wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the rehabilitation facility compared to the national average wage level for such facilities. The labor-related share is determined by identifying the national average proportion of total costs that are related to, influenced by, or vary with the local labor market. We continue to classify a cost category as labor-related if the costs are labor-intensive and vary with the local labor market.

Based on our definition of the labor-related share and the cost categories in the 2012-based IRF market basket, we proposed to include in the labor-related share for FY 2017 the sum of the FY 2017 relative importance of Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related, Administrative and Facilities Support Services, Installation, Maintenance, and Repair, All Other: Labor-related Services, and a portion of the Capital-Related cost weight from the 2012-based IRF market basket. For more details regarding the methodology for determining specific cost categories for inclusion in the 2012-based IRF labor-related share, see the FY 2016 IRF final rule (80 FR 47066 through 47068).

Using this method and the IHS Global Insight, Inc. first quarter 2016 forecast for the 2012-based IRF market basket, the proposed IRF labor-related share for FY 2017 was 71.0 percent. We proposed that if more recent data were subsequently available, we would use such data to determine the FY 2017 IRF labor-related share in the final rule.

Incorporating the most recent estimate of the 2012-based IRF market basket based on IGI's second quarter 2016 forecast with historical data through the first quarter of 2016, the sum of the relative importance for FY 2017 operating costs (Wages and Salaries, Employee Benefits, Professional Fees: Labor-related, Administrative and Facilities Support Services, Installation Maintenance & Repair Services, and All Other: Labor-related Services) using the 2012-based IRF market basket is 67.0 percent. We proposed that the portion of Capital-Related Costs that is influenced by the local labor market is estimated to be 46 percent. Incorporating the most recent estimate of the FY 2017 relative importance of Capital-Related costs from the 2012-based IRF market basket based on IGI's second quarter 2016 forecast with historical data through the first quarter of 2016, which is 8.4 percent, we take 46 percent of 8.4 percent to determine the labor-related share of Capital for FY 2017. As we proposed, we then add this amount (3.9 percent) to the sum of the relative importance for FY 2017 operating costs (67.0 percent) to determine the total labor-related share for FY 2017 of 70.9 percent.

TABLE 3—IRF LABOR-RELATED SHARE

	FY 2017 Final labor-related share [1]	FY 2016 Final labor-related share [2]
Wages and Salaries	47.7	47.6
Employee Benefits	11.3	11.4
Professional Fees: Labor-related	3.5	3.5
Administrative and Facilities Support Services	0.8	0.8
Installation, Maintenance, and Repair	1.9	2.0
All Other: Labor-related Services	1.8	1.8
Subtotal	67.0	67.1
Labor-related portion of capital (46%)	3.9	3.9
Total Labor-Related Share	70.9	71.0

[1] Based on the 2012-based IRF Market Basket, IHS Global Insight, Inc. 2nd quarter 2016 forecast.
[2] Federal Register 80 FR 47068.

Final Decision: As we did not receive any comments on the proposed labor-related share for FY 2017, we are finalizing the FY 2017 labor-related share of 70.9 percent.

D. Wage Adjustment

1. Background

Section 1886(j)(6) of the Act requires the Secretary to adjust the proportion of rehabilitation facilities' costs attributable to wages and wage-related costs (as estimated by the Secretary from time to time) by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the rehabilitation facility compared to the national average wage level for those facilities. The Secretary is required to update the IRF PPS wage index on the basis of information available to the Secretary on the wages and wage-related costs to furnish rehabilitation services. Any adjustment or updates made under section 1886(j)(6) of the Act for a FY are made in a budget-neutral manner.

For FY 2017, we proposed to maintain the policies and methodologies described in the FY 2016 IRF PPS final rule (80 FR 47036, 47068 through 47075) related to the labor market area definitions and the wage index methodology for areas with wage data. Thus, we proposed to use the CBSA labor market area definitions and the FY 2016 pre-reclassification and pre-floor hospital wage index data. The current statistical areas which were implemented in FY 2016 are based on OMB standards published on February 28, 2013, in OMB Bulletin No. 13–01. For FY 2017, we are continuing to use the new OMB delineations that we adopted beginning with FY 2016. In accordance with section 1886(d)(3)(E) of the Act, the FY 2016 pre-reclassification and pre-floor hospital wage index is based on data submitted for hospital cost reporting periods beginning on or after October 1, 2011, and before October 1, 2012 (that is, FY 2012 cost report data).

The labor market designations made by the OMB include some geographic areas where there are no hospitals and, thus, no hospital wage index data on which to base the calculation of the IRF PPS wage index. We proposed to continue to use the same methodology discussed in the FY 2008 IRF PPS final rule (72 FR 44299) to address those geographic areas where there are no

hospitals and, thus, no hospital wage index data on which to base the calculation for the FY 2017 IRF PPS wage index.

We did not receive any comments on these proposals. Therefore, we are finalizing our proposal to use the CBSA labor market area definitions and the FY 2016 pre-reclassification and pre-floor hospital wage index data for areas with wage data. We are also finalizing our proposal to continue to use the same methodology discussed in the FY 2008 IRF PPS final rule (72 FR 44299) to address those geographic areas where there are no hospitals and, thus, no hospital wage index data.

2. Update

The wage index used for the IRF PPS is calculated using the pre-reclassification and pre-floor acute care hospital wage index data and is assigned to the IRF on the basis of the labor market area in which the IRF is geographically located. IRF labor market areas are delineated based on the CBSAs established by the OMB. In the FY 2016 IRF PPS final rule (80 FR 47036, 47068), we established an IRF wage index based on FY 2011 acute care hospital wage data to adjust the FY 2016 IRF payment rates. We also adopted the revised CBSAs set forth by OMB. The current CBSA delineations (which were implemented for the IRF PPS beginning with FY 2016) are based on revised OMB delineations issued on February 28, 2013, in OMB Bulletin No. 13–01. OMB Bulletin No. 13–01 established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas in the United States and Puerto Rico, and provided guidance on the use of the delineations of these statistical areas based on new standards published on June 28, 2010, in the **Federal Register** (75 FR 37246 through 37252). A copy of this bulletin may be obtained at *http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13-01.pdf*. For FY 2017, we are continuing to use the new OMB delineations that we adopted beginning with FY 2016 to calculate the area wage indexes and the transition periods, which we discuss below.

3. Transition Period

In FY 2016, we applied a 1-year blended wage index for all IRF providers to mitigate the impact of the wage index change due to the implementation of the revised CBSA delineations. Under that policy, all IRF providers are receiving a blended wage index in FY 2016 using 50 percent of their FY 2016 wage index based on the revised OMB CBSA delineations and 50 percent of their FY 2016 wage index based on the OMB delineations used in FY 2015. For FY 2017, we proposed to maintain the policy established in FY 2016 IRF PPS final rule related to the blended one-year transition wage index (see 80 FR 47036, 47073 through 47074). Thus, the 1-year blended wage index that became effective on October 1, 2015, will expire on September 30, 2016.

We did not receive any comments on the proposal to maintain the policy established in FY 2016 IRF PPS final rule related to the blended one-year transition wage index.

Final decision: As we did not receive any comments on our proposal to maintain the 1-year blended wage index for all IRF providers, we are finalizing the expiration of this policy on September 30, 2016.

For FY 2016, in addition to the blended wage index, we also adopted a 3-year budget neutral phase out of the rural adjustment for IRFs that were rural in FY 2015 and became urban in FY 2016 under the revised CBSA delineations. In FY 2016, IRFs that were designated as rural in FY 2015 and became designated as urban in FY 2016 received two-thirds of the 2015 rural adjustment of 14.9 percent. FY 2017 represents the second year of the 3-year phase out of the rural adjustment, in which these same IRFs will receive one-third of the 2015 rural adjustment of 14.9 percent, as finalized in the FY 2016 IRF PPS final rule (80 FR 47036, 47073 through 47074).

For FY 2017, the wage index will be based solely on the previously adopted revised CBSA delineations and their respective wage index (rather than on a blended wage index). Furthermore, we will continue the 3-year phase out of the rural adjustments for IRF providers that changed from rural to urban status that was finalized in the FY 2016 IFR PPS final rule (80 FR 47036, 47073 through 47074).

We received one comment on our proposal to continue the 3-year phase out of the rural adjustments for IRF providers that changed from rural to urban status and that was finalized in the FY 2016 IFR PPS final rule.

Comment: One commenter suggested that we implement a 5-year phase-out of the rural adjustment or allow IRFs that are losing the FY 2015 rural adjustment due to the changes in the CBSA delineations to apply for reclassification back to rural status for a period of 5 years.

Response: The intent of the 3-year phase-out of the rural adjustment is to mitigate potential negative payment effects on rural facilities that are redesignated as urban facilitates, effective FY 2016. As described in more detail in the FY 2006 IRF PPS final rule (70 FR 47880), our analysis determined that a 3-year budget-neutral transition policy would best accomplish the goals of mitigating the loss of the rural adjustment for existing IRFs that were rural in FY 2005 and became urban in FY 2006 under the new CBSA designations. For a complete discussion of this policy, we refer readers to the FY 2006 IRF PPS final rule (70 FR 47880, 47921 through 47925). As discussed in the FY 2016 IRF PPS final rule (80 FR 47036, 47074), we continue to believe that a 3-year budget-neutral phase-out of the rural adjustment appropriately mitigates the adverse payment impacts for these IRFs while also ensuring that payment rates for all IRFs are set accurately and appropriately.

Final Decision: After careful consideration, we are finalizing the continuation of the 3-year phase-out of the rural adjustment for IRFs that were designated as rural in FY 2015 but changed to urban in FY 2016 under the new OMB market area delineations. For FY 2017, these IRFs will receive the full FY 2017 wage index and one-third of the FY 2015 rural adjustment. For FY 2018, these IRFs will receive the full FY 2018 wage index with no rural adjustment.

For a full discussion of our implementation of the new OMB labor market area delineations for the FY 2016 wage index, please refer to the FY 2016 IRF PPS final rule (80 FR 47036, 47068 through 47076). While conducting analysis for the FY 2017 IRF PPS final rule, an additional IRF provider was identified as being eligible for the 3-year phase out of the rural adjustments for IRF providers that changed from rural to urban status. The original 19 providers were identified in FY 2014 claims data for the FY 2016 IRF PPS proposed and final rules. This newly eligible provider was new in FY 2015 and thus had no claims data in FY 2014. An analysis of the FY 2015 claims determined that this provider should have received two-thirds of the rural adjustment in FY 2016. This provider will be added to the group of providers receiving two-thirds of the rural adjustment in FY 2016 and one-third of the rural adjustment in FY 2017. For FY 2017, 20 IRFs that were designated as rural in FY 2015 and became designated as urban in FY 2016 will receive the FY 2017 wage index (based solely on the revised CBSA delineations) and one-third of the FY 2015 rural adjustment of 14.9 percent (80 FR 47036, 47073 through 47076). The wage index applicable to FY 2017

is available on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html*. Table A is for urban areas, and Table B is for rural areas.

To calculate the wage-adjusted facility payment for the payment rates set forth in this final rule, we multiply the unadjusted federal payment rate for IRFs by the FY 2017 labor-related share based on the 2012-based IRF market basket (70.9 percent) to determine the labor-related portion of the standard payment amount. A full discussion of the calculation of the labor-related share is located in section VI.C of this final rule. We then multiply the labor-related portion by the applicable IRF wage index from the tables in the addendum to this final rule. These tables are available through the Internet on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html*.

Adjustments or updates to the IRF wage index made under section 1886(j)(6) of the Act must be made in a budget-neutral manner. We proposed to calculate a budget-neutral wage adjustment factor as established in the FY 2004 IRF PPS final rule (68 FR 45689), codified at § 412.624(e)(1), as described in the steps below. We proposed to use the listed steps to ensure that the FY 2017 IRF standard payment conversion factor reflects the update to the wage indexes (based on the FY 2012 hospital cost report data) and the labor-related share in a budget-neutral manner:

Step 1. Determine the total amount of the estimated FY 2016 IRF PPS payments, using the FY 2016 standard payment conversion factor and the labor-related share and the wage indexes from FY 2016 (as published in the FY 2016 IRF PPS final rule (80 FR 47036)).

Step 2. Calculate the total amount of estimated IRF PPS payments using the FY 2017 standard payment conversion factor and the FY 2017 labor-related share and CBSA urban and rural wage indexes.

Step 3. Divide the amount calculated in step 1 by the amount calculated in step 2. The resulting quotient is the FY 2017 budget-neutral wage adjustment factor of 0.9992.

Step 4. Apply the FY 2017 budget-neutral wage adjustment factor from step 3 to the FY 2016 IRF PPS standard payment conversion factor after the application of the adjusted market basket update to determine the FY 2017 standard payment conversion factor.

We discuss the calculation of the standard payment conversion factor for FY 2017 in section VI.E of this final rule.

We did not receive any specific comments on the proposal to calculate a budget-neutral wage adjustment factor.

Final Decision: As we did not receive any comments on the proposal to calculate a budget-natural wage adjustment factor, we are finalizing our calculation of the budget-neutral wage adjustment factor of 0.9992 for FY 2017.

We received 11 public comments on the proposed IRF wage adjustment for FY 2017, which are summarized below.

Comment: Commenters again recommended that we develop a new methodology for the area wage adjustment that eliminates hospital wage index reclassifications for all hospitals and reduces the problems associated with annual fluctuations in wage indices and across geographic boundaries. Until such time as the new methodology may be developed, commenters also recommended that we consider adopting certain wage index policies currently employed under the IPPS, because IRFs compete in a similar labor pool as acute care hospitals. Such comments included requests that CMS grant IRFs the ability to request reclassification and/or establish a rural floor policy. One commenter further recommended that, until a new wage index system is implemented, we institute a ''smoothing'' variable to the current process to reduce the fluctuations IRFs annually experience.

Response: Consistent with our previous responses to these comments (most recently published in our FY 2016 IRF PPS final rule (80 FR 47036, 47076)), we note that the IRF PPS does not account for geographic reclassification under sections 1886(d)(8) and (d)(10) of the Act, and does not apply the ''rural floor'' under section 4410 of the BBA. Furthermore, as we do not have an IRF-specific wage index, we are unable to determine at this time the degree, if any, to which a geographic reclassification adjustment or a rural floor policy under the IRF PPS would be appropriate. The rationale for our current wage index policies is fully described in the FY 2006 IRF PPS final rule (70 FR 47880, 47926 through 47928).

Additionally, while some commenters recommended that we adopt IPPS reclassification and/or floor policies, we note the MedPAC's June 2007 report to the Congress, titled ''Report to Congress: Promoting Greater Efficiency in Medicare'' (available at *http://www.medpac.gov/-documents-/reports*), recommends that Congress ''repeal the existing hospital wage index statute, including reclassification and exceptions, and give the Secretary authority to establish new wage index systems.'' We continue to believe it would not be appropriate at this time to adopt the IPPS wage index policies, such as reclassification and/or floor policies. Therefore, we will continue to use the CBSA labor market area definitions and the pre-reclassification and pre-floor hospital wage index data based on 2012 cost report data as this is the most recent final data available.

With regard to issues mentioned about ensuring that the wage index minimizes fluctuations, matches the costs of labor in the market, and provides for a single wage index policy, we note that section 3137(b) of the Affordable Care Act required us to submit a report to the Congress by December 31, 2011 that includes a plan to reform the hospital wage index system. This report describes the concept of a Commuting Based Wage Index as a potential replacement to the current Medicare wage index methodology. While this report addresses the goals of broad based Medicare wage index reform, no consensus has been achieved regarding how best to implement a replacement system. These concerns will be taken into consideration while CMS continues to explore potential wage index reforms.

The report that we submitted is available online at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Reform.html*.

Comment: Several commenters suggested that CMS use the most current wage data that is available and align the timeframe for the IRF wage index with other post-acute and acute care settings. These commenters indicated that this would position the IRF PPS to be more in line with alternative payment models that are currently being developed and tested.

Response: As we did not propose any changes to the methodology for determining the wage index for IRF providers, these comments are outside the scope of the proposed rule. We appreciate the commenters' suggestions and agree that this issue needs to be considered within the broader context of Medicare post-acute care payment reform efforts. We will consider these suggestions for future analyses.

Final Decision: After careful consideration of the comments, we are finalizing use of the FY 2016 pre-floor, pre-reclassified hospital wage index data to derive the applicable IRF PPS wage index for FY 2017. We are also continuing to implement the 3-year

phase-out of the rural adjustment for IRFs that were designated as rural in FY 2015 but changed to urban in FY 2016 under the new OMB market area delineations. For FY 2017, these IRFs will receive the full FY 2017 wage index and one-third of the FY 2015 rural adjustment. For FY 2018, these IRFs will receive the full FY 2018 wage index with no rural adjustment.

E. Description of the IRF Standard Payment Conversion Factor and Payment Rates for FY 2017

To calculate the standard payment conversion factor for FY 2017, as illustrated in Table 4, we begin by applying the adjusted market basket increase factor for FY 2017 that was adjusted in accordance with sections 1886(j)(3)(C) and (D) of the Act, to the standard payment conversion factor for FY 2016 ($15,478). Applying the 1.65 percent adjusted market basket increase for FY 2017 to the standard payment conversion factor for FY 2016 of $15,478 yields a standard payment amount of $15,733. Then, we apply the budget neutrality factor for the FY 2017 wage index and labor-related share of 0.9992, which results in a standard payment amount of $15,721. We next apply the budget neutrality factor for the revised CMG relative weights of 0.9992, which results in the standard payment conversion factor of $15,708 for FY 2017.

TABLE 4—CALCULATIONS TO DETERMINE THE FY 2017 STANDARD PAYMENT CONVERSION FACTOR

Explanation for adjustment		Calculations
Standard Payment Conversion Factor for FY 2016		$15,478
Market Basket Increase Factor for FY 2017 (2.7 percent), reduced by 0.3 percentage point for the productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act, and reduced by 0.75 percentage point in accordance with paragraphs 1886(j)(3)(C) and (D) of the Act	×	1.0165
Budget Neutrality Factor for the Wage Index and Labor-Related Share	×	0.9992
Budget Neutrality Factor for the Revisions to the CMG Relative Weights	×	0.9992
FY 2017 Standard Payment Conversion Factor	=	15,708

We did not receive comments specifically on the proposed FY 2017 standard payment conversion factor. We received comments on how the FY 2016 IRF QRP relates to the proposed FY 2017 standard payment conversion factor, which we have summarized in section IX. of this final rule.

Final Decision: As we did not receive comments specifically on the proposed FY 2017 standard payment conversion factor, we are finalizing the IRF standard payment conversion factor of $15,708 for FY 2017.

After the application of the proposed CMG relative weights described in section IV of this final rule to the FY 2017 standard payment conversion factor ($15,708), the resulting unadjusted IRF prospective payment rates for FY 2017 are shown in Table 5.

TABLE 5—FY 2017 PAYMENT RATES

CMG	Payment rate Tier 1	Payment rate Tier 2	Payment rate Tier 3	Payment rate no comorbidity
0101	$12,553.83	$11,179.38	$10,227.48	$9,762.52
0102	15,912.20	14,168.62	12,962.24	12,373.19
0103	18,591.99	16,556.23	15,145.65	14,457.64
0104	19,788.94	17,621.23	16,121.12	15,387.56
0105	22,889.70	20,382.70	18,646.97	17,798.73
0106	25,597.76	22,793.88	20,852.37	19,903.61
0107	28,568.14	25,439.11	23,271.40	22,214.25
0108	35,960.32	32,022.33	29,293.85	27,961.81
0109	32,333.35	28,791.19	26,339.17	25,140.65
0110	42,914.26	38,212.85	34,958.15	33,368.50
0201	12,178.41	9,960.44	8,977.12	8,392.78
0202	17,192.41	14,060.23	12,671.64	11,846.97
0203	19,121.35	15,637.31	14,094.79	13,175.87
0204	21,135.11	17,283.51	15,579.19	14,564.46
0205	25,484.66	20,842.95	18,785.20	17,563.11
0206	30,220.62	24,714.97	22,277.09	20,825.67
0207	39,716.11	32,481.00	29,275.00	27,369.62
0301	17,944.82	14,815.79	13,463.33	12,569.54
0302	22,090.16	18,236.99	16,573.51	15,472.38
0303	25,902.49	21,384.87	19,433.94	18,142.74
0304	33,514.59	27,668.07	25,143.80	23,474.04
0401	15,392.27	13,534.01	12,483.15	11,330.18
0402	22,072.88	19,410.38	17,900.84	16,248.36
0403	34,816.78	30,618.03	28,236.70	25,629.17
0404	60,793.10	53,459.04	49,302.70	44,750.52
0405	54,027.67	47,510.42	43,815.90	39,771.09
0501	13,389.50	10,547.92	10,045.27	9,033.67
0502	18,221.28	14,355.54	13,670.67	12,294.65
0503	22,866.14	18,015.51	17,154.71	15,428.40
0504	26,840.26	21,146.11	20,136.09	18,109.75
0505	30,798.68	24,264.15	23,104.90	20,780.11
0506	42,648.79	33,600.98	31,995.63	28,777.06

TABLE 5—FY 2017 PAYMENT RATES—Continued

CMG	Payment rate Tier 1	Payment rate Tier 2	Payment rate Tier 3	Payment rate no comorbidity
0601	16,260.92	12,888.41	11,901.95	10,899.78
0602	20,926.20	16,587.65	15,316.87	14,027.24
0603	25,778.40	20,432.97	18,868.45	17,280.37
0604	34,168.04	27,082.16	25,010.28	22,903.83
0701	15,693.86	12,780.03	12,200.40	11,077.28
0702	20,041.84	16,320.61	15,580.77	14,146.62
0703	24,163.62	19,677.41	18,783.63	17,055.75
0704	31,326.46	25,509.79	24,352.11	22,110.58
0801	12,539.70	10,120.66	9,358.83	8,601.70
0802	16,231.08	13,100.47	12,115.58	11,135.40
0803	21,713.17	17,523.84	16,205.94	14,894.33
0804	19,548.61	15,777.12	14,591.16	13,409.92
0805	23,257.26	18,769.49	17,358.91	15,954.62
0806	28,253.98	22,803.30	21,087.99	19,382.10
0901	15,455.10	12,472.15	11,554.80	10,513.36
0902	19,765.38	15,951.47	14,778.09	13,446.05
0903	24,834.35	20,043.41	18,568.43	16,893.95
0904	31,437.99	25,373.13	23,507.02	21,386.44
1001	16,831.12	14,840.92	12,878.99	11,623.92
1002	21,843.54	19,259.58	16,714.88	15,085.96
1003	30,848.94	27,201.54	23,607.55	21,306.33
1101	20,769.12	18,826.04	15,298.02	13,889.01
1102	29,771.37	26,987.91	21,929.94	19,911.46
1201	16,303.33	16,086.56	14,617.86	12,929.25
1202	18,945.42	18,692.52	16,985.06	15,023.13
1203	24,143.20	23,821.18	21,645.62	19,144.91
1301	18,753.78	14,754.52	13,650.25	12,577.40
1302	25,756.41	20,263.32	18,747.50	17,274.09
1303	31,753.72	24,982.00	23,114.32	21,296.91
1401	13,612.55	11,504.54	10,428.54	9,464.07
1402	18,551.15	15,678.15	14,211.03	12,897.84
1403	22,115.29	18,690.95	16,941.08	15,374.99
1404	27,968.09	23,637.40	21,425.71	19,444.93
1501	15,847.80	13,419.34	12,390.47	11,680.47
1502	20,021.42	16,953.64	15,654.59	14,756.10
1503	24,414.94	20,674.87	19,089.93	17,995.08
1504	30,426.40	25,764.26	23,789.77	22,424.74
1601	15,533.64	14,031.96	13,070.63	12,059.03
1602	20,264.89	18,306.10	17,051.03	15,731.56
1603	25,376.27	22,921.11	21,350.31	19,697.83
1701	17,820.73	14,542.47	13,383.22	12,049.61
1702	22,388.61	18,269.97	16,813.84	15,137.80
1703	26,683.18	21,774.43	20,040.27	18,042.21
1704	34,276.43	27,969.66	25,740.70	23,174.01
1801	20,313.59	16,642.63	14,456.07	12,965.38
1802	28,641.97	23,466.18	20,382.70	18,282.54
1803	45,069.39	36,924.80	32,074.17	28,767.63
1901	19,269.00	16,518.53	14,561.32	14,347.69
1902	35,009.99	30,011.70	26,456.98	26,067.43
1903	57,623.23	49,396.95	43,545.72	42,906.40
2001	14,490.63	11,878.39	10,904.49	9,872.48
2002	19,001.97	15,576.05	14,300.56	12,944.96
2003	23,756.78	19,473.21	17,877.27	16,183.95
2004	30,492.37	24,994.57	22,946.25	20,772.26
2101	26,544.95	26,544.95	23,657.82	21,697.46
5001	.....	.....	.....	2,489.72
5101	.....	.....	.....	10,657.88
5102	.....	.....	.....	26,084.70
5103	.....	.....	.....	12,569.54
5104	.....	.....	.....	33,300.96

F. Example of the Methodology for Adjusting the Federal Prospective Payment Rates

Table 6 illustrates the methodology for adjusting the federal prospective payments (as described in sections VI.A. through VI.F. of this final rule). The following examples are based on two hypothetical Medicare beneficiaries, both classified into CMG 0110 (without comorbidities). The unadjusted federal prospective payment rate for CMG 0110 (without comorbidities) appears in Table 5.

Example: One beneficiary is in Facility A, an IRF located in rural Spencer County, Indiana, and another beneficiary is in Facility B, an IRF located in urban Harrison County, Indiana. Facility A, a rural non-teaching hospital has a Disproportionate Share

Hospital (DSH) percentage of 5 percent (which would result in a LIP adjustment of 1.0156), a wage index of 0.8297, and a rural adjustment of 14.9 percent. Facility B, an urban teaching hospital, has a DSH percentage of 15 percent (which would result in a LIP adjustment of 1.0454 percent), a wage index of 0.8756, and a teaching status adjustment of 0.0784.

To calculate each IRF's labor and non-labor portion of the federal prospective payment, we begin by taking the unadjusted federal prospective payment rate for CMG 0110 (without comorbidities) from Table 5. Then, we multiply the labor-related share for FY 2017 (70.9 percent) described in section VI.C. of this final rule by the unadjusted federal prospective payment rate. To determine the non-labor portion of the federal prospective payment rate, we subtract the labor portion of the federal payment from the unadjusted federal prospective payment.

To compute the wage-adjusted federal prospective payment, we multiply the labor portion of the federal payment by the appropriate wage index located in tables A and B. These tables are available on CMS Web site at *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/*. The resulting figure is the wage-adjusted labor amount. Next, we compute the wage-adjusted federal payment by adding the wage-adjusted labor amount to the non-labor portion.

Adjusting the wage-adjusted federal payment by the facility-level adjustments involves several steps. First, we take the wage-adjusted federal prospective payment and multiply it by the appropriate rural and LIP adjustments (if applicable). Second, to determine the appropriate amount of additional payment for the teaching status adjustment (if applicable), we multiply the teaching status adjustment (0.0784, in this example) by the wage-adjusted and rural-adjusted amount (if applicable). Finally, we add the additional teaching status payments (if applicable) to the wage, rural, and LIP-adjusted federal prospective payment rates. Table 6 illustrates the components of the adjusted payment calculation.

TABLE 6: Example of Computing the IRF FY 2017 Federal Prospective Payment

Steps		Rural Facility A (Spencer Co., IN)		Urban Facility B (Harrison Co., IN)	
1	Unadjusted Federal Prospective Payment		$33,368.50		$33,368.50
2	Labor Share	X	0.709	X	0.709
3	Labor Portion of Federal Payment	=	$23,658.27	=	$23,658.27
4	CBSA-Based Wage Index (shown in the Addendum, Tables A and B)	X	0.8297	X	0.8756
5	Wage-Adjusted Amount	=	$19,629.27	=	$20,715.18
6	Non-Labor Amount	+	$9,710.23	+	$9,710.23
7	Wage-Adjusted Federal Payment	=	$29,339.50	=	$30,425.41
8	Rural Adjustment	X	1.149	X	1.000
9	Wage- and Rural-Adjusted Federal Payment	=	$33,711.09	=	$30,425.41
10	LIP Adjustment	X	1.0156	X	1.0454
11	FY 2017 Wage-, Rural- and LIP-Adjusted Federal Prospective Payment Rate	=	$34,236.98	=	$31,806.72
12	FY 2017 Wage- and Rural-Adjusted Federal Prospective Payment		$33,711.09		$30,425.41
13	Teaching Status Adjustment	X	0	X	0.0784
14	Teaching Status Adjustment Amount	=	$0.00	=	$2,385.35
15	FY 2017 Wage-, Rural-, and LIP-Adjusted Federal Prospective Payment Rate	+	$34,236.98	+	$31,806.72
16	Total FY 2017 Adjusted Federal Prospective Payment	=	$34,236.98	=	$34,192.08

Thus, the adjusted payment for Facility A would be $34,236.98 and the adjusted payment for Facility B would be $34,192.08.

VII. Update to Payments for High-Cost Outliers Under the IRF PPS

A. Update to the Outlier Threshold Amount for FY 2017

Section 1886(j)(4) of the Act provides the Secretary with the authority to make payments in addition to the basic IRF prospective payments for cases incurring extraordinarily high costs. A case qualifies for an outlier payment if the estimated cost of the case exceeds the adjusted outlier threshold. We calculate the adjusted outlier threshold by adding the IRF PPS payment for the case (that is, the CMG payment adjusted by all of the relevant facility-level adjustments) and the adjusted threshold amount (also adjusted by all of the relevant facility-level adjustments). Then, we calculate the estimated cost of a case by multiplying the IRF's overall CCR by the Medicare allowable covered charge. If the estimated cost of the case is higher than the adjusted outlier threshold, we make an outlier payment for the case equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold.

In the FY 2002 IRF PPS final rule (66 FR 41362 through 41363), we discussed our rationale for setting the outlier threshold amount for the IRF PPS so that estimated outlier payments would equal 3 percent of total estimated payments. For the 2002 IRF PPS final rule, we analyzed various outlier policies using 3, 4, and 5 percent of the total estimated payments, and we concluded that an outlier policy set at 3 percent of total estimated payments would optimize the extent to which we could reduce the financial risk to IRFs of caring for high-cost patients, while still providing for adequate payments for all other (non-high cost outlier) cases.

Subsequently, we updated the IRF outlier threshold amount in the FYs 2006 through 2016 IRF PPS final rules and the FY 2011 and FY 2013 notices (70 FR 47880, 71 FR 48354, 72 FR 44284, 73 FR 46370, 74 FR 39762, 75 FR 42836, 76 FR 47836, 76 FR 59256, and 77 FR 44618, 78 FR 47860, 79 FR 45872, 80 FR 47036, respectively) to maintain estimated outlier payments at 3 percent of total estimated payments. We also stated in the FY 2009 final rule (73 FR 46370 at 46385) that we would continue to analyze the estimated outlier payments for subsequent years and adjust the outlier threshold amount as appropriate to maintain the 3 percent target.

To update the IRF outlier threshold amount for FY 2017, we proposed to use FY 2015 claims data and the same methodology that we used to set the initial outlier threshold amount in the FY 2002 IRF PPS final rule (66 FR 41316 and 41362 through 41363), which is also the same methodology that we used to update the outlier threshold amounts for FYs 2006 through 2016. Based on an analysis of the preliminary data used for the proposed rule, we estimated that IRF outlier payments as a percentage of total estimated payments would be approximately 2.8 percent in FY 2016. Therefore, we proposed to update the outlier threshold amount from $8,658 for FY 2016 to $8,301 for FY 2017 to maintain estimated outlier payments at approximately 3 percent of total estimated aggregate IRF payments for FY 2017.

We note that, as we typically do, we updated our data between the FY 2017 IRF PPS proposed and final rules to ensure that we use the most recent available data in calculating IRF PPS payments. This updated data includes a more complete set of claims for FY 2015. Based on our analysis using this updated data, we now estimate that IRF outlier payments as a percentage of total estimated payments are approximately 2.7 percent in FY 2016. Therefore, we will update the outlier threshold amount from $8,658 for FY 2016 to $7,984 for FY 2017 to maintain estimated outlier payments at approximately 3 percent of total estimated aggregate IRF payments for FY 2017.

We received 7 public comments on the proposed update to the FY 2017 outlier threshold amount to maintain estimated outlier payments at approximately 3 percent of total estimated IRF payments, which are summarized below.

Comment: Commenters, while supportive of maintaining estimated payments for outlier payments at approximately 3 percent, suggested that CMS review its methodology for setting the outlier threshold amount and modify as needed so that the full 3 percent is paid as outlier payments. Some commenters suggested implementing a forecast error correction if the full amount of the outlier pool is not paid out.

Response: We will continue to monitor our IRF outlier policies to ensure that they continue to compensate IRFs appropriately for treating unusually high-cost patients and, thereby, promote access to care for patients who are likely to require unusually high-cost care. As we have indicated in previous IRF PPS final rules, we do not make adjustments to IRF PPS payment rates for the sole purpose of accounting for differences between projected and actual outlier payments. We use the best available data at the time to establish an outlier threshold for IRF PPS payments prior to the beginning of each fiscal year to help ensure that estimated outlier payments for that fiscal year will equal 3 percent of total estimated IRF PPS payments. We analyze expenditures annually, and if there is a difference from our projection, that information is used to make a prospective adjustment to lower or raise the outlier threshold for the upcoming fiscal year. We believe a retrospective adjustment would not be appropriate, given that we do not recoup or make excess payments to hospitals.

If outlier payments for a given year turn out to be greater than projected, we do not recoup money from hospitals; if outlier payments for a given year are lower than projected, we do not make an adjustment to account for the difference. Payments for a given discharge in a given fiscal year are generally intended to reflect or address the prospective average costs of that discharge in that year; that goal would be undermined if we adjusted IRF PPS payments to account for ''underpayments'' or ''overpayments'' in IRF outliers in previous years.

Comment: One commenter recommended that we expand the outlier pool from 3 percent to 5 percent in order to ensure that payments are more equitably distributed within the IRF payment system. However, this same commenter noted that such an expansion in the outlier pool could inappropriately reward facilities for inefficiencies. Several other commenters stated that expanding the outlier pool would be inappropriate for this same reason.

Response: We refer readers to the 2002 IRF PPS final rule (66 FR 41316, 41362 through 41363), for a discussion of the rationale for setting the outlier threshold amount for the IRF PPS so that estimated outlier payments would equal 3 percent of total estimated payments. For the 2002 IRF PPS final rule, we analyzed various outlier policies using 3, 4, and 5 percent of the total estimated payments, and we concluded that an outlier policy set at 3 percent of total estimated payments would optimize the extent to which we could reduce the financial risk to IRFs of caring for high-cost patients, while still providing for adequate payments for all other (non-high cost outlier)

cases. We believe that the outlier policy of 3 percent of total estimated payments optimizes the extent to which we can encourage facilities to continue to take patients that are likely to have unusually high costs, while still providing adequate payment for all other cases. Increasing the outlier pool would leave less money available to cover the costs of non-outlier cases, due to the fact that we would implement such a change in a budget-neutral manner. We believe that our current outlier policy, to set outlier payments at 3 percent of total payments, is consistent with the statute and the goals of the prospective payment system.

Comment: Several commenters recommended that CMS impose a cap on the amount of outlier payments an individual IRF can receive under the IRF PPS.

Response: Comments regarding the amount of outlier payments an individual IRF can receive are outside the scope of this rule. However, any future consideration given to imposing a limit on outlier payments would have to be carefully analyzed and would need to take into account any effect on access to IRF care it would have for certain high-cost populations.

Final Decision: Having carefully considered the public comments received and also taking into account the most recent available data, we are finalizing the outlier threshold amount of $7,984 to maintain estimated outlier payments at approximately 3 percent of total estimated aggregate IRF payments for FY 2017. This update is effective October 1, 2016.

B. Update to the IRF Cost-to-Charge Ratio Ceiling and Urban/Rural Averages

In accordance with the methodology stated in the FY 2004 IRF PPS final rule (68 FR 45674, 45692 through 45694), we proposed to apply a ceiling to IRFs' CCRs. Using the methodology described in that final rule, we proposed to update the national urban and rural CCRs for IRFs, as well as the national CCR ceiling for FY 2017, based on analysis of the most recent data that is available. We apply the national urban and rural CCRs in the following situations:

- New IRFs that have not yet submitted their first Medicare cost report.
- IRFs whose overall CCR is in excess of the national CCR ceiling for FY 2017, as discussed below.
- Other IRFs for which accurate data to calculate an overall CCR are not available.

Specifically, for FY 2017, we proposed to estimate a national average CCR of 0.562 for rural IRFs, which we calculated by taking an average of the CCRs for all rural IRFs using their most recently submitted cost report data. Similarly, we proposed to estimate a national average CCR of 0.435 for urban IRFs, which we calculated by taking an average of the CCRs for all urban IRFs using their most recently submitted cost report data. We apply weights to both of these averages using the IRFs' estimated costs, meaning that the CCRs of IRFs with higher total costs factor more heavily into the averages than the CCRs of IRFs with lower total costs. We used FY 2013 IRF cost report data for the proposed rule. (Please note that we erroneously stated in the proposed rule that we used FY 2014 cost report data.) For this final rule, we have used the most recent available cost report data (FY 2014). This includes all IRFs whose cost reporting periods begin on or after October 1, 2013, and before October 1, 2014. If, for any IRF, the FY 2014 cost report was missing or had an ''as submitted'' status, we used data from a previous fiscal year's (that is, FY 2004 through FY 2013) settled cost report for that IRF. We do not use cost report data from before FY 2004 for any IRF because changes in IRF utilization since FY 2004 resulting from the 60 percent rule and IRF medical review activities suggest that these older data do not adequately reflect the current cost of care. Using the updated FY 2014 cost report data for this final rule, we estimate a national average CCR of 0.522 for rural IRFs, and a national average CCR of 0.421 for urban IRFs.

In accordance with past practice, we proposed to set the national CCR ceiling at 3 standard deviations above the mean CCR. Using this method, we proposed a national CCR ceiling of 1.36 for FY 2017. This means that, if an individual IRF's CCR were to exceed this proposed ceiling of 1.36 for FY 2017, we would replace the IRF's CCR with the appropriate proposed national average CCR (either rural or urban, depending on the geographic location of the IRF). We calculated the proposed national CCR ceiling by:

Step 1. Taking the national average CCR (weighted by each IRF's total costs, as previously discussed) of all IRFs for which we have sufficient cost report data (both rural and urban IRFs combined).

Step 2. Estimating the standard deviation of the national average CCR computed in step 1.

Step 3. Multiplying the standard deviation of the national average CCR computed in step 2 by a factor of 3 to compute a statistically significant reliable ceiling.

Step 4. Adding the result from step 3 to the national average CCR of all IRFs for which we have sufficient cost report data, from step 1.

Using the updated FY 2014 cost report data for this final rule, we estimate a national average CCR ceiling of 1.29, using this same methodology.

We did not receive any comments on the proposed update to the IRF CCR ceiling and the urban/rural averages for FY 2017.

Final Decision: As we did not receive any comments on the proposed updates to the IRF CCR ceiling and the urban/rural averages for FY 2017, we are finalizing the national average urban CCR at 0.421, the national average rural CCR at 0.522, and the national CCR ceiling at 1.29 for FY 2017. These updates are effective October 1, 2016.

VIII. Revisions and Updates to the IRF Quality Reporting Program (QRP)

A. Background and Statutory Authority

We seek to promote higher quality and more efficient health care for Medicare beneficiaries, and our efforts are furthered by QRPs coupled with public reporting of that information. Section 3004(b) of the Affordable Care Act amended section 1886(j)(7) of the Act, requiring the Secretary to establish the IRF QRP. This program applies to freestanding IRFs, as well as IRF units affiliated with either acute care facilities or critical access hospitals (CAHs). Beginning with the FY 2014 payment determination and subsequent years, the Secretary is required to reduce any annual update to the standard federal rate for discharges occurring during such fiscal year by 2 percentage points for any IRF that does not comply with the requirements established by the Secretary. Section 1886(j)(7) of the Act requires that for the FY 2014 payment determination and subsequent years, each IRF submit data on quality measures specified by the Secretary in a form and manner, and at a time, specified by the Secretary. For more information on the statutory history of the IRF QRP, please refer to the FY 2015 IRF PPS final rule (79 FR 45908).

The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) imposed new data reporting requirements for certain PAC providers, including IRFs. For information on the statutory background of the IMPACT Act, please refer to the FY 2016 IRF PPS final rule (80 FR 47080 through 47083).

In the FY 2016 IRF PPS final rule, we reviewed general activities and finalized the general timeline and sequencing of such activities that will occur under the

IRF QRP. For further information, please refer to the FY 2016 IRF PPS final rule (80 FR 40708 through 47128). In addition, we established our approach for identifying cross-cutting measures and process for the adoption of measures, including the application and purpose of the Measures Application Partnership (MAP) and the notice-and-comment rulemaking process (80 FR 47080 through 47084). For information on these topics, please refer to the FY 2016 IRF PPS final rule (80 FR 47080).

B. General Considerations Used for Selection of Quality, Resource Use, and Other Measures for the IRF QRP

For a detailed discussion of the considerations we use for the selection of IRF QRP quality measures, such as alignment with the CMS Quality Strategy,[1] which incorporates the 3 broad aims of the National Quality Strategy,[2] please refer to the FY 2015 IRF PPS final rule (79 FR 45911) and the FY 2016 IRF PPS final rule (80 FR 47083 through 47084). Overall, we strive to promote high quality and efficiency in the delivery of health care to the beneficiaries we serve. Performance improvement leading to the highest-quality health care requires continuous evaluation to identify and address performance gaps and reduce the unintended consequences that may arise in treating a large, vulnerable, and aging population. QRPs, coupled with public reporting of quality information, are critical to the advancement of health care quality improvement efforts. Valid, reliable, relevant quality measures are fundamental to the effectiveness of our QRPs. Therefore, selection of quality measures is a priority for us in all of our QRPs.

In the IRF PPS FY 2017 proposed rule (81 FR 24178), we proposed to adopt for the IRF QRP one measure that we are specifying under section 1899B(c)(1) of the Act to meet the Medication Reconciliation domain, that is, Drug Regimen Review Conducted with Follow-Up for Identified Issues-Post Acute Care Inpatient Rehabilitation Facility Quality Reporting Program. Further, we proposed to adopt for the IRF QRP three measures to meet the resource use and other measure domains identified in section 1899B(d)(1) of the Act. These measures include: (1) Total Estimated Medicare Spending per Beneficiary: Medicare Spending per Beneficiary-Post Acute Care Inpatient Rehabilitation Facility Quality Reporting Program; (2) Discharge to Community: Discharge to Community-Post Acute Care Inpatient Rehabilitation Facility Quality Reporting Program, and (3) Potentially Preventable 30-Day Post-Discharge Readmission Measure for Inpatient Rehabilitation Facility Quality Reporting Program. We also proposed an additional measure, which is not required under the IMPACT Act: (4) Potentially Preventable Within Stay Readmission Measure for Inpatient Rehabilitation Facilities.

In our development and specification of measures, we employed a transparent process in which we seek input from stakeholders and national experts and engage in a process that allows for pre-rulemaking input on each measure, as required by section 1890A of the Act. To meet this requirement, we provided the following opportunities for stakeholder input: Our measure development contractor convened technical expert panels (TEPs) that included stakeholder experts and patient representatives on July 29, 2015, for the Drug Regimen Review Conducted with Follow-Up for Identified Issues measures; on August 25, 2015, September 25, 2015, and October 5, 2015, for the Discharge to Community measures; on August 12 and 13, 2015, and October 14, 2015, for the Potentially Preventable 30-Day Post-Discharge Readmission Measures and Potentially Preventable Within Stay Readmission Measure for IRFs; and on October 29 and 30, 2015, for the Medicare Spending per Beneficiary (MSPB) measures. In addition, we released draft quality measure specifications for public comment for the Drug Regimen Review Conducted with Follow-Up for Identified Issues measures from September 18, 2015, to October 6, 2015; for the Discharge to Community measures from November 9, 2015, to December 8, 2015; for the Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRFs and Potentially Preventable Within Stay Readmission Measure for IRFs from November 2, 2015 to December 1, 2015; and for the MSPB measures from January 13, 2016 to February 5, 2016. We implemented a public mailbox, *PACQualityInitiative@cms.hhs.gov*, for the submission of public comments. This PAC mailbox is accessible on our post-acute care quality initiatives Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-of-2014-Data-Standardization-and-Cross-Setting-MeasuresMeasures.html.*

Additionally, we sought public input from the NQF-convened MAP Post-Acute Care, Long-Term Care Workgroup during the annual in-person meeting held December 14 and 15, 2015. The MAP, composed of multi-stakeholder groups, is tasked to provide input on the selection of quality and efficiency measures described in section 1890(b)(7)(B) of the Act.

The MAP reviewed each IMPACT Act-related measure, as well as other quality measures proposed in this rule for use in the IRF QRP. For more information on the MAP's recommendations, please refer to the MAP 2016 Final Recommendations to HHS and CMS public report at *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx.*

For measures that do not have NQF endorsement, or which are not fully supported by the MAP for use in the IRF QRP, we proposed for the IRF QRP for the purposes of satisfying the measure domains required under the IMPACT Act, measures that closely align with the national priorities identified in the National Quality Strategy (*http://www.ahrq.gov/workingforquality/*) and for which the MAP supports the measure concept. Further discussion as to the importance and high-priority status of these proposed measures in the IRF setting is included under each quality measure in this final rule.

Although we did not solicit feedback on General Considerations Used for Selection of Quality, Resource Use, and Other Measures for the IRF QRP, we received a number of comments, which are summarized with our responses below.

Comment: One commenter supported CMS's intention to select measures that are already incorporated in various quality reporting programs to minimize burden. One commenter commented that CMS should recognize burden of data collection and focus on measures that are the most clinically relevant and actionable to the facility and patients. Additionally, the commenter recommended that CMS use minimum standards in the development of new measures so that they are as clear and consistent across facilities as possible.

Response: We appreciate the commenters' support of CMS's intention to select measures that are already incorporated in the various quality reporting programs to minimize burden. In addition, we note that we strive to strike a balance between minimizing burden and addressing gaps in quality

[1] *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html.*

[2] *http://www.ahrq.gov/workingforquality/nqs/nqs2011annlrpt.htm.*

of care as we continue to expand the IRF QRP. We interpret the commenter's suggestion that CMS apply minimum standards in its measure development to suggest that we simplify our approach to quality measure development itself. We will take these recommendations into consideration in our future measure development.

We also received several comments related to the proposed measures, the IMPACT Act, NQF endorsement, the NQF MAP review process, and the use of TEPs, which are addressed below.

Comment: We received several comments supporting the goals of the IMPACT Act and the implementation of cross-setting measures across PAC settings as required by the IMPACT Act. One commenter appreciated the use of TEPs and input of stakeholders. These commenters noted the importance of functional status measures and recommended that CMS include additional functional status measures in future iterations. Also, one of the commenters indicated that achieving standardized and interoperable patient assessment data will allow for better cross-setting comparisons of quality and will support the development of better quality measures with uniform risk standardization.

Response: We believe that standardizing patient assessment data will allow for the exchange of data among PAC providers in order to facilitate care coordination and improve patient outcomes. We appreciate the importance of functional status measures and will consider inclusion of additional measures. As with our measure development process, we will continue to use TEPs, public comments, open door forums, and the pre-rulemaking process in order to gather stakeholder input on all measures under development.

Comment: One commenter recommended that CMS seek an increased level of patient engagement in order to discern what quality measures are of greatest value to patients.

Response: We value the patient perspective in the measure development process. We have employed a transparent process in which we seek input from stakeholders, as described earlier. We have also have taken several steps to engage stakeholders, including patients, in all TEPs, public comments, and special open door forums. In addition, a summary of the IMPACT Act measure TEP proceedings, public comments, and special open door forums is available on the PAC Quality Initiatives Downloads and Videos Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html* Patient engagement is a priority for CMS, and we will continue to take steps to include the patient perspective, especially with regard to assembling TEP, which review and comment on our measure development activities.

Comment: Several commenters recommended that CMS delay implementation of proposed measures until NQF has completed its review and has endorsed measures that are appropriate for the specific characteristics of the IRF patient population. A few commenters suggested that CMS seek NQF's formal consensus development process instead of a time-limited endorsement, as it was perceived that the time-limited endorsement was not sufficient.

Response: We received several comments regarding the NQF endorsement status for the proposed measures, and acknowledge the commenters' recommendation to submit the measures to the NQF prior to implementation. We consider and propose appropriate measures that have been endorsed by the NQF whenever possible. However, when this is not feasible because there is no NQF-endorsed measure, we utilize our statutory authority that allows the Secretary to specify a measure for the IRF QRP that is not NQF-endorsed where, as in the case for the proposed measures, we have not been able to identify other measures that are endorsed or adopted by a consensus organization. While we appreciate the importance of consensus endorsement and intend to seek such endorsement, we must balance the need to address gaps in quality and adhere to statutorily required timelines as in the case of the quality and resource use measures that we proposed to address the IMPACT Act. In regard to the comments surrounding time-limited endorsement, NQF uses time-limited endorsement for measures that meet all of the NQF's endorsement criteria with the exception of field testing and are critical to advancing quality improvement. When measures are granted this two-year endorsement rather than the traditional three-year period, measure developers must test the measure and return results to NQF within the two-year window to maintain the endorsement. We wish to clarify that we have not yet sought endorsement of the proposed measures, time-limited or otherwise.

Comment: Several commenters stated the NQF MAP committee did not endorse the proposed measures; instead, the commenters recommended that CMS delay measure implementation until the measures are fully developed and tested and brought back to the NQF for further consideration. One commenter further stated that TEP members and other stakeholders who provided feedback in the measure development process did not support measures moving forward without further testing.

Response: We interpret this comment to address the activities of the Measures Application Partnership, a multi-stakeholder partnership convened by NQF that provides input to the U.S. Department of Health and Human Services (HHS) on its selection of measures for certain Medicare programs. We would like to clarify that the MAP ''encouraged continued development'' for the proposed measures. According to the MAP, the term ''encourage continued development'' is applied when a measure addresses a critical program objective or promotes alignment, but is in an earlier stage of development. In contrast, the MAP uses the phrase ''do not support'' when it does not support the measure at all.

Since the MAP recommendation of ''encourage continued development'' for the proposed measures during the December 2015 NQF-convened PAC LTC MAP meeting, further refinement of measure specifications and testing of measure validity and reliability have been performed. These efforts have included: A pilot test in 12 post-acute care settings, including IRFs, to determine the feasibility of assessment items for use in calculation of the Drug Regimen Review Conducted with Follow-Up for Identified Issues measure, and further development of the risk-adjusted models for the Discharge to Community, Medicare Spending per Beneficiary, Potentially Preventable Readmissions, and Potentially Preventable Within Stay Readmissions Measure for Inpatient Rehabilitation Facilities measures. Additional information regarding testing is further described in the specific measure sections. Additional information regarding testing that was performed since the MAP Meeting, TEP meetings, and public comment periods is further described below in our responses to comments on individual proposed measures.

For these reasons, we believe that the measures have been fully and robustly developed, and believe they are appropriate for implementation and should not be delayed.

Comment: Several commenters, including MedPAC, expressed concern regarding the standardization and

interoperability of the proposed measures as they perceived the measures to have different inclusion/exclusion criteria, episode constructions and risk factors, and therefore do not meet the mandate of the IMPACT Act. The commenters expressed further concern about future implications of such variations and recommend delaying implementation until measures are standardized and interoperable across PAC settings. One commenter further indicated that the measure names were different for each setting, pointing out the words ''IRF QRP'' or ''Inpatient Rehabilitation Facility'' were included in the measures' titles to designate a difference in the measure in each setting. One commenter stated implementing the quality measures in an unstandardized fashion would result in additional costs in the future for aligning measures between PAC providers.

MedPAC suggested that the measures use uniform definitions, specifications, and risk-adjustment methods, conveying that findings from their work on a unified PAC payment system suggest overlap or similar care provided for Medicare beneficiaries with similar needs across PAC settings. As a result of this work, MedPAC recommended that the IMPACT Act measures be standardized to facilitate quality comparison across PAC settings to inform Medicare beneficiary choice and provide an opportunity for CMS to evaluate the value of PAC services, noting that differences in rates should reflect differences in quality of care rather than differences in the way rates are constructed.

Response: We wish to clarify that the IMPACT Act requires that the patient assessment instruments be modified to enable the submission of standardized data, for purposes such as interoperability. However, measures themselves are not ''interoperable.''

CMS, in collaboration with our measure contractors, developed the proposed measures with the intent to standardize the measure methodology so that we are able to detect variation among PAC providers in order to be able to assess differences in quality of care. For example, the proposed patient assessment-based quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP, was developed across PAC settings with uniform definitions and specifications. This measure is not risk adjusted. The standardized development of this assessment-based measure follows the mandate of the IMPACT Act to develop standardized patient assessment-based measures for the four PAC settings (section 1899B(c)(1) of the Act). The resource use and other measures, Discharge to the Community-PAC IRF QRP and All-Condition Risk-Adjusted Potentially Preventable Hospital Readmissions Rates—PAC IRF QRP were developed to be uniform across the PAC settings in terms of their definitions, measure calculations, and risk-adjustment approach where applicable. However, there is variation in each measure primarily due to the data sources for each PAC setting. Further, the risk-adjustment approach for the resource use and other IMPACT Act measures is aligned, but is tailored to each measure based on measure testing results. Adjusting for relevant case-mix characteristics in each setting improves the validity and explanatory power of risk adjustment models, and helps ensure that any differences in measure performance reflect differences in the care provided rather than differences in patient case-mix. We employ this approach to measure development to enable appropriate cross-setting comparisons in PAC settings and to maximize measure reliability and validity. It should be noted that sections 1899B(c)(3)(B) and 1899B(d)(3)(B) of the Act require that quality measures and resource use and other measures be risk adjusted, as determined appropriate by the Secretary.

Comment: Several commenters expressed concerns regarding the validity and reliability of IMPACT Act measures and encouraged CMS to conduct further analysis of data to ensure comparability across post-acute care settings, prior to implementation and public reporting of data.

Response: We have tested for validity and reliability all of the IMPACT Act measures, and the results of that testing is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

We intend to continue to monitor the reliability and validity of the IRF QRP measures, including whether the measures are reliable and valid for cross-setting purposes.

Comment: A few commenters voiced concern regarding the burden of implementing the proposed measures in the IRF setting. One commenter requested that CMS proceed cautiously to ensure new measures are associated with minimal administrative and data collection burden. One commenter expressed concern that the new measures increase provider burden by increasing the time providers are ensuring data accuracy and move the focus away from patient-centered care towards a more metric-based focus.

Response: We appreciate the importance of avoiding undue burden on providers and will continue to evaluate and consider any unnecessary burden associated with the implementation of the IRF QRP. We wish to note that the three proposed resource measures are claims-based, and will require no additional data collection by providers and thus result in minimal increases in burden. The measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues, is calculated using assessment data and requires the addition of three items to the IRF–PAI, also requiring minimal additional burden. We address the issue of burden further under section XI.B. of this final rule.

Comment: Several commenters recommended that CMS engage in several activities which would afford greater transparency with stakeholders regarding proposed measure development. These commenters also requested that measures undergo field testing with providers prior to implementation. Commenters also requested that more detailed measure specifications be posted in order to enable providers to evaluate measure design decisions. Commenters requested that IRF providers be provided with confidential preview reports as a part of a ''dry run'' process as this would enable providers to review data and provide CMS with feedback on potential technical issues with proposed measure. Finally, the commenters requested that measure data be provided to IRFs on a patient level on a quarterly basis, similar to other quality reporting programs, in order to make effective use of the data and improve performance.

Response: With regard to the testing and analytic results provided for this measure, since the December 2015 MAP meeting, further refinement of measure specifications and testing of measure validity and reliability have been performed.

We direct readers to the Measure Specifications for Measures Adopted in the FY 2017 IRF QRP final rule are available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html,* which include detailed information regarding measure specifications, including results of the final risk adjustment models for the resource use measures. For resource use measures, our testing results are within range for similar outcome measures finalized in

public reporting and value-based purchasing programs, including the All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from IRFs (NQF #2502), previously adopted into the IRF QRP.

We appreciate the comment requesting that we provide performance data on IRF QRP measures on a more frequent, such as quarterly, basis in order to promote quality improvement. We wish to note that the proposed claims-based measures are based on 2 consecutive years of data in order to ensure a sufficient sample size to reliably assess IRFs' performance. However, we will investigate the feasibility and usability of providing IRFs with information more frequently, such as unadjusted counts of PPRs and discharge data. We also appreciate the commenters' suggestions related to the implementation of dry run activities, such as confidential reports, for the purposes of identifying any technical issues prior to public reporting, as was successfully provided in the fall of 2015 for the All Cause Unplanned Readmission Measure for 30 Days Post Discharge from IRFs (NQF#2502). We wish to note that we intend to provide confidential feedback reports beginning in October, 2017, as described in section VIII.O of this final rule, and we believe that the reports could serve as an opportunity for providers to extend to us any technical issues they may discover. We note that, as described in section VIII.P of this final rule, we are unable at this time to provide patient-level information for the claims-based measure, for example, the readmission measures, because such data comes from a separate entity. Finally, we wish to note that we intend to continue refining specifications, and we will consider pilot testing in addition to the performance testing that we currently conduct.

C. Policy for Retention of IRF QRP Measures Adopted for Previous Payment Determinations

In the CY 2013 Hospital Outpatient Prospective Payment System/Ambulatory Surgical Center (OPPS/ASC) Payment Systems and Quality Reporting Programs final rule (77 FR 68500 through 68507), we adopted a policy that allows any quality measure adopted for use in the IRF QRP to remain in effect until the measure was actively removed, suspended, or replaced, when we initially adopt a measure for the IRF QRP for a payment determination. For the purpose of streamlining the rulemaking process, when we initially adopt a measure for the IRF QRP for a payment determination, this measure will also be adopted for all subsequent years or until we remove, suspend, or replace the measure. For further information on how measures are considered for removal, suspension, or replacement, please refer to the CY 2013 OPPS/ASC final rule (77 FR 68500). We did not propose any changes to the policy for retaining IRF QRP measures adopted for previous payment determinations.

D. Policy for Adopting Changes to IRF QRP Measures

In the CY 2013 OPPS/ASC final rule (77 FR 68500 through 68507), we adopted a subregulatory process to incorporate NQF updates to IRF quality measure specifications that do not substantively change the nature of the measure. Substantive changes will be proposed and finalized through rulemaking. For further information on what constitutes a substantive versus a nonsubstantive change and the subregulatory process for nonsubstantive changes, please refer to the CY 2013 OPPS/ASC final rule (77 FR 68500). We did not propose any changes to the policy for adopting changes to IRF QRP measures.

E. Quality Measures Previously Finalized for and Currently Used in the IRF QRP

A history of the IRF QRP quality measures adopted for the FY 2014 payment determinations and subsequent years is presented in Table 7. The year in which each quality measure was first adopted and implemented, and then subsequently re-proposed or revised, if applicable, is displayed. The initial and subsequent annual payment determination years are also shown in Table 7. For more information on a particular measure, please refer to the IRF PPS final rule and associated page numbers referenced in Table 7.

Although we did not solicit feedback, we received a number of comments about previously finalized measures for and currently used in the IRF QRP. These comments are summarized and addressed below.

Comment: One commenter was generally supportive of implementing additional quality measures in post-acute care, especially those that are cross-setting, but recommended that CMS take steps to validate data and assess provider experience during the first several months of reporting. One commenter supported the retention of the NHSN measures.

With regard to the measure, Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678), several commenters recommended that future updates to the measure include clinical guidance that is consistent with the most current evidence-based processes.

We received several comments about the NHSN Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717). Several commenters recommended that CMS revise the measure so that it is only reported at the first site of discovery, to avoid penalizing IRFs for the presence of the infection that started in a previous care setting.

With regard to the measure, Application of Percent of Residents Experiencing One or More Falls with Major Injury (NQF #0674), one commenter had concerns that the nature of IRF treatment could lead to a frequency of falls higher than other settings. The commenter was concerned that including assisted falls in the definition of falls for this quality measure was inappropriate and confusing and recommended that CMS revisit the definition and include only falls with major injury.

Response: With regard to the measure Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678), we intend to continue our ongoing measure development and refinement activities to inform the ongoing evaluation of this measure, to ensure that the measure remains valid and reliable to inform quality improvement within and across each PAC setting, and to fulfill the public reporting goals of quality reporting programs, including the IRF QRP. Reviewing the most current evidence-based clinical guidance is part of that process. With regard to the comments about the NHSN Facility-Wide Inpatient Hospital-Onset CDI Outcome Measure (NQF #1717), the scope of NQF#1717 extends to acute care hospitals, long-term care hospitals, inpatient rehabilitation facilities, and cancer hospitals. The same measure specifications are used by all these facility types to report *Clostridium difficile* Laboratory Identified events to NHSN, and these measure specifications differentiate between community-onset events, which include events that had their onset at another healthcare facility, from healthcare-associated events, which are attributed to the facility reporting the event. CDC reports only incident healthcare-associated events on behalf of healthcare facilities to CMS. To limit *Clostridium difficile* Laboratory Identified event reporting to the first site of discovery offers opportunity for missed ''true'' healthcare-associated events (those recognized on or after hospital day 4) and would require

additional data collection and investigation burden to users.

The measure specifications for NQF#1717, by design, align with the NHSN LabID Event protocol, which was developed to require minimal investigation on the part of facilities and to provide a proxy measure of infection. Dates of admission and specimen collection are required and can easily be collected via electronic methods and identified as healthcare-associated (HO) or community-onset (CO). To require a facility to determine if a CDI LabID Event had been identified in another facility would call for manual review of medical records and potential communication with transferring facilities. In accordance with protocol guidelines, IRF-based events are categorized as ''incident'' (first non-duplicate event for the IRF) in addition to a CO/HO categorization. IRF facilities are analyzed independently of any other reporting facility, that is, are viewed as separate reporting facilities.

With regard to the measure, An Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674), we would like to clarify that the quality measure adopted for the IRF QRP includes only falls with a major injury, satisfying the IMPACT Act domain, Incidence of Major Falls. Thus, falls with no injury, such as those that may be considered near-falls, are not included in the measure.

Additionally, we received a number of comments specifically regarding quality measures that were finalized into the IRF QRP in the FY 2016 IRF PPS final rule.

Comment: Many commenters indicated they had concerns about the use of CARE items or the use of the CARE Tool. Several commenters were concerned that the CARE items added to the IRF–PAI would be duplicative and confusing to clinicians because they are similar to the FIM® items. One commenter suggested the FIM® items be removed from the IRF–PAI. Other commenters supported continued use of the FIM® instrument, and recommended a delay in implementing the CARE items. The commenters also had concerns about the precision of the CARE items and the patient types with which it was tested, the timeframe and six-point scale, as well as NQF-endorsement of CARE items in all settings. Commenters noted that the FIM® instrument has demonstrated increased efficiency and decreased length of stay, and allows for comparison of functional gains across patients with similar debility levels. Commenters had concerns about lack of credentialing of staff for CARE items, as this is currently required for the FIM® instrument to ensure consistent scoring.

Several commenters were concerned about the training, data submission specifications, and support CMS has provided for items being required on the IRF–PAI Version 1.4, effective October 1, 2016. Several commenters were concerned that the data were collected for research purposes. One commenter indicated there was a discrepancy between the IRF–PAI Training Manual and the data submission specifications. Many commenters had concerns about the need for further clarification about the patient's usual status, and another commenter requested clarification about the use of a dash to indicate that an item was not assessed.

Response: As we did not propose any changes to the quality measures finalized in the FY 2016 IRF PPS final rule, these comments are outside the scope of the proposed rule. However, we would like to clarify that we are not implementing the CARE Tool for the IRF QRP to meet the mandate of the IMPACT Act. To meet the mandate, and to standardize quality measures and data items, we retained the use of the IRF–PAI as the collection instrument for all IRF settings. We incorporated items from the CARE Tool into new section GG: Functional Abilities and Goals of the IRF–PAI Version 1.4 in order to calculate the 5 function quality measures that were adopted into the IRF QRP in the IRF PPS FY 2016 Final Rule (80 FR 47100 through 47120). The items were not added to the IRF–PAI for research purposes.

We refer the readers to the FY 2016 final rule (80 FR 47100 through 47120) for discussion about the testing, including the rating scale, reliability, validity and sensitivity of the function items that were added to the IRF–PAI, as well as plans for ongoing evaluation of these items, and concerns related to FIM® item duplication. With regard to training and provider support, we agree with the importance of thorough and comprehensive training. Information about and materials from each IRF QRP training are posted on the IRF–QRP Training Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Training.html.* With regard to the comments related to the data specifications, we post data specifications and errata on the CMS Web site as soon as we are able so that vendors and providers are able to review and understand the valid data codes for all items and the associated requirements: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Software.html.*

TABLE 7—QUALITY MEASURES PREVIOUSLY FINALIZED FOR AND CURRENTLY USED IN THE IRF QUALITY REPORTING PROGRAM

Measure title	Final rule	Data collection start date	Annual payment determination: Initial and subsequent APU years
National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138).	Adopted an application of the measure in FY 2012 IRF PPS Final Rule (76 FR 47874 through 47886).	October 1, 2012	FY 2014 and subsequent years.
	Adopted the NQF-endorsed version and expanded measure (with standardized infection ratio) in CY 2013 OPPS/ASC Final Rule (77 FR 68504 through 68505).	January 1, 2013	FY 2015 and subsequent years.
Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678).	Adopted application of measure in FY 2012 IRF PPS final rule (76 FR 47876 through 47878).	October 1, 2012	FY 2014 and subsequent years.
	Adopted a non-risk-adjusted application of the NQF-endorsed version in CY 2013 OPPS/ASC Final Rule (77 FR 68500 through 68507).	January 1, 2013	FY 2015 and subsequent years.

TABLE 7—QUALITY MEASURES PREVIOUSLY FINALIZED FOR AND CURRENTLY USED IN THE IRF QUALITY REPORTING PROGRAM—Continued

Measure title	Final rule	Data collection start date	Annual payment determination: Initial and subsequent APU years
	Adopted the risk adjusted, NQF-endorsed version in FY 2014 IRF PPS Final Rule (78 FR 47911 through 47912).	October 1, 2014	FY 2017 and subsequent years.
	Adopted in the FY 2016 IRF PPS final rule (80 FR 47089 through 47096) to fulfill IMPACT Act requirements.	October 1, 2015	FY 2018 and subsequent years.
Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680).	Adopted in FY 2014 IRF PPS final rule (78 FR 47906 through 47911).	October 1, 2014	FY 2017 and subsequent years.
Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431).	Adopted in FY 2014 IRF PPS final rule (78 FR 47905 through 47906).	October 1, 2014	FY 2016 and subsequent years.
All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from Inpatient Rehabilitation Facilities (NQF #2502).	Adopted in FY 2014 IRF PPS final rule (78 FR 47906 through 47910).	N/A	FY 2017 and subsequent years.
	Adopted the NQF-endorsed version in FY 2016 IRF PPS final rule (80 FR 47087 through 47089).	N/A	FY 2018 and subsequent years.
National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure (NQF #1716).	Adopted in the FY 2015 IRF PPS final rule (79 FR 45911 through 45913).	January 1, 2015	FY 2017 and subsequent years.
National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717).	Adopted in the FY 2015 IRF PPS final rule (79 FR 45913 through 45914).	January 1, 2015	FY 2017 and subsequent years.
Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674).	Adopted an application of the measure in FY 2016 IRF PPS Final Rule (80 FR 47096 through 47100).	October 1, 2016	FY 2018 and subsequent years.
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).	Adopted an application of the measure in the FY 2016 IRF PPS final rule (80 FR 47100 through 47111).	October 1, 2016	FY 2018 and subsequent years.
IRF Functional Outcome Measure: Change in Self-Care for Medical Rehabilitation Patients (NQF #2633).*	Adopted in the FY 2016 IRF PPS final rule (80 FR 47111 through 47117).	October 1, 2016	FY 2018 and subsequent years.
IRF Functional outcome Measure: Change in Mobility Score for Medical Rehabilitation (NQF #2634).*	Adopted in the FY 2016 IRF PPS final rule (80 FR 47117 through 47118).	October 1, 2016	FY 2018 and subsequent years.
IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635).	Adopted in the FY 2016 IRF PPS final rule (80 FR 47118 through 47119).	October 1, 2016	FY 2018 and subsequent years.
IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636).	Adopted in the FY 2016 IRF PPS final rule (80 FR 47119 through 47120).	October 1, 2016	FY 2018 and subsequent years.

*These measures were under review at NQF when they were finalized for use in the IRF QRP. These measures are now NQF-endorsed.

F. IRF QRP Quality, Resource Use and Other Measures Finalized for the FY 2018 Payment Determination and Subsequent Years

For the FY 2018 payment determinations and subsequent years, in addition to the quality measures we are retaining under our policy described in section VIII.C. of this final rule, we proposed four new measures. Three of these measures were developed to meet the requirements of IMPACT Act. They are:

(1) MSPB–PAC IRF QRP,

(2) Discharge to Community–PAC IRF QRP, and

(3) Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP.

The fourth measure is: (4) Potentially Preventable Within Stay Readmission Measure for IRFs. The measures are described in more detail below.

For the risk-adjustment of the resource use and other measures, we understand the important role that sociodemographic status plays in the care of patients. However, we continue to have concerns about holding providers to different standards for the outcomes of their patients of diverse sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on providers' results for our measures.

The NQF is currently undertaking a two-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. For 2 years, NQF will conduct a trial of temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some

performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are expected to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

We received several comments on the impact of sociodemographic status on quality measures, resource use, and other measures, which are summarized with our responses below.

Comment: Several commenters indicated their support for the inclusion of sociodemographic status adjustment in quality measures, resource use, and other measures. Commenters suggested that failure to account for patient characteristics could penalize IRFs for providing care to a more medically-complex and socioeconomically disadvantaged patient population and affect provider performance. Some commenters expressed concerns about standardization and interoperability of the measures as it pertain to risk-adjusting, particularly for SDS characteristics. Many commenters recommended incorporating socioeconomic factors as risk-adjustors for the measures, and several commenters suggested conducting additional testing and NQF-endorsement prior to implementation of these measures. In addition, many commenters recommended including functionality as an additional risk-adjustment factor, and several commenters suggested risk-adjustment for cognitive impairment.

A few commenters, including MedPAC, did not support risk-adjustment of measures by socioeconomic status (SES) or SDS status. One commenter did not support risk-adjustment, stating that it can hide disparities and create different standards of care for IRFs based on the demographics in the facility. MedPAC reiterated that risk adjustment can hide disparities in care and suggested that risk-adjustment reduces pressure on providers to improve quality of care for low-income Medicare beneficiaries. Instead, MedPAC supported peer provider group comparisons with providers of similar low-income beneficiary populations. Another commenter stated that SDS factors should not be included in measures that examine the patient during an IRF stay, but should only be considered for measures evaluating care after the IRF discharge.

Response: We appreciate the considerations and suggestions conveyed in relation to the measures and the importance in balancing appropriate risk adjustment along with ensuring access to high-quality care. We note that in the measures that are risk adjusted, we do take into account characteristics associated with medical complexity, as well as factors such as age where appropriate to do so. For those cross-setting post-acute measures, such as those intended to satisfy the IMPACT Act domains that use the patient assessment-based data elements for risk adjustment, we have either made such items standardized, or intend to do so as feasible. With regard to the incorporation of additional factors, such as function, we have and will continue to take such factors into account, which would include further testing as part of our ongoing measure development monitoring activities. As discussed previously, we intend to seek NQF endorsement for our measures.

We also received suggestions pertaining to the incorporation of socioeconomic factors as risk-adjustors for the measures, including in those measures that pertain to after the patient was discharged from the IRF, additional testing and/or NQF endorsement prior to implementation of these measures, and comments that pertain to potential consequences associated with such risk adjustors and alternative approaches to grouping comparative data. We wish to reiterate that as previously discussed, NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. This trial entails temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are encouraged to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model. Several measures developed by CMS have been brought to NQF since the beginning of the trial. CMS, in compliance with NQF's guidance, has tested sociodemographic factors in the measures' risk models and made recommendations about whether or not to include these factors in the endorsed measure. We intend to continue engaging in the NQF process as we consider the appropriateness of adjusting for sociodemographic factors in our outcome measures.

Furthermore, the Office of the ASPE is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

1. Measure to Address the IMPACT Act Domain of Resource Use and Other Measures: Total Estimated MSPB–PAC IRF QRP

We proposed an MSPB–PAC IRF QRP measure for inclusion in the IRF QRP for the FY 2018 payment determination and subsequent years. Section 1899B(d)(1)(A) of the Act requires the Secretary to specify resource use measures, including total estimated MSPB, on which PAC providers consisting of Skilled Nursing Facilities (SNFs), IRFs, Long-Term Care Hospitals (LTCHs), and Home Health Agencies (HHAs) are required to submit necessary data specified by the Secretary.

Rising Medicare expenditures for post-acute care as well as wide variation in spending for these services underlines the importance of measuring resource use for providers rendering these services. Between 2001 and 2013, Medicare PAC spending grew at an annual rate of 6.1 percent and doubled to $59.4 billion, while payments to inpatient hospitals grew at an annual rate of 1.7 percent over this same period.[3] A study commissioned by the Institute of Medicine discovered that variation in PAC spending explains 73 percent of variation in total Medicare spending across the United States.[4]

We reviewed the NQF's consensus-endorsed measures and were unable to identify any NQF-endorsed resource use measures for PAC settings. As such, we proposed this MSPB–PAC IRF QRP measure under the Secretary's authority

[3] MedPAC, ''A Data Book: Health Care Spending and the Medicare Program,'' (2015). 114.

[4] Institute of Medicine, ''Variation in Health Care Spending: Target Decision Making, Not Geography,'' (Washington, DC: National Academies 2013). 2.

to specify non-NQF-endorsed measures under section 1899B(e)(2)(B) of the Act. Given the current lack of resource use measures for PAC settings, our MSPB–PAC IRF QRP measure will provide valuable information to IRF providers on their relative Medicare spending in delivering services to approximately 338,000 Medicare beneficiaries.[5]

The MSPB–PAC IRF QRP episode-based measure will provide actionable and transparent information to support IRF providers' efforts to promote care coordination and deliver high quality care at a lower cost to Medicare. The MSPB–PAC IRF QRP measure holds IRF providers accountable for the Medicare payments within an ''episode of care'' (episode), which includes the period during which a patient is directly under the IRF's care, as well as a defined period after the end of the IRF treatment, which may be reflective of and influenced by the services furnished by the IRF. MSPB–PAC IRF QRP episodes, constructed according to the methodology described below, have high levels of Medicare spending with substantial variation. In FY 2013 and FY 2014, Medicare FFS beneficiaries experienced 613,089 MSPB–PAC IRF QRP episodes triggered by admission to an IRF. The mean payment-standardized, risk-adjusted episode spending for these episodes is $30,370. There is substantial variation in the Medicare payments for these MSPB–PAC IRF QRP episodes—ranging from approximately $15,059 at the 5th percentile to approximately $55,912 at the 95th percentile. This variation is partially driven by variation in payments occurring following IRF treatment.

Evaluating Medicare payments during an episode creates a continuum of accountability between providers that should improve post-treatment care planning and coordination. While some stakeholders throughout the measure development process supported the MSPB–PAC measures and believed that measuring Medicare spending was critical for improving efficiency, others believed that resource use measures did not reflect quality of care in that they do not take into account patient outcomes or experience beyond those observable in claims data. However, IRFs involved in the provision of high quality PAC care as well as appropriate discharge planning and post-discharge care coordination would be expected to perform well on this measure since beneficiaries would likely experience fewer costly adverse events (for example, avoidable hospitalizations, infections, and emergency room usage). Further, it is important that the cost of care be explicitly measured so that, in conjunction with other quality measures, we can publicly report which IRFs provide high quality care at lower cost.

We developed an MSPB–PAC measure for each of the four PAC settings. We proposed an LTCH-specific MSPB–PAC measure in the FY 2017 IPPS/LTCH proposed rule (81 FR 25216 through 25220), an IRF-specific MSBP–PAC measure in the FY 2017 IRF PPS proposed rule (81 FR 24197 through 24201), a SNF-specific MSPB–PAC measure in the FY 2017 SNF proposed rule (81 FR 24258 through 24262), and a HHA-specific MSBP–PAC measure in the CY 2017 HH proposed rule (81 FR 43760 through 43764). The four setting-specific MSPB–PAC measures are closely aligned in terms of episode construction and measure calculation. Each of the MSPB–PAC measures assess Medicare Part A and Part B spending during an episode, and the numerator and denominator are defined similarly for each of the MSPB–PAC measures. However, setting-specific measures allow us to account for differences between settings in payment policy, the types of data available, and the underlying health characteristics of beneficiaries. For example, we use the IRF setting-specific rehabilitation impairment categories (RICs) in the MSPB–PAC IRF QRP risk adjustment model, as detailed below.

The MSPB–PAC measures mirror the general construction of the inpatient prospective payment system (IPPS) hospital MSPB measure, which was adopted for the Hospital IQR Program beginning with the FY 2014 program, and was implemented in the Hospital VBP Program beginning with the FY 2015 program. The measure was endorsed by the NQF on December 6, 2013 (NQF #2158).[6] The hospital MSPB measure evaluates hospitals' Medicare spending relative to the Medicare spending for the national median hospital during a hospital MSPB episode. It assesses Medicare Part A and Part B payments for services performed by hospitals and other healthcare providers during a hospital MSPB episode, which is comprised of the periods immediately prior to, during, and following a patient's hospital stay.[7] [8] Similarly, the MSPB–PAC measures assess all Medicare Part A and Part B payments for FFS claims with a start date during the episode window (which, as discussed in this section, is the time period during which Medicare FFS Part A and Part B services are counted towards the MSPB–PAC IRF QRP episode). There are differences between the MSPB–PAC measures and the hospital MSPB measure to reflect differences in payment policies and the nature of care provided in each PAC setting. For example, the MSPB–PAC measures exclude a limited set of services (for example, clinically unrelated services) provided to a beneficiary during the episode window, while the hospital MSPB measure does not exclude any services.[9]

MSPB–PAC episodes may begin within 30 days of discharge from an inpatient hospital as part of a patient's trajectory from an acute to a PAC setting. An IRF stay beginning within 30 days of discharge from an inpatient hospital would therefore be included once in the hospital's MSPB measure, and once in the IRF provider's MSPB–PAC measure. Aligning the hospital MSPB and MSPB–PAC measures in this way creates continuous accountability and aligns incentives to improve care planning and coordination across inpatient and PAC settings.

We sought and considered the input of stakeholders throughout the measure development process for the MSPB–PAC measures. We convened a TEP consisting of 12 panelists with combined expertise in all of the PAC settings on October 29 and 30, 2015 in Baltimore, Maryland. A follow-up email survey was sent to TEP members on November 18, 2015 to which seven responses were received by December 8, 2015. The MSPB–PAC TEP Summary Report is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Technical-Expert-Panel-on-Medicare-Spending-Per-Beneficiary.pdf*. The measures were also presented to the MAP Post-Acute Care/Long-Term Care (PAC/LTC) Workgroup on December 15, 2015. As the MSPB–PAC measures were under

[5] Figures for 2013. MedPAC, ''Medicare Payment Policy,'' Report to the Congress (2015). xvii–xviii.

[6] QualityNet, ''Measure Methodology Reports: Medicare Spending per Beneficiary (MSPB) Measure,'' (2015). *http://www.qualitynet.org/dcs/ContentServer?pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772053996*.

[7] QualityNet, ''Measure Methodology Reports: Medicare Spending per Beneficiary (MSPB) Measure,'' (2015). *http://www.qualitynet.org/dcs/ContentServer?pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772053996*.

[8] FY 2012 IPPS/LTCH PPS final rule (76 FR 51619).

[9] National Quality Forum, Applications Partnership, ''Process and Approach for MAP Pre-Rulemaking Deliberations, 2015-2016'' (February 2016) *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&Ote,OD=81693*.

development, there were three voting options for members: Encourage continued development, do not encourage further consideration, and insufficient information.[10] The MAP PAC/LTC workgroup voted to ''encourage continued development'' for each of the MSPB–PAC measures.[11] The MAP PAC/LTC workgroup's vote of ''encourage continued development'' was affirmed by the MAP Coordinating Committee on January 26, 2016.[12] The MAP's concerns about the MSPB–PAC measures, as outlined in their final report ''MAP 2016 Considerations for Implementing Measures in Federal Programs: Post-Acute Care and Long-Term Care'' and Spreadsheet of Final Recommendations, were taken into consideration during the measure development process and are discussed as part of our responses to public comments, described below.[13] [14]

Since the MAP's review and recommendation of continued development, CMS continued to refine risk adjustment models and conduct measure testing for the IMPACT Act measures in compliance with the MAP's recommendations. The IMPACT Act measures are consistent with the information submitted to the MAP and support the scientific acceptability of these measures for use in quality reporting programs.

In addition, a public comment period, accompanied by draft measures specifications, was open from January 13 to 27, 2016 and extended to February 5. A total of 45 comments on the MSPB–PAC measures were received during this 3.5 week period. The comments received also covered each of the MAP's concerns as outlined in their Final Recommendations.[15] The MSPB–PAC Public Comment Summary Report is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/2016_03_24_mspb_pac_public_comment_summary_report.pdf* and the MSPB–PAC Public Comment Supplementary Materials are available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/2016_03_24_mspb_pac_public_comment_summary_report_supplementary_materials.pdf*: These documents contain the public comments, along with our responses including statistical analyses. The MSPB–PAC IRF QRP measure, along with the other MSPB–PAC measures, as applicable, will be submitted for NQF endorsement when feasible.

To calculate the MSPB–PAC IRF QRP measure for each IRF provider, we first defined the construction of the MSPB–PAC IRF QRP episode, including the length of the episode window as well as the services included in the episode. Next, we apply the methodology for the measure calculation. The specifications are discussed further in this section. More detailed specifications for the MSPB–PAC measures, including the MSPB–PAC IRF QRP measure, are available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html*.

a. Episode Construction

An MSPB–PAC IRF QRP episode begins at the episode trigger, which is defined as the patient's admission to an IRF. The admitting facility is the attributed provider, for whom the MSPB–PAC IRF QRP measure is calculated. The episode window is the time period during which Medicare FFS Part A and Part B services are counted towards the MSPB–PAC IRF QRP episode. Because Medicare FFS claims are already reported to the Medicare program for payment purposes, IRF providers would not be required to report any additional data to CMS for calculation of this measure. Thus, there would be no additional data collection burden from the implementation of this measure.

The episode window is comprised of a treatment period and an associated services period. The treatment period begins at the trigger (that is, on the day of admission to the IRF) and ends on the day of discharge from that IRF. Readmissions to the same facility occurring within 7 or fewer days do not trigger a new episode, and instead are included in the treatment period of the original episode. When two sequential stays at the same IRF occur within 7 or fewer days of one another, the treatment period ends on the day of discharge for the latest IRF stay. The treatment period includes those services that are provided directly or reasonably managed by the IRF provider that are directly related to the beneficiary's care plan. The associated services period is the time during which Medicare Part A and Part B services (with certain exclusions) are counted towards the episode. The associated services period begins at the episode trigger and ends 30 days after the end of the treatment period. The distinction between the treatment period and the associated services period is important because clinical exclusions of services may differ for each period. Certain services are excluded from the MSPB–PAC IRF QRP episodes because they are clinically unrelated to IRF care, and/or because IRF providers may have limited influence over certain Medicare services delivered by other providers during the episode window. These limited service-level exclusions are not counted towards a given IRF provider's Medicare spending to ensure that beneficiaries with certain conditions and complex care needs receive the necessary care. Certain services that are determined to be outside of the control of an IRF provider include planned hospital admissions, management of certain preexisting chronic conditions (for example, dialysis for end-stage renal disease (ESRD), and enzyme treatments for genetic conditions), treatment for preexisting cancers, organ transplants, and preventive screenings (for example, colonoscopy and mammograms). Exclusion of such services from the MSPB–PAC IRF QRP episode ensures that facilities do not have disincentives to treat patients with certain conditions or complex care needs.

An MSPB–PAC episode may begin during the associated services period of an MSPB–PAC IRF QRP episode in the 30 days post-treatment. One possible scenario occurs where an IRF provider discharges a beneficiary who is then admitted to an LTCH within 30 days. The LTCH claim will be included once as an associated service for the attributed provider of the first MSPB–PAC IRF QRP episode and once as a treatment service for the attributed

[10] National Quality Forum, Measure Applications Partnership, ''Process and Approach for MAP Pre-Rulemaking Deliberations, 2015–2016'' (February 2016) *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81693*.

[11] National Quality Forum, Measure Applications Partnership Post-Acute Care/Long-Term Care Workgroup, ''Meeting Transcript—Day 2 of 2'' (December 15, 2015) 104–106. *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81470*.

[12] National Quality Forum, Measure Applications Partnership, ''Meeting Transcript—Day 1 of 2'' (January 26, 2016) 231–232 *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81637*.

[13] National Quality Forum, Measure Applications Partnership, ''MAP 2016. Considerations for Implementing Measures in Federal Programs: Post-Acute Care and Long-Term Care'' Final Report, (February 2016) *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx*.

[14] National Quality Forum, Measure Applications Partnership, ''Spreadsheet of MAP 2016 Final Recommendations'' (February 1, 2016) *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593*.

[15] National Quality Forum, Measure Applications Partnership, ''Spreadsheet of MAP 2016 Final Recommendations'' (February 1, 2016) *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593*.

provider of the second MSPB–PAC LTCH QRP episode. As in the case of overlap between hospital and PAC episodes discussed earlier, this overlap is necessary to ensure continuous accountability between providers throughout a beneficiary's trajectory of care, as both providers share incentives to deliver high quality care at a lower cost to Medicare. Even within the IRF setting, one MSPB–PAC IRF QRP episode may begin in the associated services period of another MSPB–PAC IRF QRP episode in the 30 days post-treatment. The second IRF claim would be included once as an associated service for the attributed IRF provider of the first MSPB–PAC IRF QRP episode and once as a treatment service for the attributed IRF provider of the second MSPB–PAC IRF QRP episode. Again, this ensures that IRF providers have the same incentives throughout both MSPB–PAC IRF QRP episodes to deliver quality care and engage in patient-focused care planning and coordination. If the second MSPB–PAC IRF QRP episode were excluded from the second IRF provider's MSPB–PAC IRF QRP measure, that provider would not share the same incentives as the first IRF provider of the first MSPB–PAC IRF QRP episode. The MSPB–PAC IRF QRP measure was designed to benchmark the resource use of each attributed provider against what their spending is expected to be as predicted through risk adjustment. As discussed further in this section, the measure takes the ratio of observed spending to expected spending for each episode and then takes the average of those ratios across all of the attributed provider's episodes. The measure is not a simple sum of all costs across a provider's episodes, thus mitigating concerns about double counting.

b. Measure Calculation

Medicare payments for Part A and Part B claims for services included in MSPB–PAC IRF QRP episodes, defined according to the methodology previously discussed, are used to calculate the MSPB–PAC IRF QRP measure. Measure calculation involves determination of the episode exclusions, the approach for standardizing payments for geographic payment differences, the methodology for risk adjustment of episode spending to account for differences in patient case mix, and the specifications for the measure numerator and denominator.

(1) Exclusion Criteria

In addition to service-level exclusions that remove some payments from individual episodes, we exclude certain episodes in their entirety from the MSPB–PAC IRF QRP measure to ensure that the MSPB–PAC IRF QRP measure accurately reflects resource use and facilitates fair and meaningful comparisons between IRF providers. The episode-level exclusions are as follows:

- Any episode that is triggered by an IRF claim outside the 50 states, DC, Puerto Rico, and U.S. Territories.
- Any episode where the claim(s) constituting the attributed IRF provider's treatment have a standard allowed amount of zero or where the standard allowed amount cannot be calculated.
- Any episode in which a beneficiary is not enrolled in Medicare FFS for the entirety of a 90-day lookback period (that is, a 90-day period prior to the episode trigger) plus episode window (including where a beneficiary dies), or is enrolled in Part C for any part of the lookback period plus episode window.
- Any episode in which a beneficiary has a primary payer other than Medicare for any part of the 90-day lookback period plus episode window.
- Any episode where the claim(s) constituting the attributed IRF provider's treatment include at least one related condition code indicating that it is not a prospective payment system bill.

(2) Standardization and Risk Adjustment

Section 1899B(d)(2)(C) of the Act requires that the MSPB–PAC measures are adjusted for the factors described under section 1886(o)(2)(B)(ii) of the Act, which include adjustment for factors such as age, sex, race, severity of illness, and other factors that the Secretary determines appropriate. Medicare payments included in the MSPB–PAC IRF QRP measure are payment-standardized and risk-adjusted. Payment standardization removes sources of payment variation not directly related to clinical decisions and facilitates comparisons of resource use across geographic areas. We proposed to use the same payment standardization methodology that was used in the NQF-endorsed hospital MSPB measure. This methodology removes geographic payment differences, such as wage index and geographic practice cost index (GPCI), incentive payment adjustments, and other add-on payments that support broader Medicare program goals including indirect graduate medical education (IME) and hospitals serving a disproportionate share of uninsured patients (DSH).[16]

Risk adjustment uses patient claims history to account for case-mix variation and other factors that affect resource use but are beyond the influence of the attributed IRF provider. To assist with risk adjustment, we created mutually exclusive and exhaustive clinical case mix categories using the most recent institutional claim in the 60 days prior to the start of the MSPB–PAC IRF QRP episode. The beneficiaries in these clinical case mix categories have a greater degree of clinical similarity than the overall IRF patient population, and allow us to more accurately estimate Medicare spending. Our MSPB–PAC IRF QRP measure, adapted for the IRF setting from the NQF-endorsed hospital MSPB measure, uses a regression framework with a 90-day hierarchical condition category (HCC) lookback period and covariates including the clinical case mix categories, HCC indicators, age brackets, indicators for originally disabled, ESRD enrollment, and long-term care status, and selected interactions of these covariates where sample size and predictive ability make them appropriate. We sought and considered public comment regarding the treatment of hospice services occurring within the MSPB–PAC IRF QRP episode window. Given the comments received, we proposed to include the Medicare spending for hospice services but risk adjust for them, such that MSPB–PAC IRF QRP episodes with hospice services are compared to a benchmark reflecting other MSPB–PAC IRF QRP episodes with hospice services. We believe this strikes a balance between the measure's intent of evaluating Medicare spending and ensuring that providers do not have incentives against the appropriate use of hospice services in a patient-centered continuum of care.

We proposed to use RICs in response to commenters' concerns about the risk adjustment approach for the MSPB–PAC IRF QRP measure. Commenters suggested the use of case mix groups (CMGs); however, we believed that the use of RICs may be more appropriate given that the other covariates incorporated in the model partially account for factors in CMGs (for example, age and certain HCC indicators). RICs do not account for functional status as CMGs do, as the functional status information in CMGs is based on the IRF–PAI. Given the

[16] QualityNet, ''CMS Price (Payment) Standardization—Detailed Methods'' (Revised May 2015) *https://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772057350.*

move toward standardized data that was mandated by the IMPACT Act, we have chosen to defer risk adjustment for functional status until standardized data become available. We sought comments on whether the use of CMGs would be appropriate to include in the MSPB–PAC IRF QRP risk adjustment model.

We understand the important role that sociodemographic factors, beyond age, play in the care of patients. However, we continue to have concerns about holding providers to different standards for the outcomes of their patients of diverse sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We will monitor the impact of sociodemographic status on providers' results on our measures.

The NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. For 2 years, NQF will conduct a trial of temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are expected to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, ASPE is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as required under the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

While we conducted analyses on the impact of age by sex on the performance of the MSPB–PAC IRF QRP risk-adjustment model, we did not propose to adjust the MSPB–PAC IRF QRP measure for socioeconomic factors. As this MSPB–PAC IRF QRP measure would be submitted for NQF endorsement, we prefer to await the results of this trial and study before deciding whether to risk adjust for socioeconomic factors. We will monitor the results of the trial, studies, and recommendations. We invited public comment on how socioeconomic and demographic factors should be used in risk adjustment for the MSPB–PAC IRF QRP measure.

(3) Measure Numerator and Denominator

The MPSB–PAC IRF QRP measure is a payment-standardized, risk-adjusted ratio that compares a given IRF provider's Medicare spending against the Medicare spending of other IRF providers within a performance period. Similar to the hospital MSPB measure, the ratio allows for ease of comparison over time as it obviates the need to adjust for inflation or policy changes.

The MSPB–PAC IRF QRP measure is calculated as the ratio of the MSPB–PAC Amount for each IRF provider divided by the episode-weighted median MSPB–PAC Amount across all IRF providers. To calculate the MSPB–PAC Amount for each IRF provider, one calculates the average of the ratio of the standardized episode spending over the expected episode spending (as predicted in risk adjustment), and then multiplies this quantity by the average episode spending level across all IRF providers nationally. The denominator for an IRF provider's MSPB–PAC IRF QRP measure is the episode-weighted national median of the MSPB–PAC Amounts across all IRF providers. An MSPB–PAC IRF QRP measure of less than 1 indicates that a given IRF provider's Medicare spending is less than that of the national median IRF provider during a performance period. Mathematically, this is represented in equation (A) below:

$$(A)\ MSPB\text{-}PAC\ IRF\ Measure_j = \frac{MSPB\text{-}PAC\ Amount_j}{National\ Median\ MSPB\text{-}PAC\ Amount} = \frac{\left(\frac{1}{n_j}\sum_{i\in\{I_j\}}\frac{Y_{ij}}{\widehat{Y_{ij}}}\right)\left(\frac{1}{n}\sum_j\sum_{i\in\{I_j\}}Y_{ij}\right)}{Episode-Weighted\ Median\ of\ IRF\ Providers'\ MSPB\text{-}PAC\ Amount}$$

where

- Y_{ij} = attributed standardized spending for episode i and provider j
- $\hat{Y}_{ij}$ = expected standardized spending for episode i and provider j, as predicted from risk adjustment
- n_j = number of episodes for provider j
- n = total number of episodes nationally
- $i \in \{I_j\}$ = all episodes i in the set of episodes attributed to provider j.

c. Data Sources

The MSPB–PAC IRF QRP resource use measure is an administrative claims-based measure. It uses Medicare Part A and Part B claims from FFS beneficiaries and Medicare eligibility files.

d. Cohort

The measure cohort includes Medicare FFS beneficiaries with an IRF treatment period ending during the data collection period.

e. Reporting

We intend to provide initial confidential feedback to providers, prior to public reporting of this measure, based on Medicare FFS claims data from discharges in CY 2015 and 2016. We intend to publicly report this measure using claims data from discharges in CY 2016 and 2017.

We proposed to use a minimum of 20 episodes for reporting and inclusion in the IRF QRP. For the reliability calculation, as described in the measure specifications for which a link has been provided above, we used 2 years of data (FY 2013 and FY 2014) to increase the statistical reliability of this measure. The reliability results support the 20 episode case minimum, and 99.74 percent of IRF providers had moderate or high reliability (above 0.4).

We invited public comment on our proposal to adopt the MSPB–PAC IRF QRP measure for the IRF QRP. The comments we received, with our responses, appear below.

Comment: Several commenters expressed concern about the lack of NQF endorsement for proposed measures; some believed that the measure should not be finalized until NQF endorsement is obtained.

Response: Regarding the lack of NQF endorsement, refer to section VIII.B. of this final rule where we also discuss this topic.

Comment: Some commenters recommended the use of uniform single MSPB–PAC measure that could be used to compare providers' resource use across settings, but the commenters also recognized that we do not have a uniform PPS for all the PAC settings currently. In the absence of a single PAC PPS, the commenters recommended a single MSPB–PAC measure for each setting that could be used to compare providers within a setting. Under a single measure, the episode definitions, service inclusions/exclusions, and risk adjustment methods would be the same across all PAC settings.

Response: The four separate MSPB–PAC measures reflect the unique characteristics of each PAC setting and the population it serves. The four setting-specific MSPB–PAC measures are defined as consistently as possible across settings given the differences in the payment systems for each setting, and types of patients served in each setting. We have taken into consideration these differences and aligned the specifications, such as episode definitions, service inclusions/exclusions and risk adjustment methods for each setting, to the extent possible while ensuring the accuracy of the measures in each PAC setting.

Each of the measures assess Medicare Part A and Part B spending during the episode window which begins upon admission to the provider's care and ends 30 days after the end of the treatment period. The service-level exclusions are harmonized across settings. The definition of the numerator and denominator is the same across settings. However, specifications differ between settings when necessary to ensure that the measures accurately reflect patient care and align with each setting's payment system. For example, Medicare pays LTCHs and IRFs a stay-level payment based on the assigned MS–LTC–DRG and CMG, respectively, while SNFs are paid a daily rate based on the RUG level, and HHA providers are reimbursed based on a fixed 60-day period for standard home health claims. While the definition of the episode window is consistent across settings and is based on the period of time that a beneficiary is under a given provider's care, the duration of the treatment period varies to reflect how providers are reimbursed under the PPS that applies to each setting. The length of the post-treatment period is consistent between settings. There are also differences in services covered under the PPS that applies to each setting: For example, durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) claims are covered LTCH, IRF, and SNF services but are not covered HHA services. This affects the way certain first-day service exclusions are defined for each measure.

We recognize that beneficiaries may receive similar services as part of their overall treatment plan in different PAC settings, but believe that there are some important differences in beneficiaries' care profiles that are difficult to capture in a single measure that compares resource use across settings.

Also, the risk adjustment models for the MSPB–PAC measures share the same covariates to the greatest extent possible to account for patient case mix. However, the measures also incorporate additional setting-specific information where available to increase the predictive power of the risk adjustment models. For example, the MSPB–PAC LTCH QRP risk adjustment model uses MS–LTC–DRGs and Major Diagnostic Categories (MDCs) and the MSPB–PAC IRF QRP model includes Rehabilitation Impairment Categories (RICs). The HH and SNF settings do not have analogous variables that directly reflect a patient's clinical profile.

We will continue to work towards a more uniform measure across settings as we gain experience with these measures, and we plan to conduct further research and analyses about comparability of resource use measures across settings for clinically similar patients, different treatment periods and windows, risk adjustment, service exclusions, and other factors.

Comment: A few commenters noted that the MSPB–PAC measures are resource use measures that are not a standalone indicator of quality.

Response: We appreciate the comment regarding the proposed MSPB–PAC measures as resource use measures. The MSPB–PAC IRF QRP measure is one of five QRP measures that were proposed in the FY 2017 IRF PPS proposed rule for inclusion in the IRF QRP: In addition to the MSPB–PAC IRF QRP measure, these proposed measures were the Discharge to Community—PAC IRF QRP measure (81 FR 24201 through 24204), the Potentially Preventable 30-day Post-Discharge Readmission Measure for IRF QRP (81 FR 24204 through 24206), the Potentially Preventable Within Stay Readmission Measure for IRFs (81 FR 242096 through 24207), and the Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC IRF QRP measure (81 FR 24207 through 24209). As part of the IRF QRP, the MSPB–PAC IRF QRP measure will be paired with quality measures; we direct readers to section VIII.E. of this final for a discussion of quality measures previously finalized for use in the IRF QRP. We believe it is important that the cost of care be explicitly measured so that, in conjunction with other quality measures, we can publicly report which IRF providers are involved in the provision of high quality care at lower cost.

Comment: One commenter recommended that proposed quality measures obtain the support of a TEP including IRF representatives to ensure the applicability of the measures to the IRF setting.

Response: We thank the commenter for their recommendation. As discussed in the proposed rule (81 FR 24198), we convened a TEP consisting of 12 panelists with combined expertise in PAC settings, including IRFs, on October 29 and 30, 2015, in Baltimore, Maryland. TEPs do not formally support or endorse measures. However, their feedback on risk adjustment, episode windows, exclusions, and other key elements of measure construction were incorporated into measure development. The MSPB–PAC TEP Summary Report Web site is listed above in this section.

Comment: Several commenters recommended that the risk adjustment model for the MSPB–PAC IRF QRP measure include variables for SES/SDS factors. A commenter recommended that a ''fairer'' approach than using SES/SDS factors as risk adjustment variables would be to compare resource use levels that have not been adjusted for SES/SDS factors across peer providers (that is, providers with similar shares of beneficiaries with similar SES characteristics).

Response: With regard to the suggestions that the model include sociodemographic factors and the suggestion pertaining to an approach with which to convey data comparisons, we refer readers to section VIII.F of this final rule where we also discuss these topics.

Comment: Some commenters recommended that additional variables be included in risk adjustment to better capture clinical complexity. A few commenters suggested the inclusion of functional and cognitive status, other patient assessment data and patient-reported data. Commenters recommended that additional variables should include obesity, amputations, CVAs (hemiplegia/paresis), ventilator status, and discharged against medical advice.

Response: We thank the commenters for their suggestions. HCC indicators

that are already included in the risk adjustment model account for amputations, hemiplegia, and paresis. We believe that the other risk adjustment variables adequately adjust for ventilator dependency and obesity by accounting for HCCs, clinical case mix categories, and prior inpatient and ICU length of stay. Excluding patients who are discharged against medical advice may create incentives for providers to use this discharge status code to remove high-cost patients from their MSPB–PAC measure calculation. Patient-reported data is not currently available on Medicare FFS claims. The addition of such data would likely be burdensome on IRF providers and the reliability of the data would need to be thoroughly tested before use in Medicare programs.

We recognize the importance of accounting for beneficiaries' functional and cognitive status in the calculation of predicted episode spending. We considered the potential use of functional status information in the risk adjustment models for the MSPB–PAC measures. However, we decided not to include this information derived from current setting-specific assessment instruments given the move towards standardized data as mandated by the IMPACT Act. We will revisit the inclusion of functional status in these measures' risk adjustment models in the future when the standardized functional status data mandated by the IMPACT Act become available. Once they are available, we will take a gradual and systematic approach in evaluating how they might be incorporated. We intend to implement any changes if appropriate based on testing.

Comment: A few commenters expressed concern that the measures will give incentive to IRFs to avoid admitting medically complex patients, which would result in unintended consequences.

Response: To mitigate the risk of creating incentives for IRFs to avoid admitting medically complex patients, who may be at higher risk for poor outcomes and higher costs, we have included factors related to medical complexity in the risk adjustment methodology for the MSPB–PAC IRF QRP measure. We also intend to conduct ongoing monitoring to assess for potential unintended consequences associated with the implementation of these measures.

Comment: Several commenters recommended that IRF interrupted stays be excluded as those patients would appear more expensive for receiving necessary care outside of the control of the IRF (that is, during the interruption).

Response: We believe that IRFs are in a position to influence a patient's experience and outcomes after the initial discharge from the IRF, including the likelihood and intensity of IRF readmissions. As noted in the proposed rule (81 FR 24197), the proposed MSPB–PAC IRF QRP measure will support IRF providers' efforts to promote care coordination.

Comment: Several commenters expressed concerns over the inclusion of spending that occurs within the thirty day post-discharge timeframe in the measure, believing that providers do not have sufficient control over the patient in the post-treatment period.

Response: We believe that the post-treatment period may be reflective of and influenced by the services furnished by the PAC provider, therefore, including the 30-day post-treatment period in the MSPB–PAC IRF QRP measure creates a continuum of accountability between providers and may incentivize improvements in post-treatment care planning and coordination. The MSPB–PAC measures complement the NQF-endorsed hospital MSPB measure: As they all include a period during which post-treatment spending is attributed to the provider, this accountability incentivizes acute and PAC providers to engage in appropriate discharge planning and post-treatment care coordination to minimize the likelihood of costly adverse events, such as avoidable hospitalizations.

Comment: Several commenters recommended first day service exclusions for IRFs that are the same as other PAC settings, such as SNFs.

Response: As discussed in the MSPB–PAC Measure Specifications, the Web site that is listed above in this section, treatment services occurring on the first day of MSPB–PAC episodes are subject to exclusions related to prior institutional care such as discharge care services. IRFs provide more intense hospital-level care and have physicians or midlevel practitioners evaluate patients upon admission, which enables the facility to influence many services delivered on the first day of the PAC stay. As such, only a limited number of discharge care services are excluded. Moreover, the NQF-endorsed hospital MSPB measure includes a period during which post-treatment spending is attributed to the provider; this accountability incentivizes acute and PAC providers to engage in appropriate discharge planning and post-treatment care coordination.

Comment: Several commenters recommended that short stays be excluded from the MSPB–PAC IRF QRP measure as these patients are identified as not being suitable for IRF care.

Response: We believe that including short stay discharges in the measure promotes timely and accurate pre-admission screening, as well as discharge planning and post-discharge care coordination. Including IRF short stays maintains consistency across the MSPB–PAC measures to the greatest extent possible. Short stays constitute a very small share of IRF stays nationally; in FY 2014, approximately 1.8 percent of IRF stays were short stay discharges. Moreover, the MSPB–PAC IRF QRP measure's methodology excludes outlier episodes. Therefore, we do not believe that inclusion of short stays in the MSPB–PAC IRF QRP measure will unfairly disadvantage or advantage an IRF provider in their performance on the measure. Moreover, including short stay discharges incentivizes providers to maintain beneficiaries under their care for the appropriate length of time, and will not incentivize IRFs to prematurely discharge their beneficiaries. We are finalizing the MSPB–PAC IRF QRP measure to include short stay discharges after careful consideration of the commenter's input.

Comment: Several commenters recommended the use of CMGs for risk adjustment instead of RICs to more fully and accurately account for and explain variances in resource utilization and case mix in the IRF setting. Commenters noted that CMGs incorporate functional status and are weighted to account for patients' predicted resource requirements, while RICs only indicate patients' overall medical condition; as such there can be wide variation of reimbursement within a single RIC.

Response: We have carefully considered the commenters feedback and are proceeding to finalize the measure as proposed. We believe the beneficiary's principal diagnosis or impairment as provided by the RIC currently supports the accurate estimation of Medicare spending while also reflecting clinical information that is accurately and consistently coded on IRF claims. The inclusion of RICs as variables in the MSPB–PAC IRF QRP risk adjustment model maintains consistency between MSPB–PAC resource use measures for each setting to the greatest extent possible, in that the other settings' MSPB–PAC measures do not incorporate variables reflecting the beneficiaries' functional status information. We may reconsider how to consistently incorporate functional status into the risk adjustment models for the MSPB–PAC measures once standardized data mandated by the IMPACT Act become available in the

future. Furthermore, the covariates incorporated in the MSPB–PAC IRF QRP risk adjustment model partially account for two factors in CMGs—age and co-morbidities. For co-morbidities, the risk adjustment specifications use flags for Hierarchical Condition Categories (HCCs) defined by scanning inpatient, Part B physician/carrier, and outpatient claims during a 90-day lookback period. We appreciate commenters' thoughtful input and thank them for their engagement with this measure through the rulemaking process.

Comment: A few commenters suggested that descriptive statistics on the measure score by provider-level characteristics (for example, urban/rural status and bed size) would be useful to evaluate measure design decisions.

Response: Table 8 shows the MSPB–PAC IRF provider scores by provider characteristics, calculated using FY 2013 and FY 2014 data.

TABLE 8—MSPB–PAC IRF SCORES BY PROVIDER CHARACTERISTICS

Provider characteristic	Number of providers	Mean score	Score percentile						
			1st	10th	25th	50th	75th	90th	99th
All Providers	1,169	0.99	0.78	0.88	0.93	0.98	1.04	1.09	1.24
Urban/Rural:									
Urban	979	0.99	0.77	0.88	0.93	0.98	1.04	1.08	1.24
Rural	190	0.98	0.79	0.88	0.91	0.97	1.04	1.10	1.25
Ownership Type:									
For profit	345	1.01	0.82	0.91	0.97	1.01	1.06	1.10	1.24
Non-profit	569	0.97	0.76	0.87	0.91	0.97	1.02	1.07	1.28
Government	142	0.98	0.81	0.88	0.93	0.98	1.02	1.08	1.23
Unknown	113	0.97	0.77	0.88	0.91	0.96	1.02	1.06	1.31
Census Division:									
New England	36	1.03	0.86	0.92	0.97	1.03	1.08	1.12	1.16
Middle Atlantic	153	0.99	0.79	0.89	0.93	0.98	1.05	1.09	1.30
East North Central	210	0.96	0.79	0.87	0.91	0.97	1.01	1.04	1.10
West North Central	103	0.94	0.76	0.83	0.90	0.94	0.99	1.03	1.14
South Atlantic	162	1.00	0.80	0.90	0.95	1.00	1.05	1.09	1.24
East South Central	78	1.00	0.87	0.92	0.96	0.99	1.04	1.08	1.11
West South Central	226	1.01	0.85	0.91	0.95	1.02	1.05	1.12	1.24
Mountain	91	1.00	0.79	0.88	0.93	0.98	1.05	1.12	1.99
Pacific	106	0.96	0.74	0.83	0.89	0.95	1.02	1.08	1.32
Other	4	0.88	0.74	0.74	0.79	0.90	0.97	0.98	0.98
Bed Count:									
0–49	114	1.01	0.79	0.91	0.96	1.01	1.04	1.12	1.25
50–99	188	1.01	0.80	0.91	0.96	1.00	1.06	1.09	1.30
100–199	231	0.98	0.79	0.87	0.92	0.98	1.04	1.10	1.24
200–299	184	0.97	0.77	0.87	0.91	0.97	1.01	1.07	1.44
300 +	452	0.98	0.77	0.88	0.92	0.97	1.03	1.08	1.24
Number of Episodes:									
0–99	108	1.00	0.74	0.81	0.89	0.97	1.07	1.16	1.83
100–249	344	0.97	0.76	0.86	0.90	0.96	1.03	1.08	1.31
250–499	327	0.98	0.82	0.88	0.92	0.97	1.03	1.08	1.23
500–1000	216	0.99	0.83	0.92	0.95	0.99	1.03	1.07	1.17
1000 +	174	1.01	0.89	0.94	0.97	1.02	1.06	1.08	1.15
Teaching:									
Non-teaching	1,059	0.98	0.77	0.88	0.93	0.98	1.03	1.08	1.24
Patient to ADC less than 10%	63	0.99	0.83	0.90	0.93	0.98	1.04	1.08	1.30
Patient to ADC 10%–20%	36	1.02	0.83	0.89	0.95	1.00	1.06	1.11	1.83
Patient to ADC greater than 20%	11	1.00	0.88	0.90	0.91	1.03	1.06	1.07	1.08

Comment: One commenter recommended that a geographic-specific (for example, state or regional) median should be used instead of the national median, citing differences in cost, patient population, and regulation.

Response: As noted in the proposed rule (81 FR 24199), we proposed to use the same payment standardization methodology that used in the NQF-endorsed hospital MSPB measure to account for variation in Medicare spending. This methodology removes geographic payment differences, such as wage index and geographic practice cost index (GPCI), incentive payment adjustments, and other add-on payments that support broader Medicare program goals including indirect graduate medical education (IME) and hospitals serving a disproportionate share of uninsured patients (DSH). We believe that this approach accounts for the differences that the commenter raises while also maintaining consistency with the NQF-endorsed hospital MSPB measure's methodology for addressing regional variation through payment standardization.

Comment: Some commenters recommended that the measure be tested for reliability and validity prior to finalization.

Response: The MSPB–PAC IRF QRP measure has been tested for reliability using 2 years of data (FY 2013 and FY 2014). The reliability results support the 20 episode case minimum, and 99.74 percent of IRF providers had moderate or high reliability (above 0.4). Further details on the reliability calculation are provided in the MSPB–PAC Measure Specifications Web site that is listed above in this section.

Comment: Some commenters recommended an initial confidential

data preview period for providers, prior to public reporting.

Response: Providers will receive a confidential preview report with 30 days for review in advance of their data and information being publically displayed.

Comment: A few commenters believed that the measure is a burden for providers.

Response: We appreciate the importance of avoiding undue burden on providers. The MSPB–PAC IRF QRP measure relies on Medicare FFS claims, which are already reported to the Medicare program for payment purposes. PAC providers will not be required to report additional data to CMS for calculation of this measure

Comment: One commenter requested that if the measures are finalized after a trial, that the same FIM Rating system be used to eliminate confusion and ensure that providers are submitting accurate information.

Response: The MSPB–PAC IRF QRP Measure focuses on comparing resource use among providers within a given PAC setting and does not measure clinical outcomes such as severity of disability.

In summary, after consideration of the public comments we received, we are finalizing the specifications of the MSPB–PAC IRF QRP resource use measure, as proposed. A Web site for the measure specifications has been provided above in this section.

Specifically, we are finalizing the definition of an MSPB–PAC IRF QRP episode, beginning from episode trigger. An episode window comprises a treatment period beginning at the trigger and ended upon discharge, and associated services period beginning at the trigger and ending 30 days after the end of the treatment period. Readmissions to the same IRF within 7 or fewer days do not trigger a new episode and are instead included in the treatment period of the first episode.

We exclude certain services that are clinically unrelated to IRF care and/or because IRF providers may have limited influence over certain Medicare services delivered by other providers during the episode window. We also exclude certain episodes in their entirety from the MSPB–PAC IRF QRP measure, such as where a beneficiary is not enrolled in Medicare FFS for the entirety of the lookback period plus episode window.

We finalize the inclusion of Medicare payments for Part A and Part B claims for services included in the MSPB–PAC IRF QRP episodes to calculate the MSPB–PAC IRF QRP measure.

We are finalizing our proposal to risk adjust using covariates including age brackets, HCC indicators, prior inpatient stay length, ICU stay length, clinical case mix categories, and indicators for originally disabled, ESRD enrollment, long-term care status, and hospice claim in episode window. The measure also adjusts for geographic payment differences such as wage index and GPCI, and adjust for Medicare payment differences resulting from IME and DSH.

We calculate the individual providers' MSPB–PAC Amount which is inclusive of MSPB–PAC IRF QRP observed episode spending over the expected episode spending as predicted through risk adjustment. Individual IRF providers' scores are calculated as their individual MSPB–PAC Amount divided by the median MSPB–PAC amount across all IRFs.

2. Measure To Address the IMPACT Act Domain of Resource Use and Other Measures: Discharge to Community-Post Acute Care (PAC) Inpatient Rehabilitation Facility (IRF) Quality Reporting Program (QRP)

Sections 1899B(d)(1)(B) and 1899B(a)(2)(E)(ii) of the Act require the Secretary to specify a measure to address the domain of discharge to community by SNFs, LTCHs, and IRFs by October 1, 2016, and HHAs by January 1, 2017. We proposed to adopt the measure, Discharge to Community-PAC IRF QRP, for the IRF QRP for the FY 2018 payment determination and subsequent years as a Medicare FFS claims-based measure to meet this requirement.

This measure assesses successful discharge to the community from an IRF setting, with successful discharge to the community including no unplanned rehospitalizations and no death in the 31 days following discharge from the IRF. Specifically, this measure reports an IRF's risk-standardized rate of Medicare FFS patients who are discharged to the community following an IRF stay, and do not have an unplanned readmission to an acute care hospital or LTCH in the 31 days following discharge to community, and who remain alive during the 31 days following discharge to community. The term ''community'', for this measure, is defined as home or self care, with or without home health services, based on Patient Discharge Status Codes 01, 06, 81, and 86 on the Medicare FFS claim.[17] [18] This measure is conceptualized uniformly across the PAC settings, in terms of the definition of the discharge to community outcome, the approach to risk adjustment, and the measure calculation.

Discharge to a community setting is an important health care outcome for many patients for whom the overall goals of post-acute care include optimizing functional improvement, returning to a previous level of independence, and avoiding institutionalization. Returning to the community is also an important outcome for many patients who are not expected to make functional improvement during their IRF stay, and for patients who may be expected to decline functionally due to their medical condition. The discharge to community outcome offers a multi-dimensional view of preparation for community life, including the cognitive, physical, and psychosocial elements involved in a discharge to the community.[19] [20]

In addition to being an important outcome from a patient and family perspective, patients discharged to community settings, on average, incur lower costs over the recovery episode, compared with those discharged to institutional settings.[21] [22] Given the high costs of care in institutional settings, encouraging IRFs to prepare patients for discharge to community, when clinically appropriate, may have cost-saving implications for the Medicare program.[23] Also, providers have discovered that successful discharge to community was a major driver of their ability to achieve savings, where capitated payments for post-acute care

[17] National Uniform Billing Committee Official UB–04 Data Specifications Manual 2017, Version 11, July 2016, Copyright 2016, American Hospital Association.

[18] This definition is not intended to suggest that board and care homes, assisted living facilities, or other settings included in the definition of ''community'' for the purpose of this measure are the most integrated setting for any particular individual or group of individuals under the Americans with Disabilities Act (ADA) and Section 504.

[19] El-Solh AA, Saltzman SK, Ramadan FH, Naughton BJ. Validity of an artificial neural network in predicting discharge destination from a postacute geriatric rehabilitation unit. *Archives of physical medicine and rehabilitation.* 2000;81(10):1388–1393.

[20] Tanwir S, Montgomery K, Chari V, Nesathurai S. Stroke rehabilitation: Availability of a family member as caregiver and discharge destination. *European journal of physical and rehabilitation medicine.* 2014;50(3):355–362.

[21] Dobrez D, Heinemann AW, Deutsch A, Manheim L, Mallinson T. Impact of Medicare's prospective payment system for inpatient rehabilitation facilities on stroke patient outcomes. *American journal of physical medicine & rehabilitation/Association of Academic Physiatrists.* 2010;89(3):198–204.

[22] Gage B, Morley M, Spain P, Ingber M. *Examining Post Acute Care Relationships in an Integrated Hospital System. Final Report.* RTI International;2009.

[23] *Ibid.*

were in place.[24] For patients who require long-term care due to persistent disability, discharge to community could result in lower long-term care costs for Medicaid and for patients' out-of-pocket expenditures.[25]

Analyses conducted for ASPE on PAC episodes, using a 5 percent sample of 2006 Medicare claims, revealed that relatively high average, unadjusted Medicare payments are associated with discharge to institutional settings from IRFs, SNFs, LTCHs or HHAs, as compared with payments associated with discharge to community settings.[26] Average, unadjusted Medicare payments associated with discharge to community settings ranged from $0 to $4,017 for IRF discharges, $0 to $3,544 for SNF discharges, $0 to $4,706 for LTCH discharges, and $0 to $992 for HHA discharges. In contrast, payments associated with discharge to non-community settings were considerably higher, ranging from $11,847 to $25,364 for IRF discharges, $9,305 to $29,118 for SNF discharges, $12,465 to $18,205 for LTCH discharges, and $7,981 to $35,192 for HHA discharges.[27]

Measuring and comparing facility-level discharge to community rates is expected to help differentiate among facilities with varying performance in this important domain, and to help avoid disparities in care across patient groups. Variation in discharge to community rates has been reported within and across post-acute settings; across a variety of facility-level characteristics, such as geographic location (for example, regional location, urban or rural location), ownership (for example, for-profit or nonprofit), and freestanding or hospital-based units; and across patient-level characteristics, such as race and gender.[28 29 30 31 32 33] Discharge to community rates in the IRF setting have been reported to range from about 60 to 80 percent.[34 35 36 37 38 39] Longer-term studies show that rates of discharge to community from IRFs have decreased over time as IRF length of stay has decreased.[40 41] In the IRF Medicare FFS population, using CY 2013 national claims data, we discovered that approximately 69 percent of patients were discharged to the community. Greater variation in discharge to community rates is seen in the SNF setting, with rates ranging from 31 to 65 percent.[42 43 44 45] A multi-center study of 23 LTCHs demonstrated that 28.8 percent of 1,061 patients who were ventilator-dependent on admission were discharged to home.[46] A single-center study revealed that 31 percent of LTCH hemodialysis patients were discharged to home.[47] One study noted that 64 percent of beneficiaries who were discharged from the home health episode did not use any other acute or post-acute services paid by Medicare in the 30 days after discharge.[48] However, significant numbers of patients were admitted to hospitals (29 percent) and lesser numbers to SNFs (7.6 percent), IRFs (1.5 percent), home health (7.2 percent) or hospice (3.3 percent).[49]

Discharge to community is an actionable health care outcome, as targeted interventions have been shown to successfully increase discharge to community rates in a variety of post-acute settings.[50 51 52 53] Many of these

[24] Doran JP, Zabinski SJ. Bundled payment initiatives for Medicare and non-Medicare total joint arthroplasty patients at a community hospital: Bundles in the real world. *The journal of arthroplasty.* 2015;30(3):353–355.

[25] Newcomer RJ, Ko M, Kang T, Harrington C, Hulett D, Bindman AB. Health Care Expenditures After Initiating Long-term Services and Supports in the Community Versus in a Nursing Facility. *Medical Care.* 2016;54(3):221–228.

[26] Gage B, Morley M, Spain P, Ingber M. *Examining Post Acute Care Relationships in an Integrated Hospital System. Final Report.* RTI International;2009.

[27] *Ibid.*

[28] Reistetter TA, Karmarkar AM, Graham JE, et al. Regional variation in stroke rehabilitation outcomes. *Archives of physical medicine and rehabilitation.* 2014;95(1):29–38.

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[52] Berkowitz RE, Jones RN, Rieder R, et al. Improving disposition outcomes for patients in a geriatric skilled nursing facility. *Journal of the American Geriatrics Society.* 2011;59(6):1130–1136.

[53] Kushner DS, Peters KM, Johnson-Greene D. Evaluating use of the Siebens Domain Management Model during inpatient rehabilitation to increase functional independence and discharge rate to

interventions involve discharge planning or specific rehabilitation strategies, such as addressing discharge barriers and improving medical and functional status.[54] [55] [56] [57] The effectiveness of these interventions suggests that improvement in discharge to community rates among post-acute care patients is possible through modifying provider-led processes and interventions.

A TEP convened by our measure development contractor was strongly supportive of the importance of measuring discharge to community outcomes, and implementing the measure, Discharge to Community-PAC IRF QRP in the IRF QRP. The panel provided input on the technical specifications of this measure, including the feasibility of implementing the measure, as well as the overall measure reliability and validity. A summary of the TEP proceedings is available on the PAC Quality Initiatives Downloads and Videos Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We also solicited stakeholder feedback on the development of this measure through a public comment period held from November 9, 2015, through December 8, 2015. Several stakeholders and organizations, including the MedPAC, among others, supported this measure for implementation. The public comment summary report for the measure is available on our Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

The NQF-convened MAP met on December 14 and 15, 2015, and provided input on the use of this Discharge to Community-PAC IRF QRP measure in the IRF QRP. The MAP encouraged continued development of the measure to meet the mandate of the IMPACT Act. The MAP supported the alignment of this measure across PAC settings, using standardized claims data. More information about the MAP's recommendations for this measure is available at *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx*.

Since the MAP's review and recommendation of continued development, we have continued to refine risk-adjustment models and conduct measure testing for this measure, as recommended by the MAP. This measure is consistent with the information submitted to the MAP, and the original MAP submission and our continued refinements support its scientific acceptability for use in quality reporting programs. As discussed with the MAP, we fully anticipate that additional analyses will continue as we submit this measure to the ongoing measure maintenance process.

We reviewed the NQF's consensus-endorsed measures and were unable to identify any NQF-endorsed resource use or other measures for post-acute care focused on discharge to community. In addition, we are unaware of any other post-acute care measures for discharge to community that have been endorsed or adopted by other consensus organizations. Therefore, we proposed the measure, Discharge to Community-PAC IRF QRP, under the Secretary's authority to specify non-NQF-endorsed measures under section 1899B(e)(2)(B) of the Act.

We proposed to use data from the Medicare FFS claims and Medicare eligibility files to calculate this measure. We proposed to use data from the ''Patient Discharge Status Code'' on Medicare FFS claims to determine whether a patient was discharged to a community setting for calculation of this measure. In all PAC settings, we tested the accuracy of determining discharge to a community setting using the ''Patient Discharge Status Code'' on the PAC claim by examining whether discharge to community coding based on PAC claim data agreed with discharge to community coding based on PAC assessment data. We found excellent agreement between the two data sources in all PAC settings, ranging from 94.6 percent to 98.8 percent. Specifically, in the IRF setting, using 2013 data, we found 98.8 percent agreement in coding of community and non-community discharges when comparing discharge status codes on claims and the Discharge to Living Setting (item 44A) codes on the IRF–PAI. We further examined the accuracy of the ''Patient Discharge Status Code'' on the PAC claim by assessing how frequently discharges to an acute care hospital were confirmed by follow-up acute care claims. We discovered that 88 percent to 91 percent of IRF, LTCH, and SNF claims with acute care discharge status codes were followed by an acute care claim on the day of, or day after, PAC discharge. We believed these data support the use of the claims ''Patient Discharge Status Code'' for determining discharge to a community setting for this measure. In addition, this measure can feasibly be implemented in the IRF QRP because all data used for measure calculation are derived from Medicare FFS claims and eligibility files, which are already available to CMS.

Based on the evidence discussed above, we proposed to adopt the measure, Discharge to Community-PAC IRF QRP, for the IRF QRP for FY 2018 payment determination and subsequent years. This measure is calculated using 2 years of data. We proposed a minimum of 25 eligible stays in a given IRF for public reporting of the measure for that IRF. Since Medicare FFS claims data are already reported to the Medicare program for payment purposes, and Medicare eligibility files are also available, IRFs will not be required to report any additional data to us for calculation of this measure. The measure denominator is the risk-adjusted expected number of discharges to community. The measure numerator is the risk-adjusted estimate of the number of patients who are discharged to the community, do not have an unplanned readmission to an acute care hospital or LTCH in the 31-day post-discharge observation window, and who remain alive during the post-discharge observation window. The measure is risk-adjusted for variables such as age and sex, principal diagnosis, comorbidities, ESRD status, and dialysis, among other variables. For technical information about the proposed measure, including information about the measure calculation, risk adjustment, and denominator exclusions, we referred readers to the document titled, Proposed Measure Specifications for Measures Proposed in the FY 2017 IRF QRP proposed rule, available at *https://*

home in stroke patients. *PM & R: The journal of injury, function, and rehabilitation.* 2015;7(4):354–364.

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www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.

We stated in the proposed rule that we intend to provide initial confidential feedback to IRFs, prior to public reporting of this measure, based on Medicare FFS claims data from discharges in CY 2015 and 2016. We intend to publicly report this measure using claims data from discharges in CY 2016 and 2017. We will submit this measure to the NQF for consideration for endorsement.

In the CY 2013 OPPS/ASC final rule (77 FR 68500), we finalized our policy to use a subregulatory approach to incorporate non-substantive changes to measures adopted in the IRF QRP, including changes to exclusions. In that rule, we noted that we expect to make this determination on a measure-by-measure basis and that examples of non-substantive changes to measures might include exclusions for a measure. For the proposed Discharge to Community-IRF QRP measure, we have added an exclusion of patients/residents with a hospice benefit in the post-discharge observation window, in response to comments received during measure development and our ongoing analysis and testing. The rationale for the exclusion of patients/residents with a hospice benefit in the post-discharge observation window aligns with the rationale for exclusion of discharges to hospice. Based on testing, we found that patients/residents with a post-discharge hospice benefit have a much higher death rate in the post-discharge observation window compared with patients/residents without a hospice benefit. We determined that the addition of this hospice exclusion enhances the measure by excluding patients/residents with a high likelihood of post-discharge death and improves the national observed discharge to community rate for IRFs by approximately 0.8 percent. With the addition of this hospice exclusion, we do not believe burden is added, nor that the addition of this exclusion is a substantive change to the overall measure. Failure to include this hospice exclusion could lead to unintended consequences and access issues for terminally-ill patients/residents in our PAC populations.

We invited public comment on our proposal to adopt the measure, Discharge to Community-PAC IRF QRP, for the IRF QRP. The comments we received on this topic, with our responses, appear below.

Comment: Multiple commenters, including MedPAC, supported the Discharge to Community-PAC IRF QRP measure, noting that it is a critical measure assessing the ability of PAC providers to avoid patient institutionalization. One commenter noted that measuring the rate that the various PAC settings discharge patients to the community, without an admission (or readmission) to an acute care hospital within 30 days, is one of the most relevant patient-centered measures that exists in the post-acute care area. One commenter conveyed that successful transitions to the community are expected to decrease potentially preventable readmissions, while another was appreciative that the measure did not place additional data collection burden on facilities. One commenter stated that achieving a standardized and interoperable patient assessment data set and stable quality measures as quickly as possible will allow for better cross-setting comparisons and the evolution of better quality measures with uniform risk standardization.

Response: We thank the commenters for their support of the Discharge to Community-PAC IRF QRP measure, and their recognition of the patient-centeredness of this measure, its potential to decrease post-discharge readmissions, and its lack of data collection burden. We also thank the commenter for their support of standardized and interoperable patient assessment data and quality measures. As mandated by the IMPACT Act, we are moving toward the goal of standardized patient assessment data and quality measures across PAC settings.

Comment: One commenter interpreted our measure proposal language as suggesting that functional improvement is not a requirement, and encouraged that Medicare coverage for maintenance nursing and therapy be ensured and reflected by the measure.

Response: Our intent in the measure proposal was to acknowledge that discharge to community can be an important goal even for patients who may not be able to make functional improvement. This measure does not impact Medicare coverage rules for maintenance nursing and therapy.

Comment: Several commenters expressed concerns regarding the use of the Patient Discharge Status Code variable to define community discharges. Commenters emphasized that it was important to ensure that only home and community based settings were included in the definition of community, and were concerned that Code 01 (Discharge to home or self-care) included institutional settings such as jail or law enforcement. One commenter expressed that many settings included under Code 01 do not satisfy the home and community based settings rule, and may be inconsistent with the integration mandate of the Americans with Disabilities Act. Commenters strongly recommended that CMS either revise Patient Discharge Status Code 01 to exclude non community-based settings, or use alternative variables to capture discharge to community.

Response: We agree with the commenters that the discharge to community measure should only capture discharges to home and community based settings. We believe that the comment referring to the ''home and community based settings rule'' refers to Medicaid regulations applicable to services authorized under sections 1915(c), 1915(i) and 1915(k) of the Social Security Act (the Act), which are provided through waivers or state plans amendments approved by CMS. We would like to clarify that this measure only captures discharges to home and community based settings, not to institutional settings, and is consistent with both Medicaid regulations requiring home and community based settings to support integration, and also with the Americans with Disabilities Act (ADA), based on Patient Discharge Status Codes 01, 06, 81, and 86 on the Medicare FFS PAC claim.[58] Discharges to court or law enforcement are not included under Code 01 of the Patient Discharge Status Code; rather these are included under Code 21 (Discharged/transferred to Court/Law Enforcement).

We also note that Title II of the ADA requires public entities to administer services, programs, and activities in the most integrated setting appropriate to the needs of qualified individuals with disabilities (28 CFR 35.130(d)). The preamble discussion of the ''integration regulation'' explains that ''the most integrated setting'' is one that enables individuals with disabilities to interact with nondisabled persons to the fullest extent possible. Integrated settings are those that provide individuals with disabilities opportunities to live, work, and receive services in the greater community, like individuals without disabilities (28 CFR part 35, app. A (2010) (addressing § 35.130)).

Comment: Several commenters stated that PAC patients/residents discharged to a nursing facility as long-term care

[58] National Uniform Billing Committee Official UB–04 Data Specifications Manual 2017, Version 11, July 2016, Copyright 2016, American Hospital Association.

residents should not be considered discharges to community, particularly if they were discharged to the nursing facility from the Medicare-certified skilled nursing part of the same nursing home, and even if they resided in a long-term nursing facility at baseline. Commenters emphasized that a nursing home does not represent an individual's own home in their own community. These commenters interpreted the measure specifications as allowing these discharges to nursing facility to be coded as ''group home'', ''foster care'', or ''other residential care arrangement'' under discharge status code 01. Commenters expressed concern that coding discharges from the SNF to residential/long-term care facility within the same nursing home as discharges to community would unfairly advantage SNFs and artificially inflate their discharge to community rates, would disadvantage other PAC providers, and would miscommunicate a facility's actual discharge to community performance to the average Medicare beneficiary. One commenter suggested exclusion of patients discharged to a non-Medicare certified residence, such as a ''group home'' or ''foster care'' or other arrangement.

Response: We agree with the commenters that discharges to long-term care nursing facilities, or any other institutional settings, should not be coded as discharges to community. We also recognize the differences in required discharge planning processes and resources for discharging a patient/resident to the community compared with discharging to a long-term nursing facility. The discharge to community measure only captures discharges to home and community based settings as discharges to community, based on Patient Discharge Status Codes 01, 06, 81, and 86 on the Medicare FFS PAC claim.[59] These codes do not include discharges to long-term care nursing facilities or any other institutional setting that may violate the integration mandate of Title II of the ADA. Instead, depending on the nature of the facility to which patients/residents are discharged, such discharges may be coded on the Medicare FFS claim as 04, 64, 84, 92, or another appropriate code for an institutional discharge.

In response to the commenters' concerns that SNFs may be unfairly advantaged by this measure as compared with other PAC providers, we would like to note that, in our measure development samples, the national discharge to community rate for SNFs was 47.26 percent, while this rate for IRFs was considerably higher (69.51 percent). Further, using an MDS-claims linked longitudinal file, we found that of the SNF stays that had a pre-hospitalization non-PPS MDS assessment suggesting prior nursing facility residence, two-thirds had a discharge status code of 30 (still patient), and approximately 18 percent had a discharge status code of 02 (acute hospital). Less than 5 percent of these patients had a Discharge Status Code of 01 (discharge to home or self care). Thus, the commenters' concerns that discharges from SNF to nursing facility are largely coded as Patient Discharge Status Code 01 are not reflected in our data.

Comment: Some commenters expressed concern that the discharge to community measure fails to distinguish patients/residents who lived in a long-term care nursing facility at baseline and returned to the nursing facility after their PAC stay. Commenters recommended that baseline long-stay nursing facility residents be excluded from the discharge to community measure, as they could not be reasonably expected to discharge back to the community. One commenter noted that these residents have a very different discharge process back to the nursing facility compared with patients discharged to the community. The commenter recommended that different measures be developed for the baseline nursing facility resident population, such as return to prior level of function, improvement in function, prevention of further functional decline, development of pressure ulcers, or accidental falls. The commenter also recognized CMS's current efforts in monitoring transitions of care and quality requirements in long-term care facilities. Commenters suggested that CMS could use longitudinal Minimum Data Set-linkage to identify and exclude baseline nursing facility residents.

Response: We appreciate the commenters' concerns and their recommendation to exclude baseline nursing facility residents from the discharge to community measure, and to distinguish baseline custodial nursing facility residents who are discharged back to the nursing facility after their PAC stay. We recognize that patients/residents who permanently lived in a nursing facility at baseline may not be expected to discharge back to a home and community based setting after their PAC stay. We also recognize that, for baseline nursing facility residents, a discharge back to their nursing facility represents a discharge to their baseline residence. We agree with the commenter about the differences in discharge planning processes when discharging a patient/resident to the community compared with discharging to a long-term nursing facility. However, using Medicare FFS claims alone, we are unable to accurately identify baseline nursing facility residents. Potential future modifications of the measure could include the assessment of the feasibility and impact of excluding baseline nursing facility residents from the measure through the addition of patient assessment-based data. However, we note that, currently, the IRF–PAI is the only PAC assessment that contains an item related to pre-hospital baseline living setting.

Comment: A few commenters questioned the inclusion of only Medicare FFS patients/residents in the measure, and stated whether the measure would be expanded to include patients/residents with other payers or plan types. One commenter recommended that the patient populations be consistent across IRF measures, and not vary by payer or plan type, stating that consistency in measure populations across IRF measures was important for facilities to understand their quality metrics. Other commenters recommended that the discharge to community measure include other payer populations, and particularly emphasized the importance of including Medicare Advantage patients in the measure, highlighting that Medicare Advantage patients were included in the IRF Drug Regimen Review measure. The commenters noted that the Medicare Advantage population was a rapidly growing Medicare population, warranting their inclusion in quality measures.

Response: We agree that is it important to monitor quality and resource use outcomes of all post-acute care patients/residents, not just Medicare FFS patients/residents. The discharge to community measure is limited to the Medicare FFS population through the use of a Medicare FFS claim, but we will consider the appropriateness and feasibility of including Managed Care patients/residents in future modifications of the measure. We would like to note that further expansion of the measure to include Medicare Managed Care or other payer populations would require standardized data collection across all settings and payer populations.

Comment: MedPAC recommended that CMS confirm discharge to a community setting with the absence of a subsequent claim to a hospital, IRF, SNF, or LTCH, to ensure that discharge to community rates reflect actual facility performance. Other commenters also

[59] *Ibid.*

recommended that CMS assess the reliability and validity of the Patient Discharge Status Code on PAC claims. Commenters cited MedPAC and other studies, noting that Patient Discharge Status Codes often have low reliability, and that this could impact accurate portrayal of measure performance.

Response: We are committed to developing measures based on reliable and valid data. This measure does confirm the absence of hospital or LTCH claims following discharge to a community setting. Unplanned hospital and LTCH readmissions following the discharge to community, including those on the day of IRF discharge, are considered an unfavorable outcome. We will consider verifying the absence of IRF and SNF claims following discharge to a community setting, as we continue to refine this measure. Nonetheless, we would like to note that an ASPE report on post-acute care relationships found that, following discharge to community settings from IRFs, LTCHs, or SNFs in a 5 percent Medicare sample, IRFs or SNFs were very infrequently reported as the next site of post-acute care.[60]

Because the discharge to community measure is a measure of discharge destination from the PAC setting, we have chosen to use the PAC-reported discharge destination (from the Medicare FFS claims) to determine whether a patient/resident was discharged to the community (based on discharge status codes 01, 06, 81, 86). We assessed the reliability of the claims discharge status code(s) by examining agreement between discharge status on claims and assessment instruments in all four PAC settings. We found between 94 and 99 percent agreement in coding of community discharges on matched claims and assessments in each of the PAC settings. We also assessed how frequently discharges to acute care, as indicated on the PAC claim, were confirmed by follow-up acute care claims, and found that 88 percent to 91 percent of IRF, LTCH, and SNF claims indicating acute care discharge were followed by an acute care claim on the day of, or day after, PAC discharge. We believe that these data support the use of the ''Patient Discharge Status Code'' from the PAC claim for determining discharge to a community setting for this measure.

The use of the claims discharge status code to identify discharges to the community was discussed at length with the TEP convened by our measure development contractor. TEP members did not express significant concerns regarding the accuracy of the claims discharge status code in coding community discharges, nor about our use of the discharge status code for defining this quality measure. A summary of the TEP proceedings is available on the PAC Quality Initiatives Downloads and Videos Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

Comment: A few commenters conveyed the importance of ensuring consistency in coding of discharge status codes across PAC settings, and requested a clear definition of community discharge for purposes of this measure.

Response: This measure captures discharges to home and community based settings, with or without home health services. Community, for this measure, is defined as Patient Discharge Status codes 01, 06, 81, and 86 on the PAC claim. Code 01 refers to discharge to home or self care; Code 06 refers to discharge with home health services; Code 81 refers to discharge to home or self care with a planned acute care readmission; and Code 86 refers to discharge with home health services with a planned acute care readmission. We refer readers to the National Uniform Billing Committee Data Specifications Manual for coding instructions.[61] For further details on measure specifications, including the definition of community, we refer readers to the Measure Specifications for Measures Adopted in the FY 2017 IRF QRP final rule, posted on the CMS IRF QRP Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html*.

Comment: Some commenters were concerned about overlap between the discharge to community and readmissions measures, specifically expressing concern that a single post-discharge readmission would affect a facility's performance on two measures. One commenter expressed that the discharge to community measure essentially functioned as a readmission measure, and that different definitions of readmissions could be confusing for providers and patients, lead to unintended differences in the data CMS receives, and skew the data. One commenter indicated that the IMPACT Act measures overemphasized reducing readmissions and did not adequately address the domains they are meant to measure. This commenter suggested that quality measures should exclude aspects measured by other domains and/or quality measures, and instead should measure unique domains. This commenter further recommended that the Secretary suspend this measure until CMS can evaluate whether the inclusion of readmissions within each quality measure is necessary, and whether it produces duplicative results within the various quality reporting programs.

Response: There are distinct differences between the discharge to community and readmission measures under the IRF QRP. Although there may be some overlap in the outcomes captured across the two measures (for example, patients who have a post-discharge readmission also have an unsuccessful discharge to community), the discharge to community and readmission measures each have a distinct purpose, outcome definition, and measure population. For example, the discharge to community measure assesses the rate of successful discharges to the community, defined as discharge to a community setting without post-discharge unplanned readmissions or death, while the readmission measures assess the rate of readmissions for patients discharged to lower levels of care from the IRF.

Our goal is to develop measures that are meaningful to patients and consumers, and assist them in making informed choices when selecting post-acute providers. Since the goal of PAC for most patients and family members is to be discharged to the community and remain in the community, from a patient/consumer perspective, it is important to assess whether a patient remained in the community after discharge and to separately report discharge to community rates. In addition to assessing the success of community discharges, the inclusion of post-discharge readmission and death outcomes in this measure is intended to avoid the potential unintended consequence of inappropriate discharges to the community.

Comment: Several commenters expressed concern that the discharge to community measure holds IRFs accountable for post-discharge adverse outcomes, including unplanned readmissions and death. Commenters expressed that IRFs have little control

[60] Gage B, Morley M, Spain P, Ingber M. Examining Post Acute Care Relationships in an Integrated Hospital System Final Report. RTI International; 2009.

[61] National Uniform Billing Committee Official UB–04 Data Specifications Manual 2017, Version 11, July 2016, Copyright 2016, American Hospital Association.

over patient behavior or adherence once the patient is discharged from the facility, and should not be penalized for post-discharge events. We received recommendations to exclude patients who have been discharged to the community and then expire within the post-discharge window; this recommendation was based on the explanation that the types of patients treated in IRFs greatly varied and that including post-discharge death in the measure could lead to an inaccurate reflection of the quality of care furnished by the IRF.

Response: We monitor 31-day post-discharge unplanned readmissions and death in the measure to more accurately capture successful discharge to community outcomes, and to avoid the potential unintended consequence of inappropriate discharges to the community. We expect that improved care transitions and care coordination across providers will reduce these post-discharge adverse outcomes. Members of our TEP unanimously believed that the definition of discharge to community should be broader than discharge destination alone, and should incorporate indicators of post-discharge patient outcomes. TEP members agreed with the inclusion of both post-discharge readmissions and death in the discharge to community measure.

We found, through our analyses in our measure development sample, that death in the 31 days following discharge to community is an infrequent event, with only 0.9 percent of IRF Medicare FFS beneficiaries dying during that period. By risk adjusting for prior service use (that is, number of hospitalizations in the past year), our intent is to adjust for patient characteristics, such as access, patient compliance, or sociodemographic and socioeconomic factors that may influence the likelihood of post-discharge readmissions. Additionally, by excluding patients discharged against medical advice from the measure, we are excluding patients who demonstrate non-compliance or non-adherence during the PAC stay.

We would like to note that we do not expect facilities to achieve a 0 percent readmission or death rate in the measure's post-discharge observation window; the focus is to identify facilities with unexpectedly high rates of unplanned readmissions and death for quality monitoring purposes.

Comment: Multiple commenters suggested that the measure include risk adjustment for sociodemographic factors such as home and community caregivers and supports, and socioeconomic factors of patients and communities.

Response: We understand the importance of home and community supports, sociodemographic factors, and socioeconomic factors in ensuring a successful discharge to community outcome. The discharge to community measure is a claims-based measure in its first phase of development. Currently, there are no standardized data on variables such as living status or family and caregiver supports across the four PAC settings. As we refine the measure in the future, we will consider testing and adding additional relevant data sources and standardized items for risk adjustment of this measure. We refer readers to section VIII.F of this final rule for a more detailed discussion of the role of SES/SDS factors in risk adjustment of our measures.

Comment: A few commenters emphasized the relationship between functional gains during the IRF stay and the ability to discharge to the community, stating that functional status measures are important indicators of recovery and achievement of rehabilitation goals and should be more intimately embedded in the proposed discharge to community measure. One commenter stated that return to one's previous home represents part of the goal of care. The commenter noted that, additionally, it is also important that the patient is able to function to the greatest possible extent in the home and community setting and achieve the highest quality of life possible. The commenter recommended that CMS delay adopting this measure until it incorporated metrics that assess whether patients achieved their functional and independence goals based on their plan of care and their specific condition.

Multiple commenters suggested that the measure include risk adjustment for functional status in all settings, as it is closely associated with patients' discharge destination. One commenter noted that functional status is associated with increased risk of 30-day all-cause hospital readmissions, and since readmissions and discharge to community are closely related, functional status risk adjustment is also important for this measure. One commenter suggested that the SNF and LTCH measures include risk adjustment that is similar to the risk adjustment for CMGs in the IRF setting and Activities of Daily Living in the HHA setting. One commenter interpreted the measure proposal as stating that CMS will not adjust the quality measures, including the discharge to community measure, to account for functional status of beneficiaries until such data are collected under the IMPACT Act.

Response: We agree that it is important to assess various aspects of patient outcomes that are indicative of successful discharge from the IRF setting. We also agree that functional status may be related to discharge to community outcomes, and that it is important to test admission functional status risk adjustment when assessing discharge to community outcomes. The discharge to community measure does include functional status risk adjustment in the IRF setting using CMGs from claims, and in the home health setting using Activities of Daily Living from claims.

As mandated by the IMPACT Act, we are moving toward the goal of collecting standardized patient assessment data for functional status across PAC settings. The IRF QRP includes five NQF-endorsed functional status quality measures, with a data collection start date of October 1, 2016. Two measures are related to mobility functional outcomes, two are related to self-care functional outcomes, and one is a process measure. Once standardized functional status data become available across settings, it is our intent to use these data to assess patients' functional gains during their PAC stay, and to examine the relationship between functional status, discharge destination, and patients' ability to discharge to the community. As we examine these relationships between functional outcomes and discharge to community outcomes in the future, we will assess the feasibility of leveraging these standardized patient assessment data to incorporate functional outcomes into the discharge to community measure. Standardized cross-setting patient assessment data will also allow us to examine interrelationships between the quality and resource use measures in each PAC setting, and to understand how these measures are correlated.

Comment: One commenter questioned the appropriateness of using HCCs for risk adjustment in the new quality measures proposed for the IRF QRP. The commenters noted that HCCs were initially developed for setting payment benchmarks for the Medicare Advantage program, and broad application of HCCs across quality measures may be beyond the scope of their appropriate use. The commenter cited reports suggesting that the HCC risk model was inaccurate at cost-estimation, and recommended that CMS reconsider the validity and reliability of the HCC risk-adjustment model. The commenter suggested that CMS instead develop a refined model that encompasses the diversity and complexity of PAC patients to a greater

extent, and is more sensitive to their levels of resource use.

Response: We agree that comorbidities are important risk adjusters when examining quality and resource use measures. The HCCs were developed to separate clinically-related codes by Medicare utilization implications; they represent diagnosis-based, clinically meaningful clusters of ICD codes that have also been grouped by cost implications. When we apply HCCs for risk adjustment of quality or resources use measures, we do not use the HCC models applied to payment. In our measure development, we typically test individual HCCs that are relevant to the outcome of interest; we estimate the effects of the individual HCCs or clusters on the dependent variable in the particular model and retain those that are significant or meaningful predictors of outcomes. We believe that risk adjusting for individual HCCs or small clusters provides greater sensitivity than using a single comorbidity index, which is based on selected diagnoses. Our approach accounts for an average effect for each comorbidity or comorbidity group, rather than an overall burden of comorbidities.

The HCCs are more comprehensive than the simpler diagnosis-based systems, such as the Elixhauser Comorbidity Index or Charlson Comorbidity Index, which were targeted for predicting specific outcomes (for example, hospital mortality). We believe that HCCs provide a good representation of health risk, and their use to examine outcomes other than costs is supported in the literature.[62] [63] A study comparing the ability of five comorbidity indices to predict discharge functional status of IRF patients found that HCCs slightly outperformed other comorbidity indices.[64] The superior performance of HCCs was hypothesized to be related to the inclusion of more medical conditions, and the inclusion of more ICD codes per condition in HCCs, making them a slightly more sensitive index for predicting clinical outcomes compared with other comorbidity indices.[65]

We have successfully used HCCs as risk adjusters in several other quality measures, such as the readmissions and functional status measures for post-acute care. We have found HCCs to be significant and important predictors of outcomes across these quality measures.

Comment: One commenter stated that ventilator use is included as a risk adjuster in the LTCH setting only, but should be used across all settings. This commenter also requested information on the hierarchical logistic regression modeling and variables that will be used for risk adjustment.

Response: We would like to clarify that risk adjustment for ventilator use is included in both LTCH and SNF settings. We investigated the need for risk adjustment for ventilator use in IRFs, but found that less than 0.01 percent of the IRF population (19 patient stays in 2012, and 9 patient stays in 2013) had ventilator use in the IRF. Given the low frequency of ventilator use in IRFs, any associated estimates would not be reliable, and therefore, ventilator use is not included as a risk adjuster in the IRF setting measure. However, we will continue to assess this risk adjuster for inclusion in the IRF model for this measure.

For details on measure specifications, modeling, and calculations, we refer readers to the Measure Specifications for Measures Adopted in the FY 2017 IRF QRP final rule, posted on the CMS IRF QRP Web page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html*.

Comment: Two commenters requested clarification on the dual status of IRFs as qualifying hospitals for the purposes of the SNF ''3-Day Stay'' rule, and PAC providers for purposes of the discharge to community measure. Specifically, the commenters questioned whether a discharge from a SNF back to an IRF would count as a readmission under this measure (and thus result in a ''failed'' community discharge for the SNF), or whether it would only count as a non-community discharge.

Response: For the discharge to community measure, a PAC stay must be preceded by an acute care stay in the past 30 days to be included in the measure. IRF stays are not considered qualifying stays for the purposes of inclusion in the discharge to community measure. When examining discharge destination from PAC, a discharge to an IRF would be considered a non-community discharge. Additionally, in the current measure specification, if a patient is discharged from PAC to the community and has a subsequent IRF admission in the post-discharge observation window, this IRF admission does not translate into a failed community discharge. In future measure work, we will assess the impact of flagging IRF admissions in the post-discharge window as failed discharges to community.

Comment: One commenter encouraged CMS to provide PAC settings with access to measure performance data as early as possible so providers have time to adequately review these data, and implement strategies to decrease readmissions where necessary.

Response: We intend to provide initial confidential feedback to PAC providers, prior to public reporting of this measure, based on Medicare FFS claims data from discharges in CY 2015 and 2016.

Comment: A few commenters were concerned about potential unintended consequences associated with perceived conflicting incentives of measures within the IRF QRP. One commenter noted that while the discharge to community measure may incentivize IRFs to discharge patients with home health services in order to continue their recovery and function in a safe, lower cost setting, the MSPB measure may create an opposite incentive for IRFs to avoid the use of home health to reduce post-discharge resource utilization. Another commenter conveyed that IRFs may not be incentivized to discharge patients to the community as there is a risk of post-discharge readmissions affecting their measure performance. The commenter expressed that decreased discharge to community rates may result in increased costs.

Response: We expect that, on average, discharges to community settings rather than institutional settings, will result in lower healthcare costs. We choose measures for our quality reporting programs that reflect patient-centeredness, and assess healthcare outcomes and utilization that may be indicators of poor quality of care or inefficient resource use. As with all our measures, we will monitor for unintended consequences as part of measure monitoring and evaluation to ensure that measures do not reduce quality of care or access for patients.

Comment: Several commenters expressed concern that the discharge to community measure had not been endorsed by the NQF, and had not been fully developed and tested when presented to the NQF MAP. Some commenters recommended that CMS delay measure implementation and seek

[62] Li P, Kim MM, Doshi JA. Comparison of the performance of the CMS Hierarchical Condition Category (CMS–HCC) risk adjuster with the Charlson and Elixhauser comorbidity measures in predicting mortality. BMC Health Serv Res. 2010 Aug 20;10:245. doi: 10.1186/1472–6963–10–245.

[63] Kumar A, Graham JE, Resnik L, Karmarkar AM, Tan A, Deutsch A, Ottenbacher KJ. Comparing Comorbidity Indices to Predict Post-Acute Rehabilitation Outcomes in Older Adults. Am J Phys Med Rehabil. 2016 May 4. [Epub ahead of print]

[64] *Ibid.*

[65] *Ibid.*

NQF endorsement before measure adoption, while others recommended that CMS submit the measures for NQF endorsement as soon as feasible after measure adoption. A few commenters suggested that CMS obtain the support of a TEP before deciding whether to implement new quality measures, and that the TEP include IRF setting representatives.

Response: We would like to clarify that the discharge to community measure has been fully developed and tested. We plan to submit the Discharge to Community-PAC IRF QRP measure to the NQF for consideration for endorsement.

As with all measure development, our measure development contractor held three TEP meetings to seek input to guide development of the Discharge to Community measure. The TEP represented members of IRF, LTCH, SNF and home health agency settings. A summary of the TEP proceedings is available on the PAC Quality Initiatives Downloads and Videos Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*. TEP members were very supportive of the discharge to community measure concept across all PAC settings. We incorporated various TEP member recommendations into the measure specifications.

Final Decision: After careful consideration of the public comments, we are finalizing our proposal to adopt the measure, Discharge to Community-PAC IRF QRP as a Medicare FFS claims-based measure for the FY 2018 payment determination and subsequent years, with the added exclusion of patients with a hospice benefit in the 31-day post-discharge observation window.

For measure specifications, we refer readers to the Measure Specifications for Measures Adopted in the FY 2017 IRF QRP final rule, posted on the CMS IRF QRP Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html*.

3. Measure To Address the IMPACT Act Domain of Resource Use and Other Measures: Potentially Preventable 30-Day Post-Discharge Readmission Measure for Inpatient Rehabilitation Facility Quality Reporting Program

Sections 1899B(a)(2)(E)(ii) and 1899B(d)(1)(C) of the Act require the Secretary to specify measures to address the domain of all-condition risk-adjusted potentially preventable hospital readmission rates by SNFs, LTCHs, and IRFs by October 1, 2016, and HHAs by January 1, 2017. We proposed the measure Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP as a Medicare FFS claims-based measure to meet this requirement for the FY 2018 payment determination and subsequent years.

The measure assesses the facility-level risk-standardized rate of unplanned, potentially preventable hospital readmissions for Medicare FFS beneficiaries in the 30 days post IRF discharge. The IRF admission must have occurred within up to 30 days of discharge from a prior proximal hospital stay which is defined as an inpatient admission to an acute care hospital (including IPPS, CAH, or a psychiatric hospital). Hospital readmissions include readmissions to a short-stay acute-care hospital or an LTCH, with a diagnosis considered to be unplanned and potentially preventable. This measure is claims-based, requiring no additional data collection or submission burden for IRFs. Because the measure denominator is based on IRF admissions, each Medicare beneficiary may be included in the measure multiple times within the measurement period. Readmissions counted in this measure are identified by examining Medicare FFS claims data for readmissions to either acute care hospitals (IPPS or CAH) or LTCHs that occur during a 30-day window beginning 2 days after IRF discharge. This measure is conceptualized uniformly across the PAC settings, in terms of the measure definition, the approach to risk adjustment, and the measure calculation. Our approach for defining potentially preventable hospital readmissions is described in more detail below.

Hospital readmissions among the Medicare population, including beneficiaries that utilize PAC, are common, costly, and often preventable.[66] [67] MedPAC and a study by Jencks et al. estimated that 17 to 20 percent of Medicare beneficiaries discharged from the hospital were readmitted within 30 days. MedPAC found that more than 75 percent of 30-day and 15-day readmissions and 84 percent of 7-day readmissions were considered ''potentially preventable.'' [68] In addition, MedPAC calculated that annual Medicare spending on potentially preventable readmissions were $12 billion for 30-day, $8 billion for 15-day, and $5 billion for 7-day readmissions in 2005.[69] For hospital readmissions from one post-acute care setting, SNFs, MedPAC deemed 76 percent of these readmissions as ''potentially avoidable''–associated with $12 billion in Medicare expenditures.[70] Mor et al. analyzed 2006 Medicare claims and SNF assessment data (Minimum Data Set), and reported a 23.5 percent readmission rate from SNFs, associated with $4.3 billion in expenditures.[71] Fewer studies have investigated potentially preventable readmission rates from the remaining post-acute care settings.

We have addressed the high rates of hospital readmissions in the acute care setting as well as in PAC. For example, we developed the following measure: All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502), as well as similar measures for other PAC providers (NQF #2512 for LTCHs and NQF #2510 for SNFs).[72] These measures are endorsed by the NQF, and the NQF-endorsed IRF measure (NQF #2502) was adopted into the IRF QRP in the FY 2016 IRF PPS final rule (80 FR 47087 through 47089). Note that these NQF-endorsed measures assess all-cause unplanned readmissions.

Several general methods and algorithms 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, approaches developed by MedPAC, and proprietary approaches, such as the 3M™ algorithm for Potentially Preventable Readmissions.[73] [74] [75] Recent

[66] Friedman, B., and Basu, J.: The rate and cost of hospital readmissions for preventable conditions. *Med. Care Res. Rev.* 61(2):225–240, 2004. doi:10.1177/1077558704263799.

[67] Jencks, S.F., Williams, M.V., and Coleman, E.A.: Rehospitalizations among patients in the Medicare Fee-for-Service Program. *N. Engl. J. Med.* 360(14):1418–1428, 2009. doi:10.1016/j.jvs.2009.05.045.

[68] MedPAC: Payment policy for inpatient readmissions, in *Report to the Congress: Promoting Greater Efficiency in Medicare.* Washington, DC, pp. 103–120, 2007. Available from *http://www.medpac.gov/documents/reports/Jun07_EntireReport.pdf*.

[69] ibid.

[70] ibid.

[71] Mor, V., Intrator, O., Feng, Z., et al.: The revolving door of rehospitalization from skilled nursing facilities. *Health Aff.* 29(1):57–64, 2010. doi:10.1377/hlthaff.2009.0629.

[72] National Quality Forum: *All-Cause Admissions and Readmissions Measures.* pp. 1–319, April 2015. Available from *http://www.qualityforum.org/Publications/2015/04/All-Cause_Admissions_and_Readmissions_Measures_-_Final_Report.aspx*.

[73] Goldfield, N.I., McCullough, E.C., Hughes, J.S., et al.: Identifying potentially preventable readmissions. *Health Care Finan. Rev.* 30(1):75–91,

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work led by Kramer et al. for MedPAC identified 13 conditions for which readmissions were deemed as potentially preventable among SNF and IRF populations.[76] [77] Although much of the existing literature addresses hospital readmissions more broadly and potentially avoidable hospitalizations for specific settings like long-term care, these findings are relevant to the development of potentially preventable readmission measures for PAC.[78] [79] [80]

Potentially Preventable Readmission Measure Definition: We conducted a comprehensive environmental scan, analyzed claims data, and obtained input from a TEP to develop a definition and list of conditions for which hospital readmissions are potentially preventable. The Ambulatory Care Sensitive Conditions and Prevention Quality Indicators, developed by AHRQ, served as the starting point in this work. For patients in the 30-day post-PAC discharge period, a potentially preventable readmission refers to a readmission for which the probability of occurrence could be minimized with adequately planned, explained, and implemented post-discharge instructions, including the establishment of appropriate follow-up ambulatory care. Our list of PPR conditions is categorized by 3 clinical rationale groupings:

- Inadequate management of chronic conditions;
- Inadequate management of infections; and
- Inadequate management of other unplanned events.

Additional details regarding the definition for potentially preventable readmissions are available in the document titled, Proposed Measure Specifications for Measures Proposed in the FY 2017 IRF QRP proposed rule, available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

This measure focuses on readmissions that are potentially preventable and also unplanned. Similar to the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502), this measure uses the current version of the CMS Planned Readmission Algorithm as the main component for identifying planned readmissions. A complete description of the CMS Planned Readmission Algorithm, which includes lists of planned diagnoses and procedures, can be found on the CMS Web site *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.* In addition to the CMS Planned Readmission Algorithm, this measure incorporates procedures that are considered planned in post-acute care settings, as identified in consultation with TEPs. Full details on the planned readmissions 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 Measure Specifications for Measures Proposed in the FY 2017 IRF QRP proposed rule, available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

The measure, Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP, assesses potentially preventable readmission rates while accounting for patient demographics, principal diagnosis in the prior hospital stay, comorbidities, and other patient factors. While estimating the predictive power of patient characteristics, the model also estimates a facility-specific effect, common to patients treated in each facility. This measure is calculated for each IRF based on the ratio of the predicted number of risk-adjusted, unplanned, potentially preventable hospital readmissions that occur within 30 days after an IRF discharge, including the estimated facility effect, to the estimated predicted number of risk-adjusted, unplanned inpatient hospital readmissions for the same patients treated at the average IRF. A ratio above 1.0 indicates a higher than expected readmission rate (worse) while a ratio below 1.0 indicates a lower than expected readmission rate (better). This ratio is referred to as the standardized risk ratio (SRR). The SRR is then multiplied by the overall national raw rate of potentially preventable readmissions for all IRF stays. The resulting rate is the risk-standardized readmission rate (RSRR) of potentially preventable readmissions.

An eligible IRF stay is followed until: (1) The 30-day post-discharge period ends; or (2) the patient is readmitted to an acute care hospital (IPPS or CAH) or LTCH. If the readmission is unplanned and potentially preventable, it is counted as a readmission in the measure calculation. If the readmission is planned, the readmission is not counted in the measure rate. This measure is risk adjusted. The risk adjustment modeling estimates the effects of patient characteristics, comorbidities, and select health care variables on the probability of readmission. More specifically, the risk-adjustment model for IRFs accounts for demographic characteristics (age, sex, original reason for Medicare entitlement), principal diagnosis during the prior proximal hospital stay, body system specific surgical indicators, IRF case-mix groups which capture motor function, comorbidities, and number of acute care hospitalizations in the preceding 365 days.

The measure is calculated using 2 consecutive calendar years of FFS claims data, to ensure the statistical reliability of this measure for facilities. In addition, we proposed a minimum of 25 eligible stays for public reporting of the measure.

A TEP convened by our measure contractor provided recommendations on the technical specifications of this measure, including the development of an approach to define potentially preventable hospital readmission for PAC. 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 Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/*

2008. Available from *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4195042/.*

[74] National Quality Forum: *Prevention Quality Indicators Overview.* 2008.

[75] 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.*

[76] Kramer, A., Lin, M., Fish, R., et al.: *Development of Inpatient Rehabilitation Facility Quality Measures: Potentially Avoidable Readmissions, Community Discharge, and Functional Improvement.* pp. 1–42, 2015. Available from *http://www.medpac.gov/documents/contractor-reports/development-of-inpatient-rehabilitation-facility-quality-measures-potentially-avoidable-readmissions-community-discharge-and-functional-improvement.pdf?sfvrsn=0.*

[77] Kramer, A., Lin, M., Fish, R., et al.: *Development of Potentially Avoidable Readmission and Functional Outcome SNF Quality Measures.* pp. 1–75, 2014. Available from *http://www.medpac.gov/documents/contractor-reports/mar14_snfqualitymeasures_contractor.pdf?sfvrsn=0.*

[78] Allaudeen, N., Vidyarthi, A., Maselli, J., et al.: Redefining readmission risk factors for general medicine patients. *J. Hosp. Med.* 6(2):54–60, 2011. doi:10.1002/jhm.805.

[79] [4] Gao, J., Moran, E., Li, Y.-F., et al.: Predicting potentially avoidable hospitalizations. *Med. Care* 52(2):164–171, 2014. doi:10.1097/MLR.0000000000000041.

[80] 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.x.

IMPACT-Act-Downloads-and-Videos.html. We also solicited stakeholder feedback on the development of this measure through a public comment period held from November 2 through December 1, 2015. Comments on the measure varied, with some commenters supportive of the measure, while others either were not in favor of the measure, or suggested potential modifications to the measure specifications, such as including standardized function data. A summary of the public comments is also available on our Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The MAP encouraged continued development of the proposed measure. Specifically, the MAP stressed the need to promote shared accountability and ensure effective care transitions. More information about the MAP's recommendations for this measure is available at *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx.* At the time, the risk-adjustment model was still under development. Following completion of that development work, we were able to test for measure validity and reliability as identified in the measure specifications document provided above. Testing results are within range for similar outcome measures finalized in public reporting and value-based purchasing programs, including the All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from IRFs (NQF #2502) adopted into the IRF QRP.

We reviewed the NQF's consensus endorsed measures and were unable to identify any NQF-endorsed measures focused on potentially preventable hospital readmissions. We are unaware of any other measures for this IMPACT Act domain that have been endorsed or adopted by other consensus organizations. Therefore, we proposed the Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP, under the Secretary's authority to specify non-NQF-endorsed measures under section 1899B(e)(2)(B) of the Act, for the IRF QRP for the FY 2018 payment determination and subsequent years, given the evidence previously discussed above.

We plan to submit the measure to the NQF for consideration of endorsement. We stated in the proposed rule that we intended to provide initial confidential feedback to providers, prior to public reporting of this measure, based on 2 calendar years of data from discharges in CY 2015 and 2016. We also stated that we intended to publicly report this measure using data from CY 2016 and 2017.

We invited public comment on our proposal to adopt the measure, Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP. We received several comments, which are summarized with our responses below.

Comment: We received several comments in support of the proposed Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP. In particular, MedPAC supported this measure and believes that IRFs should be held accountable for readmissions in the post-discharge readmission window. Some commenters preferred a potentially preventable readmission measure over an all-cause readmission measure.

Response: We thank commenters for their support of this measure.

Comment: One commenter specifically supported the inclusion of infectious conditions in the *inadequate management of infections and inadequate management of other unplanned events* categories in the measure's definition of potentially preventable hospital readmissions. Another commenter expressed concern over being ''penalized'' for readmissions that are clinically unrelated to a patient's original reason for IRF admission. One commenter recommended that CMS continue evaluating and testing the measure to ensure that the codes used for the PPR definition are clinically relevant. Another commenter expressed concern over using DRGs as the basis for defining the reasons for receiving inpatient rehabilitation or the reason for a subsequent hospital readmission given variation in coding practices in acute care hospitals.

Response: As described in the proposed rule, the definition for potentially preventable readmissions for this measure was developed based on existing evidence and was vetted by a TEP, which included clinicians and post-acute care experts. We also conducted a comprehensive environmental scan to identify conditions for which readmissions may be considered potentially preventable. Results of this environmental scan and details of the TEP input received were made available in the PPR TEP summary report available on the CMS Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.* We also solicited stakeholder feedback on the development of this measure through a public comment period held from November 2 through December 1, 2015. Comments on the measure varied, with some commenters supportive of the proposed measure, while others either were not in favor of the measure, or suggested potential modifications to the measure specifications, such as including standardized function data. A summary of the public comments is also available on the CMS Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Though readmissions may be considered potentially preventable even if they may not appear to be clinically related to the patient's original reason for IRF admission, there is substantial evidence that the conditions included in the definition may be preventable with adequately planned, explained, and implemented post-discharge instructions, including the establishment of appropriate follow-up ambulatory care. Furthermore, this measure is based on Medicare FFS claims data and it may not always be feasible to determine whether a subsequent readmission is or is not clinically related to the reason why the patient was receiving inpatient rehabilitation. We intend to conduct ongoing evaluation and monitoring of this measure, and will take these comments into consideration.

With regard to the comment related to DRGs, we wish to clarify that this measure does not use hospital DRGs to define PPRs or in the risk adjustment. Potentially preventable hospital readmissions are defined by the principal diagnosis on the readmission claim. Our risk-adjustment model uses diagnoses (not DRGs) from the prior hospital claim as risk adjusters. Though there may be variation in coding practices, claims data are the most reliable source to identify potentially preventable hospital readmissions post-IRF discharge. We would also like to clarify that the reason for receiving inpatient rehabilitation is captured as a risk adjuster by the use of the IRF PPS CMGs which also incorporate the RICs as well as function.

Comment: Several commenters expressed support for the cross-setting standardization of the inclusion and exclusion criteria for the PPR measures. MedPAC and another commenter

commented that the measure definition and risk adjustment should be identical across PAC settings so that potentially preventable readmission rates can be compared across settings. One commenter expressed concern over the ''nonalignment'' specifically between the IRF and SNF versions of the measure, adding that this may lead to confusion. Another commenter suggested a single or harmonized measure to better inform patients, caregivers, and payers. One comment encouraged CMS to assess readmission measures across the agency's programs to ensure that they promote collaboration and support readmission reduction efforts.

Response: The PPR definition (that is, list of conditions for which readmissions would be considered potentially preventable) is aligned for measures with the same readmission window, regardless of PAC setting. Specifically, the post-PAC discharge PPR measures that were developed for each of the PAC settings contain the same list of PPR conditions. Although there are some minor differences in the specifications across these potentially preventable readmissions measures (for example, years of data used to calculate the measures to ensure reliability and some of the measure exclusions necessary to attribute responsibility to the individual settings), the IMPACT Act PPR measures are standardized. As described for all IMPACT Act measures in section VIII.B in this final rule, the statistical approach for risk adjustment is also aligned across the measures; however, there is variation in the exact risk adjusters. The risk-adjustment models are empirically driven and differ between measures as a consequence of case mix differences, which is necessary to ensure that the estimates are valid. We appreciate the comment that the readmission measures across our programs be assessed to ensure they promote collaboration and support readmission reduction efforts. As we continually evaluate and monitor the PAC quality reporting and other CMS programs, we will take the commenter's suggestion into consideration.

Comment: Several commenters expressed concern that this measure would capture outcomes that are outside of PAC providers' control, specifically with respect to chronically ill patients, instances of poor patient compliance, unhealthy choices, and various SDS factors, such as lack of resources or limited access to follow up or primary care. One commenter also expressed concern over the added risk of caring for a high volume of transplant patients that other IRFs may choose not to admit. Another commenter noted that even though the risk adjustment will account for some of these circumstances, it is difficult for providers to fully evaluate the risk-adjustment model because the testing and risk-adjustment coefficients have not been finalized. A few commenters recommend these measures be suspended until CMS explains how the measures will treat each of these scenarios.

Response: As noted by one commenter, the measure's comprehensive risk-adjustment approach and exclusion criteria are intended to capture many of these factors. As described above, there is substantial evidence that the conditions included in the definition may be preventable with adequately planned, explained, and implemented post-discharge instructions, including the establishment of appropriate follow-up ambulatory care. We would like to clarify that the focus of the PPR measure is to identify excess PPR rates for the purposes of quality improvement.

We would also like to clarify that the finalized risk-adjustment models and coefficients are included in the measure specifications available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

Comment: Several commenters expressed concern over the overlap between the proposed PPR measure and other IRF QRP measures, including the existing all-cause readmission measure. Commenters expressed concern that public reporting of more than one hospital readmission measure for IRFs may result in confusion among the public; the commenters also noted providers could face confusion over two distinct but similar measures, which could potentially pose challenges for quality improvement efforts. One commenter noted that the proposed PPR measures and the existing all-cause measure are distinct yet overlapping, adding that the PPR measure is a subset of the all-cause readmission measure. Given this overlap, one commenter was concerned that providers who perform poorly on the all-cause readmission measure are likely to do so for the proposed PPR measure as well, and suggested CMS suspend the measure until it could evaluate the necessity of each measure. Some commenters requested that CMS clarify the overlap and intent of these measures, and provide more education to providers and the public on the multiple IRF QRP readmission measures. Another commenter suggested that CMS conduct dry runs of the readmission measures, similar to those conducted for the all-cause measure.

One commenter supported the use of Medicare claims data to calculate these measures because it does not require the submission of additional data by IRFs. Another commenter noted that despite the lack of a data collection burden for providers, multiple readmission measures in the program will create burden on the part of providers to track and improve performance. Another commenter expressed concern that the measures are ''extensive'' and will place additional financial burden on providers.

Response: The All-Cause Unplanned Hospital Readmission Measure for 30 Days Post-IRF Discharge (NQF #2502) was adopted for the IRF QRP prior to the IMPACT Act. The measure of potentially preventable hospital readmissions was developed in response to the statutory mandate of the IMPACT Act. We would like to clarify that providers are not held financially accountable for their performance on these measures, but only whether they report the necessary data for the IRF QRP.

With regard to overlap with the existing IRF QRP readmission measure, retaining the all-cause measure will allow us to monitor trends in both all-cause and PPR rates in order to assess the extent to which changes in facility performance for one measure are reflected in the other. We are committed to ensuring that measures in the IRF QRP are useful in assessing quality and will continue to evaluate all readmission measures over time.

We thank commenters for their feedback related to provider burden on the measure. We would like to note that the PPR measure uses Medicare claims data and is not collected by means of an assessment instrument. Therefore, the measure does not increase data collection burden on the provider as this data is currently collected by providers. Despite the lack of data collection burden, we appreciate the comments that more education will be required for the public and providers to understand the differences between the readmission measures in the IRF QRP.

Comment: Several commenters raised concerns over the risk-adjustment approach for the PPR measure. One commenter expressed concern that the HCC risk-adjustment method is insufficient at predicting costs for certain patient populations. The commenter suggested CMS research and develop a refined risk-adjustment model that encompasses more of the diversity

and complexity of PAC patients and is more sensitive to their levels of resource use. Several commenters expressed concern that the proposed measure is not adjusted for socio-economic factors, and a couple commenters, including MedPAC, suggested the use of peer group comparisons of performance rates to address this issue.

Another commenter supported the proposed risk-adjustment methodology commenting it will provide a valid assessment of quality of care in preventing unplanned, preventable hospital readmissions. One commenter also suggested that, in addition to the measure exclusion for non-surgical treatment of cancer, that other conditions with similar disease trajectories be excluded from the measure, citing end-stage Multiple Sclerosis (MS), motor neuron disease, and Alzheimer's disease.

Response: We would like to note that the measure is fully developed and the finalized risk-adjustment model and coefficients are included in the measure specifications available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

The HCCs were developed to separate clinically-related codes by Medicare utilization implications; they represent diagnosis-based, clinically meaningful clusters of ICD codes that have also been grouped by cost implications. When we apply HCCs for risk adjustment of quality or resources use measures, we do not use the HCC models applied to payment. In our measure development, we typically test individual HCCs that are relevant to the outcome of interest; we estimate the effects of the individual HCCs or clusters on the dependent variable in the particular model and retain those that are significant or meaningful predictors of outcomes. We believe that risk adjusting for individual HCCs or small clusters provides greater sensitivity than using a single comorbidity index, which is based on selected diagnoses. Our approach accounts for an average effect for each comorbidity or comorbidity group, rather than an overall burden of comorbidities.

The HCCs are more comprehensive than the simpler diagnosis-based systems, such as the Elixhauser Comorbidity Index or Charlson Comorbidity Index, which were targeted for predicting specific outcomes (for example, hospital mortality). We believe that HCCs provide a good representation of health risk, and their use to examine outcomes other than costs is supported in the literature.[81] [82] A study comparing the ability of five comorbidity indices to predict discharge functional status of IRF patients found that HCCs slightly outperformed other comorbidity indices.[83] The superior performance of HCCs was hypothesized to be related to the inclusion of more medical conditions in HCCs, and the inclusion of more ICD codes per condition in HCCs, making them a slightly more sensitive index for predicting clinical outcomes compared with other comorbidity indices.[84]

We wish to clarify that the model included in the specifications using HCCs as risk adjusters for comorbidities posted for the proposed rule demonstrated sufficient discrimination power. The model had a c-statistic of 0.74 which is within range, if not higher than, similar readmission measures finalized in public reporting programs, including the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502) previously adopted for the IRF QRP.

With regard to the suggestions that the model include sociodemographic factors and the suggestion pertaining to an approach with which to convey data comparisons, we refer the readers to section VIII.F of this final rule where we also discuss these topics. In response to the suggestion to include additional conditions from the measure, such as end-stage MS, motor neuron disease, and Alzheimer's disease, we wish to clarify that we risk adjust for these clinical characteristics in our risk-adjustment model. These are low prevalence conditions and the claims data are limited in their ability to identify disease progression. However, we will take this suggestion into consideration.

Comment: Several commenters expressed concern that the measures are not NQF-endorsed, and some had additional concerns over measure testing and development. Some of these commenters recommended that CMS should adopt measures endorsed by the NQF in quality reporting programs or recommended that CMS submit the measures through the NQF endorsement process as soon as feasible.

Response: With regard to NQF endorsement, as noted in the proposed rule, we intend to submit this measure to NQF for consideration of endorsement. In addition, we noted that we reviewed the NQF's consensus endorsed measures and were unable to identify any NQF endorsed measures focused on potentially preventable hospital readmissions. We are unaware of any other measures for this IMPACT Act domain that have been endorsed or adopted by other consensus organizations. Therefore, we proposed the Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP, under the Secretary's authority to specify non-NQF endorsed measures under section 1899B(e)(2)(B) of the Act, for the IRF QRP.

We would also like to clarify that the finalized risk-adjustment models and coefficients are included in the measure specifications available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.* We will make additional testing results available in the future.

We would like to clarify that the MAP encouraged continued development of the proposed measure. More information about the MAP's recommendations for this measure is available at *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx.*

Comment: Some commenters raised concerns over unintended consequences of the measure. One commenter was concerned that the measure could create an incentive for IRFs to be selective about the types of patients they admit (that is, ''cherry pick'' their patients) in order to reduce the risk of PPRs. Another comment suggested that IRFs should not be held accountable for IRF patients with planned procedures that are not admitted and treated as observation stays and requested that CMS provide clarification on how these types of patients will be assessed by the measure.

Response: We intend to conduct ongoing monitoring to assess for potential unintended consequences

[81] Kumar A, Graham JE, Resnik L, Karmarkar AM, Tan A, Deutsch A, Ottenbacher KJ. Comparing Comorbidity Indices to Predict Post-Acute Rehabilitation Outcomes in Older Adults. Am J Phys Med Rehabil. 2016 May 4. [Epub ahead of print]

[82] Li P, Kim MM, Doshi JA. Comparison of the performance of the CMS Hierarchical Condition Category (CMS–HCC) risk adjuster with the Charlson and Elixhauser comorbidity measures in predicting mortality. BMC Health Serv Res. 2010 Aug 20;10:245. doi: 10.1186/1472–6963–10–245.

[83] Kumar A, Graham JE, Resnik L, Karmarkar AM, Tan A, Deutsch A, Ottenbacher KJ. Comparing Comorbidity Indices to Predict Post-Acute Rehabilitation Outcomes in Older Adults. Am J Phys Med Rehabil. 2016 May 4. [Epub ahead of print]

[84] Kumar A, Graham JE, Resnik L, Karmarkar AM, Tan A, Deutsch A, Ottenbacher KJ. Comparing Comorbidity Indices to Predict Post-Acute Rehabilitation Outcomes in Older Adults. Am J Phys Med Rehabil. 2016 May 4. [Epub ahead of print]

associated with the implementation of this measure and will take these suggestions into account.

In response to the concern regarding holding an IRF accountable for planned procedures that are treated as observation stays instead of planned hospital readmissions, we appreciate the commenter's concern and expect that this is a relatively infrequent occurrence given that most of the planned procedures are invasive surgical procedures. The measure is of hospital readmissions and does not count planned procedures that are treated as observation stays. We will take this issue into consideration for future measure development.

Comment: One commenter expressed concern over using claims data for hospital readmissions, noting that these data may not be accurate.

Response: We appreciate the commenter's concern over the accuracy of claims data. However, we wish to clarify that claims data have been validated for the purposes of assessing hospital readmissions and are used for several NQF-endorsed measures adopted for CMS programs, including the IRF QRP. Multiple studies have been conducted to examine the validity of using Medicare hospital claims to calculate several NQF-endorsed quality measures for public reporting.[85] [86] [87]Additionally, although assessment and other data sources may be valuable for risk adjustment, we are not aware of any other data source aside from Medicare claims data that could be used to reliably assess potentially preventable hospital readmissions for this measure.

Final Decision: After careful consideration of the public comments, we are finalizing our proposal to adopt the measure, Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP. Measure Specifications for Measures Adopted in the FY 2017 IRF QRP final rule are available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

[85] Bratzler DW, Normand SL, Wang Y, et al. An administrative claims model for profiling hospital 30-day mortality rates for pneumonia patients. PLoS One 2011;6(4):e17401.

[86] Keenan PS, Normand SL, Lin Z, et al. An administrative claims measure suitable for profiling hospital performance on the basis of 30-day all-cause readmission rates among patients with heart failure. Circulation 2008;1(1):29–37.

[87] Krumholz HM, Wang Y, Mattera JA, et al. An administrative claims model suitable for profiling hospital performance based on 30-day mortality rates among patients with heart failure. Circulation 2006;113:1693–1701.

4. Potentially Preventable Within Stay Readmission Measure for Inpatient Rehabilitation Facilities

In addition to the measure finalized in section VIII.F.3. of this final rule, Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP, we proposed the Potentially Preventable Within Stay Readmission Measure for IRFs for the FY 2018 payment determination and subsequent years. This measure is similar to the Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP; however, the readmission window for this measure focuses on potentially preventable hospital readmissions that take place *during* the IRF stay as opposed to during the 30-day post-discharge period. The two PPR measures are intended to function in tandem, covering readmissions during the IRF stay and for 30 days following discharge from the IRF. Utilizing two PPR measures in the IRF QRP will enable us to assess different aspects of care and care coordination. The within stay measure focuses on the care transition into inpatient rehabilitation as well as the care provided during the IRF stay, whereas the 30-day post-IRF discharge measure focuses on transitions from the IRF into less-intensive levels of care or the community.

Similar to the Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP measure for IRFs, this measure assesses the facility-level risk-standardized rate of unplanned, potentially preventable hospital readmissions during the IRF stay. Hospital readmissions include readmissions to a short-stay acute-care hospital or an LTCH, with a diagnosis considered to be unplanned and potentially preventable. This Medicare FFS measure is claims-based, requiring no additional data collection or submission burden for IRFs. As described in section VIII.F.3. of this final rule, we developed the approach for defining PPR measure based on a comprehensive environmental scan, analysis of claims data, and TEP input. Also, we obtained public comment.

The definition for PPRs differs by readmission window. For the within-IRF stay window, PPRs should be avoidable with sufficient medical monitoring and appropriate patient treatment. The list of PPR conditions for the Potentially Preventable Within Stay Readmission Measure for IRFs are categorized by 4 clinical rationale groupings:

- Inadequate management of chronic conditions;
- Inadequate management of infections;
- Inadequate management of other unplanned events; and
- Inadequate injury prevention.

Additional details regarding the definition for PPRs are available in our document titled, Proposed Measure Specifications for Measures Proposed in the FY 2017 IRF QRP proposed rule available on our Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

Section VIII.F of this final rule discusses the relevant background and details that are also relevant for this measure. This measure defines planned readmissions in the same manner as described in section VIII.F.3 of this final rule, for the Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP. In addition, similar to the Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP measure, this measure uses the same risk-adjustment and statistical approach as described in section VIII.F.3 of this final rule. Note the full methodology is detailed in the document titled, Proposed Measure Specifications for Measures Proposed in the FY 2017 IRF QRP proposed rule, at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.* This measure is also based on 2 consecutive calendar years of Medicare FFS claims data.

A TEP convened by our measure contractor provided recommendations on the technical specifications of this measure, including the development of an approach to define potentially preventable hospital readmission for PAC. 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 our Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.* We also solicited stakeholder feedback on the development of this measure through a public comment period held from November 2 through December 1, 2015. Comments on this and other PAC measures of PPR measures varied, with some commenters supportive of the proposed measure, while others either were not in favor of the measure, or suggested potential modifications to the

measure specifications, such as including standardized function data. A summary of our public comment period is also available on our Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The MAP encouraged continued development of the proposed measure. Specifically, the MAP stressed the need to promote shared accountability and ensure effective care transitions. More information about the MAP's recommendations for this measure is available at *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx.* At the time, the risk-adjustment model was still under development. Following completion of that development work, we were able to test for measure validity and reliability as described in the measure specifications document provided above. Testing results are within range for similar outcome measures finalized in public reporting and value-based purchasing programs, including the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502) that we previously adopted into the IRF QRP.

We plan to submit the measure to the NQF for consideration of endorsement. We stated in the proposed rule that we intended to provide initial confidential feedback to providers, prior to public reporting of this measure, based on 2 calendar years of claims data from discharges in 2015 and 2016. We proposed a minimum of 25 eligible stays in a given IRF for public reporting of the measure for that IRF. We also stated that we intended to publicly report this measure using claims data from calendar years 2016 and 2017.

We invited public comment on our proposal to adopt this measure, Potentially Preventable Within Stay Readmission Measure for IRFs. We received several comments, which are summarized with our responses below.

Comment: CMS received comments in support of this measure. In particular, MedPAC supported this measure, and further suggested that it should be applied identically across the four PAC settings so that post-discharge rates can be meaningfully compared.

Response: We wish to clarify that this particular measure, developed and proposed for use in the IRF QRP, is unique in that it is a within stay readmission measure. Analogous measures applicable to other PAC settings may be considered in future rulemaking.

Comment: Several commenters expressed concern over cross-setting alignment of measures, some urging CMS to delay implementation of this measure until there are equivalent within stay PPR measures for each PAC setting. Commenters noted this measure is not required by the IMPACT Act and that incongruences between measures in the different PAC settings present concerns for cross-setting comparisons and potential confusion for IRFs about their quality performance. One commenter was particularly concerned about the differences between the IRF within stay measure and the SNF PPR measure proposed for the SNF VBP Program that assess PPRs 30 days after discharge from the prior hospital.

Response: We are clarifying that though this within-stay PPR measure is not required by the IMPACT Act, capturing potentially preventable readmission measures during an IRF stay assesses important aspects of inpatient post-acute care. The measure is a starting point for this work, which is being conducted in phases, and additional measures that calculate PPRs using different readmission windows in other PAC settings will be considered in the future. We will take this comment into consideration.

Comment: Some commenters expressed that IRFs may not be able to control or prevent hospital readmissions that take place during an IRF stay, especially within the first few days of admission, if patients are admitted to IRFs prior to the availability of diagnostic testing results, or if they did not receive adequate acute care. One commenter cited the example of patients with leukemia, who are often readmitted to the hospital for treatment. Another commenter noted that even though the risk adjustment will account for some of these circumstances, it is difficult for providers to fully evaluate the risk-adjustment model because the testing and risk-adjustment coefficients have not been finalized. The commenter recommended these measures be suspended until CMS explains how the measures will treat each of these scenarios. Commenters suggested that the IRF within-stay PPR measure should account for the three-day, short-stay and transfer care policies that exist in the IRF PPS. One commenter expressed concern that the proposed measure's readmission window and IRF payment rules would cause a ''double penalty'' for short-stay episodes that end in a readmission. Commenters noted that the home health measures account for short-stay payment policies and that the IRF measure should be designed in a similar manner.

Response: We recognize the concerns raised related to potential delays in receiving diagnostic information and/or inadequate care provided in the prior acute setting for some patients. However, we wish to clarify that this measure is intended to address potentially preventable hospital readmissions and does not count all hospital readmissions that take place during the IRF stay. The goal of this measure is to improve care transitions and coordination of care, which is important for all patients. Furthermore, providers assume the responsibility for this outcome for all patients that they admit into their facility, including those with shorter lengths of stay.

We would like to clarify that for the commenter's example regarding patients with leukemia, these patients would most likely be excluded from the measure because non-surgical treatment of cancer is a measure exclusion. Based on analysis of data from 2013, 0.5 percent of the IRF sample was excluded because the prior short-term acute-care stay was for nonsurgical treatment of cancer which includes leukemia. In addition, leukemia and other cancer patients that are not excluded from the measure are more likely being readmitted for planned procedures and treatments; however, this is a measure of potentially preventable hospital readmissions that are also unplanned.

With regard to excluding readmissions during the first three days of an IRF stay, we would like to clarify that the policy cited is for IRF payment determination and is not related to measurement of quality of care. This measure focuses on care transitions and coordination which is relevant to all patients, including those with shorter lengths of stay. Furthermore, excluding readmissions during the first three days of an IRF stay may result in transferring patients back sooner in order to exclude patients from the measure.

We would also like to clarify that the finalized risk-adjustment models and coefficients are included in the measure specifications available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

Comment: Some commenters expressed concern over the ''multiplicity'' of the IRF QRP's readmission measures, adding that this may lead to confusion and make it difficult for IRFs to track and improve performance. There was also concern

that this IRF within stay PPR measure was not required by the IMPACT Act, nor did it align with a domain in CMS's National Quality Strategy. Several commenters expressed concern over the overlap between the PPR measure and the existing all-cause readmission measures adopted for the IRF QRP. A few commenters recommended CMS not to adopt this measure, or to postpone implementation, commenting that the purpose and implications of the measure were ambiguous and its introduction was premature. The commenters respectfully recommended CMS not to adopt this measure, and some commenters suggested postponing the implementation of this measure pending further development or use in a cross-setting and standardized manner.

Response: We appreciate the comment related to the potential challenges that may be associated with proposing multiple readmission measures for the program. However, given that each measure focuses on a different aspect of care, we believe that each measure provides value in the program. We are committed to ensuring that measures in the IRF QRP are useful in assessing quality and will evaluate the readmission measures in the future.

In addition, we wish to clarify that though this measure is not required by the IMPACT Act, capturing potentially preventable readmission measures during an IRF stay assesses important aspects of inpatient post-acute care, including care coordination. Like other hospital readmission measures for post-acute care, the measure fits within the National Quality Strategy communication and care coordination priority area. We also wish to clarify that this measure does not overlap readmission captured in other readmission measures proposed or adopted for the IRF QRP.

We would also like to clarify that the full measure specifications including preliminary results were made available at the time of the proposed rule's display. The measure is fully developed and the final measure specifications, including the finalized risk-adjustment models and descriptive statistics on IRFs' risk-standardized within-stay PPR rates, are available are included in the measure specifications available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

Comment: One commenter specifically supported the inclusion of infectious conditions in the *inadequate management of infections and inadequate management of other unplanned events* categories in the measure's definition of potentially preventable hospital readmissions. Another commenter expressed support for the inclusion of chronic conditions and infections as conditions for which readmissions would be considered potentially preventable, citing infection prevention and other interventions that are effective in preventing such readmissions. Another commenter expressed appreciation for the focus on preventable readmissions, but recommended that CMS continue evaluating and testing the measure to ensure that the codes used for the PPR definition are clinically relevant. One commenter expressed concern over being ''penalized'' for readmissions that are clinically unrelated to a patient's original reason for IRF admission.

Response: As described in the proposed rule, the definition for potentially preventable readmissions for this measure was developed based on existing evidence and was vetted by a TEP, which included clinicians and post-acute care experts. We also conducted a comprehensive environmental scan to identify conditions for which readmissions may be considered potentially preventable. Results of this environmental scan and details of the TEP input received were made available in the PPR TEP summary report available on the CMS Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Though readmissions may be considered potentially preventable even if they may not appear to be clinically related to the patient's original reason for IRF admission, there is substantial evidence that the conditions included in the definition may be preventable with sufficient medical monitoring and appropriate patient treatment. Furthermore, this measure is based on Medicare claims data and it may not always be feasible to determine whether a subsequent readmission is or is not clinically related to the reason why the patient was receiving inpatient rehabilitation. We intend to conduct ongoing evaluation and monitoring of this measure, and will take these comments into consideration.

Comment: One commenter expressed concern that the measure could create an incentive for IRFs to be selective about the types of patients they admit in order to reduce the risk of PPRs (that is, ''cherry pick'' less complex patients for IRF admission). Another commenter noted this measure could incentivize longer acute hospital stays and delay admission to IRFs, expressing concern over being penalized for brief readmissions for follow-up procedures.

Response: We wish to clarify that this measure does not count planned procedures as these types of readmissions do not reflect quality of care or care transitions. We intend to conduct ongoing monitoring to assess for potential unintended consequences associated with the implementation of this measure, and will take these suggestions into account.

Comment: One commenter raised concerns over the risk-adjustment approach for the within-stay PPR measure. The commenter expressed concern that the HCC risk-adjustment method is insufficient at predicting costs for certain patient populations. The commenters suggested CMS reconsider the validity and reliability of the HCC risk-adjustment model, and research and develop a refined risk-adjustment model that encompasses more of the diversity and complexity of PAC patients and is more sensitive to their levels of resource use. The commenter also expressed concern that the proposed measure is not adjusted for socio-economic factors.

Response: We appreciate the comment received regarding the risk-adjustment model and will take this comment into consideration. We refer readers to our response on the use of HCCs as described in section VIII.F.3. of this final rule. We wish to clarify that the model included in the specifications using HCCs as risk adjusters for comorbidities posted for the proposed rule demonstrated more than adequate discrimination power. The model had a c-statistic of 0.74 which is within range if not higher for similar readmission measures finalized in public reporting programs, including the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502) previously adopted for the IRF QRP. We would also like to clarify that the finalized risk-adjustment models and coefficients are included in the measure specifications available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

With regard to the suggestions that the model include sociodemographic factors and the suggestion pertaining to an approach with which to convey data comparisons, we refer the readers to section VIII.F of this final rule where we also discuss these topics.

Comment: Some commenters expressed concern over provider burden and questioned CMS's intention of applying both all-cause and potentially preventable readmission measures. The commenters also noted that with the finalization of all required measures by the IMPACT Act, the industry would be subject to significant changes and an increased data reporting burden with regard to the quality reporting program. Some commenters noted that there would not be an additional reporting or data collection burden given the measure is claim-based; however, providers would take on additional burdens, including understanding the measure design, evaluating its implications, and reconciling the CASPER Quality Measure feedback data.

Response: We would like to note that the within-stay PPR measures use a data source of claims data and are not collected by means of an assessment instrument. Therefore, the measure does not increase data collection burden on the provider as this data is currently collected by providers. Despite the lack of data collection burden, we appreciate the comments that more education will be required for the public and providers to understand the differences between the readmission measures in the IRF QRP. We also wish to clarify that the within-stay readmission measure does not overlap any existing readmission measures.

Comment: Several commenters expressed concern that the measures are not NQF-endorsed, some with additional concerns over measure testing and development. Some of these commenters recommended that CMS should adopt measures endorsed by the NQF in quality reporting programs or recommended that CMS submit the measures through the NQF endorsement process as soon as feasible.

Response: With regard to NQF endorsement, as noted in the proposed rule, we intend to submit this measure to NQF for consideration of endorsement. We are unaware of any other measures that assess potentially preventable readmissions during an IRF stay. We appreciate the comments related to the measure's testing. We would also like to clarify that the finalized risk-adjustment models and coefficients are included in the measure specifications available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.* We will make results of additional testing and evaluation of the measure beyond those provided in the final measure specifications available in the future.

Final Decision: After careful consideration of the public comments, we are finalizing our proposal to adopt this measure, Potentially Preventable Within Stay Readmission Measure for IRFs. Measure Specifications for Measures Adopted in the FY 2017 IRF QRP Final Rule are available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

G. IRF QRP Quality Measure Finalized for the FY 2020 Payment Determination and Subsequent Years

We proposed to adopt one new quality measure to meet the requirements of the IMPACT Act beginning with the FY 2020 payment determination and subsequent years. The measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC IRF QRP, addresses the IMPACT Act quality domain of Medication Reconciliation.

1. Quality Measure Addressing the IMPACT Act Domain of Medication Reconciliation: Drug Regimen Review Conducted With Follow-Up for Identified Issues—Post Acute Care Inpatient Rehabilitation Facility Quality Reporting Program

Sections 1899B(a)(2)(E)(i)(III) and 1899B(c)(1)(C) of the Act, as added by the IMPACT Act, require the Secretary to specify a quality measure to address the quality domain of medication reconciliation by October 1, 2018 for IRFs, LTCHs and SNFs by January 1, 2017 for HHAs. We proposed to adopt the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC IRF QRP, for the IRF QRP as a patient-assessment based, cross-setting quality measure to meet the IMPACT Act requirements with data collection beginning October 1, 2018 for the FY 2020 payment determinations and subsequent years.

This measure assesses whether PAC providers were responsive to potential or actual clinically significant medication issue(s) when such issues were identified. Specifically, the quality measure reports the percentage of patient stays in which a drug regimen review was conducted at the time of admission and timely follow-up with a physician occurred each time potential clinically significant medication issues were identified throughout that stay.

For this quality measure, drug regimen review is defined as the review of all medications or drugs the patient is taking to identify any potential clinically significant medication issues. The quality measure utilizes both the processes of medication reconciliation and a drug regimen review, in the event an actual or potential medication issue occurred. The measure informs whether the PAC facility identified and addressed each clinically significant medication issue and if the facility responded or addressed the medication issue in a timely manner. Of note, drug regimen review in PAC settings is generally considered to include medication reconciliation and review of the patient's drug regimen to identify potential clinically significant medication issues.[88] This measure is applied uniformly across the PAC settings.

Medication reconciliation is a process of reviewing an individual's complete and current medication list. Medication reconciliation is a recognized process for reducing the occurrence of medication discrepancies that may lead to Adverse Drug Events (ADEs).[89] Medication discrepancies occur when there is conflicting information documented in the medical records. The World Health Organization regards medication reconciliation as a standard operating protocol necessary to reduce the potential for ADEs that cause harm to patients. Medication reconciliation is an important patient safety process that addresses medication accuracy during transitions in patient care and in identifying preventable ADEs.[90] The Joint Commission added medication reconciliation to its list of National Patient Safety Goals (2005), suggesting that medication reconciliation is an integral component of medication safety.[91] The Society of Hospital Medicine published a statement in agreement of the Joint Commission's emphasis and value of medication reconciliation as a patient safety goal.[92] There is universal agreement that medication reconciliation directly addresses patient safety issues that can result from medication

[88] Institute of Medicine. Preventing Medication Errors. Washington DC: National Academies Press; 2006.

[89] Ibid.

[90] Leotsakos A., et al. Standardization in patient safety: The WHO High 5s project. Int J Qual Health Care. 2014:26(2):109–116.

[91] The Joint Commission. 2016 Long Term Care: National Patient Safety Goals Medicare/Medicaid Certification-based Option. (NPSG.03.06.01).

[92] Greenwald, J.L., Halasyamani, L., Greene, J., LaCivita, C., et al. (2010). Making inpatient medication reconciliation patient centered, clinically relevant and implementable: A consensus statement on key principles and necessary first steps. Journal of Hospital Medicine, 5(8), 477–485.

miscommunication and unavailable or incorrect information.[93] [94] [95]

The performance of timely medication reconciliation is valuable to the process of drug regimen review. Preventing and responding to ADEs is of critical importance as ADEs account for significant increases in health services utilization and costs [96] [97] [98] including subsequent emergency room visits and re-hospitalizations.[99] Annual health care costs in the United States from ADEs are estimated at $3.5 billion, resulting in 7,000 deaths annually.[100] [101]

Medication errors include the duplication of medications, delivery of an incorrect drug, inappropriate drug omissions, or errors in the dosage, route, frequency, and duration of medications. Medication errors are one of the most common types of medical error and can occur at any point in the process of ordering and delivering a medication. Medication errors have the potential to result in an ADE.[102] [103] [104] [105] [106] [107] Inappropriately prescribed medications are also considered a major healthcare concern in the United States for the elderly population, with costs of roughly $7.2 billion annually.[108]

There is strong evidence that medication discrepancies occur during transfers from acute care facilities to post-acute care facilities. Discrepancies occur when there is conflicting information documented in the medial records. Almost one-third of medication discrepancies have the potential to cause patient harm.[109] An estimated 50 percent of patients experienced a clinically important medication error after hospital discharge in an analysis of two tertiary care academic hospitals.[110]

Medication reconciliation has been identified as an area for improvement during transfer from the acute care facility to the receiving post-acute care facility. PAC facilities report gaps in medication information between the acute care hospital and the receiving post-acute-care setting when performing medication reconciliation.[111] [112] Hospital discharge has been identified as a particularly high risk time point, with evidence that medication reconciliation identifies high levels of discrepancy.[113] [114] [115] [116] [117] [118] Also, there is evidence that medication reconciliation discrepancies occur throughout the patient stay.[119] [120] For older patients, who may have multiple comorbid conditions and thus multiple medications, transitions between acute and post-acute care settings can be further complicated,[121] and medication reconciliation and patient knowledge (medication literacy) can be inadequate post-discharge.[122] The quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP, evaluates an important component of care coordination for PAC settings and will affect a large proportion of the Medicare population who transfer from hospitals into PAC services each year. For example, in 2013, 1.7 million Medicare FFS beneficiaries had SNF stays, 338,000 beneficiaries had IRF stays, and 122,000 beneficiaries had LTCH stays.[123]

A TEP convened by our measure development contractor provided input on the technical specifications of this quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP, including components of reliability, validity, and the feasibility of implementing the measure across PAC settings. The TEP supported the measure's implementation across PAC settings and was supportive of our plans to standardize this measure for cross-setting development. A summary of the TEP proceedings is available on the PAC Quality Initiatives Downloads and

[93] Leotsakos A., et al. Standardization in patient safety: The WHO High 5s project. Int J Qual Health Care. 2014:26(2):109–116.

[94] The Joint Commission. 2016 Long Term Care: National Patient Safety Goals Medicare/Medicaid Certification-based Option. (NPSG.03.06.01).

[95] IHI. Medication Reconciliation to Prevent Adverse Drug Events [Internet]. Cambridge, MA: Institute for Healthcare Improvement; [cited 2016 Jan 11]. Available from: *http://www.ihi.org/topics/adesmedicationreconciliation/Pages/default.aspx.*

[96] Institute of Medicine. Preventing Medication Errors. Washington DC: National Academies Press; 2006.

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[99] Kohn LT, Corrigan JM, Donaldson MS. To Err Is Human: Building a Safer Health System Washington, DC: National Academies Press; 1999.

[100] Greenwald, J.L., Halasyamani, L., Greene, J., LaCivita, C., et al. (2010). Making inpatient medication reconciliation patient centered, clinically relevant and implementable: A consensus statement on key principles and necessary first steps. Journal of Hospital Medicine, 5(8), 477–485.

[101] Phillips, David P.; Christenfeld, Nicholas; and Glynn, Laura M. Increase in US Medication-Error Deaths between 1983 and 1993. The Lancet. 351:643–644, 1998.

[102] Institute of Medicine. To err is human: Building a safer health system. Washington, DC: National Academies Press; 2000.

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[106] Barker KN, Flynn EA, Pepper GA, Bates DW, & Mikeal RL. Medication errors observed in 36 health care facilities. JAMA. 2002: 162(16):1897–1903.

[107] Bates DW, Boyle DL, Vander Vliet MB, Schneider J, & Leape L. Relationship between medication errors and adverse drug events. J Gen Intern Med. 1995:10(4): 199–205.

[108] Fu, Alex Z., et al. ''Potentially inappropriate medication use and healthcare expenditures in the US community-dwelling elderly.'' Medical care 45.5 (2007): 472–476.

[109] Wong, Jacqueline D., et al. ''Medication reconciliation at hospital discharge: Evaluating discrepancies.'' Annals of Pharmacotherapy 42.10 (2008): 1373–1379.

[110] Kripalani S, Roumie CL, Dalal AK, et al. Effect of a pharmacist intervention on clinically important medication errors after hospital discharge: A randomized controlled trial. Ann Intern Med. 2012:157(1):1–10.

[111] Gandara, Esteban, et al. ''Communication and information deficits in patients discharged to rehabilitation facilities: An evaluation of five acute care hospitals.'' Journal of Hospital Medicine 4.8 (2009): E28–E33.

[112] Gandara, Esteban, et al. ''Deficits in discharge documentation in patients transferred to rehabilitation facilities on anticoagulation: Results of a system wide evaluation.'' Joint Commission Journal on Quality and Patient Safety 34.8 (2008): 460–463.

[113] Coleman EA, Smith JD, Raha D, Min SJ. Post hospital medication discrepancies: Prevalence and contributing factors. Arch Intern Med. 2005 165(16):1842–1847.

[114] Wong JD, Bajcar JM, Wong GG, et al. Medication reconciliation at hospital discharge: Evaluating discrepancies. Ann Pharmacother. 2008 42(10):1373–1379.

[115] Hawes EM, Maxwell WD, White SF, Mangun J, Lin FC. Impact of an outpatient pharmacist intervention on medication discrepancies and health care resource utilization in post hospitalization care transitions. *Journal of Primary Care & Community Health.* 2014; 5(1):14–18.

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[117] Pherson EC, Shermock KM, Efird LE, et al. Development and implementation of a post discharge home-based medication management service. *Am J Health Syst Pharm.* 2014; 71(18): 1576–1583.

[118] Pronovosta P, Weasta B, Scwarza M, et al. Medication reconciliation: A practical tool to reduce the risk of medication errors. J Crit Care. 2003; 18(4): 201–205.

[119] Bates DW, Cullen DJ, Laird N, Petersen LA, Small SD, et al. Incidence of adverse drug events and potential adverse drug events. Implications for prevention. JAMA. 1995:274(1): 29–34.

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[121] Chhabra, P.T., et al. (2012). ''Medication reconciliation during the transition to and from long-term care settings: A systematic review.'' *Res Social Adm Pharm* 8(1): 60–75.

[122] Kripalani S, Roumie CL, Dalal AK, et al. Effect of a pharmacist intervention on clinically important medication errors after hospital discharge: A randomized controlled trial. Ann Intern Med. 2012:157(1):1–10.

[123] *March 2015 Report to the Congress: Medicare Payment Policy.* Medicare Payment Advisory Commission; 2015.

Video Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We solicited stakeholder feedback on the development of this measure by means of a public comment period held from September 18 through October 6, 2015. Through public comments submitted by several stakeholders and organizations, we received support for implementation of this measure. The public comment summary report for the measure is available on the CMS Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The NQF-convened MAP met on December 14 and 15, 2015, and provided input on the use of this measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP. The MAP encouraged continued development of the quality measure to meet the mandate added by the IMPACT Act. The MAP agreed with the measure gaps identified by CMS, including medication reconciliation, and stressed that medication reconciliation be present as an ongoing process. More information about the MAPs recommendations for this measure is available at *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx.*

Since the MAP's review and recommendation of continued development, we have continued to refine this measure in compliance with the MAP's recommendations. The measure is consistent with the information submitted to the MAP and supports its scientific acceptability for use in quality reporting programs. Therefore, we proposed this measure for implementation in the IRF QRP as required by the IMPACT Act.

We reviewed the NQF's endorsed measures and identified one NQF-endorsed cross-setting and quality measure related to medication reconciliation, which applies to the SNF, LTCH, IRF, and HHA settings of care: Care for Older Adults (COA), (NQF #0553). The quality measure, Care for Older Adults (COA), (NQF #0553) assesses the percentage of adults 66 years and older who had a medication review. The Care for Older Adults (COA), (NQF #0553) measure requires at least one medication review conducted by a prescribing practitioner or clinical pharmacist during the measurement year and the presence of a medication list in the medical record. This is in contrast to the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP, which reports the percentage of patient stays in which a drug regimen review was conducted at the time of admission and that timely follow-up with a physician occurred each time one or more potential clinically significant medication issues were identified throughout that stay.

After careful review of both quality measures, we decided to propose the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP for the following reasons:

- The IMPACT Act requires the implementation of quality measures, using patient assessment data that are standardized and interoperable across PAC settings. The quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP, employs three standardized patient-assessment data elements for each of the four PAC settings so that data are standardized, interoperable, and comparable; whereas, the Care for Older Adults (COA), (NQF #0553) quality measure does not contain data elements that are standardized across all four PAC settings.
- The quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP, requires the identification of potential clinically significant medication issues at the beginning, during, and at the end of the patient's stay to capture data on each patient's complete PAC stay; whereas, the Care for Older Adults (COA), (NQF #0553) quality measure only requires annual documentation in the form of a medication list in the medical record of the target population.
- The quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP, includes identification of the potential clinically significant medication issues and communication with the physician (or physician designee) as well as resolution of the issue(s) within a rapid timeframe (by midnight of the next calendar day); whereas, the Care for Older Adults (COA), (NQF #0553) quality measure does not include any follow-up or timeframe in which the follow-up would need to occur.
- The quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP, does not have age exclusions; whereas, the Care for Older Adults (COA), (NQF #0553) quality measure limits the measure's population to patients aged 66 and older.
- The quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP, will be reported to IRFs quarterly to facilitate internal quality monitoring and quality improvement in areas such as patient safety, care coordination, and patient satisfaction; whereas, the Care for Older Adults (COA), (NQF #0553) quality measure would not enable quarterly quality updates, and thus data comparisons within and across PAC providers would be difficult due to the limited data and scope of the data collected.

Therefore, based on the evidence discussed above, we proposed to adopt the quality measure entitled, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP, for the IRF QRP for FY 2020 payment determination and subsequent years. We plan to submit the quality measure to the NQF for consideration for endorsement.

The calculation of the quality measure is based on the data collection of three standardized items to be included in the IRF–PAI. The collection of data by means of the standardized items will be obtained at admission and discharge. For more information about the data submission required for this measure, we refer readers to section VIII.I.c of this final rule.

The standardized items used to calculate this quality measure do not duplicate existing items currently used for data collection within the IRF–PAI. The measure denominator is the number of patient stays with a discharge assessment during the reporting period. The measure numerator is the number of stays in the denominator where the medical record contains documentation of a drug regimen review conducted at: (1) Admission and (2) discharge with a lookback through the entire patient stay with all potential clinically significant medication issues identified during the course of care and followed up with a physician or physician designee by midnight of the next calendar day. This measure is not risk adjusted. For technical information about this measure, including information about the measure calculation and discussion pertaining to the standardized items used to calculate this measure, we refer readers to the document titled, Proposed Measure Specifications for Measures Proposed in the FY 2017 IRF QRP proposed rule available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-*

Quality-Reporting-Program-Measures-Information-.html.

Data for the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP, will be collected using the IRF–PAI with submission through the Quality Improvement Evaluation System (QIES) Assessment Submission and Processing (ASAP) system.

We invited public comment on our proposal to adopt the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP for the IRF QRP. We received several comments, which are summarized with our responses below.

Comment: Several commenters, including MedPAC, expressed support for the quality measure. Commenters supported the medication reconciliation concept, and one commenter conveyed that preventing and responding to ADEs that account for increases in health services utilization and cost is critically important. MedPAC further noted that the medication reconciliation and follow-up process can help reduce medication errors that are especially common among patients who have multiple health care providers and multiple comorbidities.

Response: We agree that medication reconciliation is an important patient safety process for addressing medication accuracy during transitions in patient care and identifying preventable ADEs, which may lead to reduced health services utilization and associated costs.

Comment: Several commenters recommended that CMS add an additional response option, to indicate that the item N2003 Medication Follow-up (completed at admission) is not applicable if a patient does not take any medication. Alternatively, commenters suggested that CMS clarify whether this item would be mandatory in the event that a patient is not taking any medications.

Response: We wish to point out that Measure item N2003 has a skip pattern that allows the user to skip over this item if the patient does not take medication. Additional guidance will be included in the IRF–PAI training manual.

Comment: We received several comments regarding concerns about whether the measure has been fully developed and tested. Many commenters noted that the NQF-convened MAP recommended continued development for the measure and requested testing of the measure to ensure that it is appropriate for the IRF setting. Several commenters expressed concern that the measure was not NQF-endorsed.

Response: Since the time of the NQF-convened MAP, with our measure contractor, we tested this measure in a pilot test involving twelve post-acute care facilities (IRF, SNF, LTCH), representing variation across geographic location, size, profit status, and clinical records system. Two clinicians in each facility collected data on a sample of 10 to 20 patients for a total of 298 records (147 qualifying pairs). Analysis of agreement between coders within each participating facility indicated a 71 percent agreement for item DRR–01 [124] Drug Regimen Review (admission); 69 percent agreement for item DRR–02 [125] Medication Follow-up (admission); and 61 percent agreement for DRR–03 [126] Medication Intervention (during stay and discharge). Overall, pilot testing enabled us to verify feasibility of the measure. Furthermore, measure development included convening a TEP to provide input on the technical specifications of this quality measure, including components of reliability, validity and the feasibility of implementing the measure across PAC settings. The TEP included stakeholders from the IRF setting and was supportive of our plans to standardize this measure for cross-setting development. A summary of the TEP proceedings is available on the PAC Quality Initiatives Downloads and Videos Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

As noted above, we plan to conduct further testing on this measure once we have started collecting data from the PAC settings. Once we have completed this additional measure performance testing, we plan to submit the measure to NQF for endorsement.

Comment: We received several comments about guidance and training. One commenter requested clear and consistent information for training staff and resources to meet the requirements of the measure. We received several comments requesting guidance regarding the definition of ''clinically significant medication issues.'' Several commenters were concerned that the phrase could be interpreted differently by the many providers involved in a patient's treatment and that this could result in a challenge to collect reliable and accurate data for this quality measure. One commenter further conveyed that there are likely to be variations in measure performance that are not based on differences in care, but rather on differences in data collection. In addition, one commenter requested a specific definition in the measure specifications for the word ''potential,'' and another commenter requested further guidance on what would be considered an ''adequate response'' to a clinically significant medication issue.

Response: For this measure, potential clinically significant medication issues are defined as those issues that, in the clinician's professional judgment, warrant interventions, such as alerting the physician and/or others, and the timely completion of any recommended actions (by midnight of the next calendar day) so as to avoid and mitigate any untoward or adverse outcomes. The definition of ''clinically significant'' in this measure was conceptualized during the measure development process. For purposes of the measure, the decision regarding whether or not a medication issue is ''clinically significant'' will need to be made on a case-by-case basis, but we also intend to provide additional guidance and training on this issue.

Comment: We received several comments regarding the patient populations for the measure, specifically conveying concern that the populations are not standardized across PAC settings. For example, many commenters noted that IRF QRP measure includes data collection for Medicare Fee for Service and Medicare Advantage patients, while the SNF QRP measure only includes Medicare Part A patients, and the LTCH QRP includes all patients. Commenters were concerned that this could result in selective sampling of the patient population that would skew the collected data and distort or otherwise invalidate meaningful comparisons across measures and across settings, thereby falling short of the PAC standardization goals of the IMPACT Act. Several commenters suggested that CMS exclude Medicare Advantage patients, while others recommended that they be included for all measures across all PAC settings.

Response: We are working to standardize all measures as mandated by the IMPACT Act to increase data comparability and interoperability. We will take the commenter's comments and concerns into consideration as we work to standardize the proposed measure.

[124] DRR pilot items DRR–01, DRR–02 and DRR–03 are equivalent to the proposed rule DRR PAC instrument items N. 2001, N. 2003 and N. 2005

[125] DRR pilot items DRR–01, DRR–02 and DRR–03 are equivalent to the proposed rule DRR PAC instrument items N. 2001, N. 2003 and N. 2005

[126] DRR pilot items DRR–01, DRR–02 and DRR–03 are equivalent to the proposed rule DRR PAC instrument items N. 2001, N. 2003 and N. 2005

Comment: We received several comments regarding the time period for the proposed measure. One commenter disagreed with the measure's requirement that a facility must respond to urgent medication issues within one calendar day, noting that some medication issues may need to be resolved much more quickly for the patient's well-being. Another commenter was concerned that the measure tracks medication issues during any point of the patient's stay, citing that medication reconciliation occurs only during transitions of care such as admission, transfer and discharge. Therefore, this commenter had concerns that this drug regimen review process was fundamentally different than a medication reconciliation measure that focused only on care transitions.

Response: We appreciate the challenges in coordinating patient care in IRF settings. However, we chose to set the intervention timeline as midnight of the next calendar day because we believe this timeline is consistent with current standard clinical practice where a clinically significant medication issue arises. The measure evaluates responsiveness to potential or actual clinically significant medication issues when such issues are identified. The measure evaluates responsiveness to potential or actual clinically significant medication issues when such issues are identified. We would like to note that the measure is simply assessing responsiveness to issues and does not prevent clinicians from acting more quickly when an issue is identified.

We agree that medication discrepancies can occur during patient admissions, transfers, and discharges. We wish to clarify that the quality measure requires the identification of potential clinically significant medication issues for each patient's complete IRF stay, from admission to discharge. Medication reconciliation and drug regimen review are interrelated activities; while medication reconciliation is a process that identifies the most accurate and current list of medications, particularly during transitions of care, it also includes the evaluation of the name, dosage, frequency, and route. Drug regimen review is a process that necessitates and includes the review of all medications for additional purposes such as the identification of potential adverse effects. The process of drug regimen review includes medication reconciliation at the time of patient transitions and throughout the patient's stay.

Comment: We received several comments pertaining to the scope of the measure. Several commenters commented that medication reconciliation and drug regimen review are distinct processes. Several commenters were concerned that the measure does not meet the medication reconciliation domain of the IMPACT Act. Commenters maintained that the services provided as part of drug regimen review are distinctly different from the services provided as part of medication reconciliation, and that they are completed by different members of the care team. These commenters believe that the measure goes beyond the statutory mandate of the medication reconciliation domain of the IMPACT Act. One commenter was also concerned that, according to the definition provided in the Home Health Conditions of Participation, drug regimen review includes taking into consideration a patient's noncompliance with drug therapy, significant side effects, and ineffective drug therapy, which are not feasible for a facility to assess during admission. The commenter conveyed that this was distinct from medication reconciliation. Many commenters were concerned that the measure only evaluates whether the patient's current medications are being reviewed and does not determine whether this review affects the patient's quality of care.

Response: We disagree with the commenters' suggestion that the measure does not meet the requirements of the IMPACT Act. Medication reconciliation and drug regimen review are interrelated activities; while medication reconciliation is a process that identifies the most accurate and current list of medications, particularly during transitions in care, it also includes the evaluation of the name, dosage, frequency, and route. Drug regimen review is a process that necessitates, and includes the review of all medications for additional purposes, such as the identification of potential adverse effects. The process of drug regimen review includes medication reconciliation at the time of patient transitions and throughout the patient's stay. Therefore, we believe that medication reconciliation and drug regimen review are processes that are appropriate to combine into a single measure for purposes of the IRF QRP. We would also like to note that during the development of the measure, the definitions of medication reconciliation and drug regimen review, as detailed in the State Operations Manual (SOM), which includes the Conditions of Participation, were taken into consideration. We do not believe that the measure's use of the term ''clinically significant'' overrides or conflicts with the guidance as outlined in the SOM. Further, we wish to clarify that the specification of the measure does not preclude the activities of drug regimen reviews that are consistent with the SOM. The measure encompasses the IMPACT Act's medication reconciliation domain.

Comment: Several commenters were concerned that the measure does not specify which healthcare provider is required to perform the drug regimen review, or the level of clinical training required to do so. The commenters were concerned that this lack of standardization could lead to differences across the PAC settings. Many commenters conveyed that in the IRF setting, medication reconciliation is complicated and time consuming, as IRF patients with multiple clinical needs often arrive from an acute hospital where many physicians, including specialists, have made changes to patients' prescriptions. One commenter noted that patient medications may be adjusted more frequently in an IRF due to the high level of physician supervision and was concerned that the measure would not count the extensive drug regimen review being done if a clinically significant medication issue was not identified during the stay. However, commenters note that other PAC settings may lack the clinical expertise required to perform such thorough medication reviews. Commenters were concerned that the assessment items proposed do not capture the intense involvement of a pharmacist, physician, and nurse that occurs in complex cases.

Response: We wish to clarify that the measure does not override, supersede or conflict with current CMS guidance or regulations related to drug regimen review. The measure also does not specify what clinical professional is required to perform these activities. We do not prescribe guidance on which clinician may complete patient assessments. We also appreciate concerns about standardization across the PAC settings and acknowledge the complexity of drug regimen review in the IRF settings. While we agree that this measure does not capture every aspect of the drug regimen review process undertaken for each IRF patient, we emphasize that it is intended to assess whether PAC providers were responsive to potential or actual clinically significant medication issue(s) when such issues were identified. As noted in the measure specifications, the

measure's assessment items are standardized.

Comment: Many commenters, including MedPAC, encouraged CMS to develop a measure to evaluate medication reconciliation throughout the care continuum. Commenters, including MedPAC, suggested CMS focus on discharge from the PAC setting and evaluate whether the PAC sends a medication list to the patient's primary care physician or to the next PAC provider. One commenter recommended that CMS not proceed with the measure and instead focus on medication reconciliation at discharge.

Response: PAC facilities are expected to document information pertaining to the process of a drug regimen review, which includes medication reconciliation, in the patient's discharge medical record. Further, it is standard practice for patient discharge records to include a medication list to be transferred to the admitting PAC facility. We appreciate MedPAC and other commenters' recommendation for a quality measure that assesses post-discharge medication communication with primary care providers for patients discharged to home. We will take the recommendation into consideration for future measure development in accordance with the IMPACT Act, which emphasizes the transfer of interoperable patient information across the continuum of care.

Comment: We received a number of comments related to unintended consequences of the measure. One commenter expressed concern that the measure would discourage PAC clinicians from reporting and correcting medication errors. Another commenter was concerned that the measure does not require an IRF to take steps to identify clinically significant medication issues, but instead measures whether steps were taken once an issue was identified, which could be abused by PAC providers who limit the identification of clinically significant medication issues in order to artificially increase their score.

Response: Since it is a professional standard of practice for all providers to address potential clinically significant medication issues before they lead to avoidable harm to the patient, we do not believe that the measure will discourage a clinician from reporting a significant medication issue. We reiterate that the quality measure encourages PAC providers to conduct thorough drug regimen review to identify, address, and follow up for all clinically significant medication errors. The measure was informed by current evidence surrounding medication reconciliation and drug regimen review, as well as a review of best practice and professional standards of care.

Comment: We received multiple comments related to burden and expenses related to this measure. One commenter expressed concern that the requirements required increased resources without clear benefit or increase in pay to providers for additional expenses. One commenter conveyed concern that providers' existing electronic medical record systems (EMRs) likely do not include data collection and reporting capabilities required by the measure. The commenter conveyed the challenge of collecting the data for this measure manually and had concerns about the cost of doing so, and resulting data inaccuracy.

Response: We are very sensitive to the issue of burden associated with data collection and have proposed only the minimal number of items needed to calculate the quality measures. We emphasize that this measure follows standard clinical practice requirements of ongoing review, documentation, and timely reconciliation of all patient medications, with appropriate follow-up to address all clinically significant medication concerns. While we support the use of EMRs, we do not require that providers use EMRs to populate assessment data.

Comment: One commenter suggested that CMS exclude patients from the measure who were unexpectedly discharged before the medication reconciliation process is completed.

Response: We would like to clarify that this IRF measure includes all Medicare Part A and Medicare Advantage patient stays, including stays where a patient has an unexpected discharge. Data for coding N2005 Medicare Interventions can be obtained from the patient's medical records, so it is feasible to code the measure item when a patient has an unexpected discharge.

Comment: One commenter conveyed concern that drug regimen review occurs differently across the care settings. The commenter specifically expressed that inpatient settings may handle clinically significant medication issues more immediately than home health agencies.

Response: We believe that this comment is immaterial to the intent of the measure. It should be noted that we strive for consistency in the collection and application of the measure across all PAC settings.

Comment: One commenter requested for clarification about whether the measure is intended to include instances where a drug was reviewed for potential adverse effects and drug reactions prior to being ordered. The commenter conveyed that the measure only included medications that have been ordered for the patient but not those that were prevented from being ordered by a drug regimen process.

Response: We appreciate the commenter's concern regarding medications that were prevented from being ordered by the drug regimen review process. If finalized, we would provide guidance on these and other clinical examples as part of the training efforts.

Final Decision: After careful consideration of the public comments, we are finalizing our proposal to adopt the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP measure for the IRF QRP for FY 2020 payment determination and subsequent years, as described in the Measure Specifications for Measures Adopted in the FY 2017 IRF QRP final rule, available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Technical-Information.html*.

H. IRF QRP Quality Measures and Measure Concepts under Consideration for Future Years

We invited comment on the importance, relevance, appropriateness, and applicability of each of the quality measures listed in Table 8 for future years in the IRF QRP. We are developing a measure related to the IMPACT Act domain, ''Accurately communicating the existence of and providing for the transfer of health information and care preferences of an individual to the individual, family caregiver of the individual, and providers of services furnishing items and services to the individual, when the individual transitions.'' We considered the possibility of adding quality measures that rely on the patient's perspective; that is, measures that include patient-reported experience of care and health status data. We recently posted a ''Request for Information to Aid in the Design and Development of a Survey Regarding Patient and Family Member Experiences with Care Received in Inpatient Rehabilitation Facilities'' (80 FR 72725). Also, we are considering a measure focused on pain that relies on the collection of patient-reported pain data. Finally, we are considering a measure related to patient safety, Venous Thromboembolism Prophylaxis.

We received several comments about IRF QRP quality measures under

consideration for future years which are summarized with our responses below.

Comment: Commenters had concerns about the current process for seeking stakeholder feedback, noting that seven- and fourteen-day public comment periods are unreasonable for stakeholders. Other commenters did not support the addition of process measures, citing administrative burden and expense, and recommended that CMS focus on outcome measures and postpone any measures outside the requirements of the IMPACT Act.

Many commenters remarked on the limited number of items in the IRF–PAI related to communication, cognition, and swallowing and noted that these domains are important in treating individuals with neurological disorders. One commenter encouraged CMS to adopt a specific screening instrument (Montreal Cognitive Assessment (MoCA)) or similar screening tools and assessment tools (such as the Continuity Assessment Record and Evaluation-Community, or CARE–C) to best meet the needs of Medicare beneficiaries and the intent of the IMPACT Act. Another commenter requested that CMS add a functional cognition assessment item to the IRF discharge assessment and that this information be provided to the next provider when a patient is transferred. The commenters offered to collaborate with CMS to develop future measures in the area of cognitive function.

Response: We wish to note that several of the measures currently adopted in the IRF QRP are outcome measures, including: Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678), NHSN CAUTI Outcome Measure (NQF #0138), All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from an IRF (NQF #2502), NHSN Facility-wide Inpatient Hospital-onset MRSA Bacteremia Outcome Measure (NQF #1716), and NHSN Facility-wide Inpatient Hospital-onset CDI Outcome Measure (NQF #1717). Measures that have been finalized for implementation October 1, 2016 also include outcome measures: Application of Percent of Residents Experiencing One or More Falls with Major Injury (NQF #0674), IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633), IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634), Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635), Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636) We agree that future development of outcome measures should include other areas of function, such as communication, cognition and swallowing, and are important components of functional assessment and improvement for patients who receive care in PAC settings, including IRFs. We appreciate comments related to the public comment periods during the measure development and stakeholder feedback process, and will continue to engage stakeholders as we develop and implement quality measures to meet the requirements of the IMPACT Act.

Comment: Several commenters supported a Venous Thromboembolism (VTE) Prophylaxis measure but suggested that the measure take into account that not all VTEs can be prevented due to its complexity. Some commenters did not support a process measure, since VTE prophylaxis is already a standard of practice and the measure would add burden, but have no clinical significance. These commenters do support the development of a VTE outcome measure.

Response: We thank the commenters for their comments on the VTE Prophylaxis measure under consideration for future implementation in the IRF QRP and will take into consideration the commenters' recommendations.

Comment: Several commenters recommended that a pain measure take into consideration pain that might be experienced as the result of intense therapy. One commenter suggested that pain management was a more meaningful measure for IRF patients and requested guidance on the definitions of moderate and severe pain.

Response: We will take these suggested quality measure concepts and recommendations regarding measure specifications into consideration in our ongoing measure development and testing efforts.

Comment: We received several comments regarding the patient experience of care measure. Several commenters had concerns about survey fatigue across the continuum of care. Many commenters were concerned that for one episode of care, a patient could receive a survey from each setting which could result in confusion in responses and inaccurate results. Many commenters were concerned that since many IRFs are small units, their data may not be statistically representative or may show high variability. The commenters recommended that CMS take a systems-based approach with patient experience surveys to avoid these problems.

Many commenters supported a patient experience of care measure, and supported accepting proxy response from family members and caregivers to support accurate and reliable results at the facility level. Other commenters supported a measure of patient experience, instead of only patient satisfaction, and recommended that it include several aspects unique to IRF care, including goal setting and discharge planning. Commenters recommended that CMS implement the survey as a voluntary tool prior to requiring it, which would allow IRFs to transition operationally and find a vendor, if needed. Commenters also recommended that the quality measure adjust for factors already in place for existing CAHPS® surveys, including adjusting for mode of survey administration, as well as IRF-specific patient-mix adjustment. The commenter also suggested converting responses to a 0 to 100 linear-scaled score. Several commenters recommended that CMS seek stakeholder input on the development of a patient experience of care measure.

Response: We will take these recommendations regarding measure specifications and survey fatigue across the care continuum into consideration in our ongoing measure development and testing efforts, and will continue to engage stakeholders in the development process.

Comment: We received several comments regarding the transfer of health information and care preferences measure. Many commenters recommended that development efforts for this measure should recognize that there is a large amount of variation in the different health information systems used by different IRFs to record, store, retrieve, and share patient information. The commenter noted that hospitals are already required to transfer health information and care preferences as part of their Medicare Conditions of Participation, and posited that adding such a measure to the IRF QRP would rely on receiving accurate and complete discharge information from a prior level of care, which may be out of the IRF's control.

Response: As we move through the development of this measure concept, we will consider the variation in health information systems used by different IRFs, as well as the concerns about receiving complete discharge information from a prior level of care for these measure concepts.

TABLE 9—IRF QRP QUALITY MEASURES UNDER CONSIDERATION FOR FUTURE YEARS

IMPACT Act Domain	Accurately communicating the existence of and providing for the transfer of health information and care preferences of an individual to the individual, family caregiver of the individual, and providers of services furnishing items and services to the individual, when the individual transitions.
IMPACT Act Measure	• Transfer of health information and care preferences when an individual transitions.
NQS Priority	Patient- and Caregiver-Centered Care.
Measures	• Patient Experience of Care. • Percent of Patients with Moderate to Severe Pain.
NQS Priority	Patient Safety.
Measure	• Venous Thromboembolism Prophylaxis.

I. Form, Manner, and Timing of Quality Data Submission for the FY 2018 Payment Determination and Subsequent Years

1. Background

Section 1886(j)(7)(C) of the Act requires that, for the FY 2014 payment determination and subsequent years, each IRF submit to the Secretary data on quality measures specified by the Secretary. In addition, section 1886(j)(7)(F) of the Act requires that, for the fiscal year beginning on the specified application date, as defined in section 1899B(a)(2)(E) of the Act, and each subsequent year, each IRF submit to the Secretary data on measures specified by the Secretary under section 1899B of the Act. The data required under section 1886(j)(7)(C) and (F) of the Act must be submitted in a form and manner, and at a time, specified by the Secretary. As required by section 1886(j)(7)(A)(i) of the Act, for any IRF that does not submit data in accordance with section 1886(j)(7)(C) and (F) of the Act for a given fiscal year, the annual increase factor for payments for discharges occurring during the fiscal year must be reduced by 2 percentage points.

a. Timeline for Data Submission Under the IRF QRP for the FY 2018, FY 2019 and Subsequent Year Payment Determinations

Tables 10 through 18 represent our finalized data collection and data submission quarterly reporting periods, as well as the quarterly review and correction periods and submission deadlines for the quality measure data submitted via the IRF–PAI and the CDC/NHSN affecting the FY 2018 and subsequent year payment determinations. We also provide in Table 10 our previously finalized claims-based measures for FY 2018 and subsequent years, although we note that, for claims-based measures, there is no corresponding quarterly-based data collection or submission reporting periods with quarterly-based review and correction deadline periods.

Further, in the FY 2016 IRF PPS final rule (80 FR 47122 through 47123), we established that the IRF–PAI-based measures finalized for adoption into the IRF QRP will transition from reporting based on the fiscal year to an annual schedule consistent with the calendar year, with quarterly reporting periods followed by quarterly review and correction periods and submission deadlines, unless there is a clinical reason for an alternative data collection time frame. The pattern for annual, calendar year-based data reporting, in which we use 4 quarters of data, is illustrated in Table 10 and is in place for all Annual Payment Update (APU) years except for the measure in Table 10 for which the FY 2018 APU determination will be based on 5 calendar year quarters in order to transition this measure from FY to CY reporting. We also wish to clarify that payment determinations for the measures finalized for use in the IRF QRP that use the IRF–PAI or CDC NHSN data sources will subsequently use the quarterly data collection/submission and review, correction and submission deadlines described in Table 10 unless otherwise specified, as is with the measure NQF #0680: Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine. For this measure, we clarify in a subsequent discussion that the data collection and reporting periods, which are based on the Influenza Season, span 2 consecutive years from July 1 through June 30th and we therefore separately illustrate those collection/submission quarterly reporting periods, review and correction periods, and submission deadlines for FY 2019 and subsequent years in Table 10. We also separately distinguish the reporting periods and data submission timeframes for the finalized measure Influenza Vaccination Coverage among Healthcare Personnel which spans 2 consecutive years, as this measure is based on the Influenza vaccination season, in Table 10.

TABLE 10—ANNUAL QRP CY IRF–PAI & CDC/NHSN DATA COLLECTION/SUBMISSION REPORTING PERIODS AND DATA SUBMISSION/CORRECTION DEADLINES ** PAYMENT DETERMINATIONS ^

Proposed CY data collection quarter	Data Collection/submission quarterly reporting period	QRP Quarterly review and correction periods data submission deadlines for payment determination **	
Quarter 1	January 1–March 31 *	April 1–August 15 *	Deadline: August 15.*
Quarter 2	April 1–June 30	July 1–November 15	Deadline: November 15.
Quarter 3	July 1–September 30	October 1–February 15	Deadline: February 15.
Quarter 4	October 1–December 31 *	January 1–May 15 *	Deadline: May 15.*

* We refer readers to Table 10 for the annual data collection time frame for the measure, Influenza Vaccination Coverage among Healthcare Personnel

** We note that the submission of IRF–PAI data must also adhere to the IRF PPS deadlines

^ We refer readers to Table 10 for the 12 month (July–June) data collection/submission quarterly reporting periods, review and correction periods and submission deadlines for APU determinations for the measure NQF #0680: Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine

TABLE 11—SUMMARY DETAILS ON DATA COLLECTION PERIOD AND DATA SUBMISSION TIMELINE FOR PREVIOUSLY ADOPTED QUALITY MEASURE AFFECTING THE FY 2018 PAYMENT DETERMINATION THAT WILL USE 5 CY QUARTERS IN ORDER TO TRANSITION FROM A FY TO A CY REPORTING CYCLE

Finalized Measure:

- NQF # 0678 Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (80 FR 47122)

Submission method	Data collection/submission quarterly reporting period(s)	Quarterly review and correction periods data submission deadlines for payment determination */**	APU Determination affected
IRF–PAI/QIES ASAP System	CY 15 Q4, 10/1/15–12/31/15	1/1/2016–5/15/16 deadline	FY 2018.
	CY 16 Q1, 1/1/16–3/31/16	4/1/2016–8/15/16 deadline.
	CY 16 Q2, 4/1/16–6/30/16	7/1/16–11/15/16 deadline.
	CY 16 Q3, 7/1/16–9/30/16	10/1/16–2/15/17 deadline.
	CY 16 Q4, 10/01/16–12/31/16	1/1/17–5/15/17 deadline.

* We refer readers to the Table 11 for an illustration of the data collection/submission quarterly reporting periods and correction and submission deadlines

** We note that the submission of IRF–PAI data must also adhere to the IRF PPS deadlines

TABLE 12—SUMMARY DETAILS ON DATA COLLECTION PERIOD AND DATA SUBMISSION TIMELINE FOR PREVIOUSLY ADOPTED IRF–PAI QUALITY MEASURE, NQF #0680 PERCENT OF RESIDENTS OR PATIENTS WHO WERE ASSESSED AND APPROPRIATELY GIVEN THE SEASONAL INFLUENZA VACCINE, AFFECTING THE FY 2018 PAYMENT DETERMINATION

Finalized Measure:

- NQF #0680 Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (80 FR 47122)

Submission method	Data collection/submission quarterly reporting period(s)	Quarterly review and correction periods data submission deadlines for payment determination *	APU Determination affected
IRF–PAI/QIES ASAP System	CY 15 Q4, 10/1/15–12/31/15	1/1/2016–5/15/16 deadline	FY 2018.
	CY 16 Q1, 1/1/16–3/31/16	4/1/2016–8/15/16 deadline.
	CY 16 Q2, 4/1/16–6/30/16	7/1/16–11/15/16 deadline.

* We note that the submission of IRF–PAI data must also adhere to the IRF PPS deadlines

TABLE 13—SUMMARY DETAILS ON DATA COLLECTION PERIOD AND DATA SUBMISSION TIMELINE FOR PREVIOUSLY ADOPTED QUALITY MEASURES AFFECTING THE FY 2018 PAYMENT DETERMINATION THAT WILL USE ONLY 1 CY QUARTER OF DATA INITIALLY FOR THE PURPOSE OF DETERMINING PROVIDER COMPLIANCE

Finalized Measure:

- NQF #0674 Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (80 FR 47122)
- NQF #2631 Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (80 FR 47122)
- NQF #2633 IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (80 FR 47122)
- NQF #2634 IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (80 FR 47122)
- NQF #2635 IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (80 FR 47122)
- NQF #2636 IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (80 FR 47122)

Submission method	Data collection/submission quarterly reporting period(s)	Quarterly review and correction periods data submission deadlines for payment determination */**	APU Determination affected
IRF–PAI/QIES ASAP System	CY 16 Q4, 10/1/16–12/31/16	1/1/2017–5/15/17	FY 2018.

* We refer readers to the Table 12 for an illustration of the data collection/submission quarterly reporting periods and correction and submission deadlines, which will be followed for the above measures, for all payment determinations subsequent to that of FY 2018.

** We note that the submission of IRF–PAI data must also adhere to the IRF PPS deadlines.

TABLE 14—SUMMARY DETAILS ON DATA COLLECTION PERIOD AND DATA SUBMISSION TIMELINE FOR PREVIOUSLY ADOPTED CDC/NHSN QUALITY MEASURES AFFECTING THE FY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS THAT WILL USE 4 CY QUARTERS *

Finalized Measures:

- NQF #0138 NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (80 FR 47122 through 47123)
- NQF #1716 NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure (80 FR 47122 through 47123)
- NQF #1717 NHSN Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (79 FR 45917)

TABLE 14—SUMMARY DETAILS ON DATA COLLECTION PERIOD AND DATA SUBMISSION TIMELINE FOR PREVIOUSLY ADOPTED CDC/NHSN QUALITY MEASURES AFFECTING THE FY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS THAT WILL USE 4 CY QUARTERS *—Continued

Submission method	Data Collection/submission Quarterly Reporting Period(s)	Quarterly Review and Correction Periods Data Submission Deadlines for Payment Determination	APU determination affected
CDC/NHSN	CY 16 Q1, 1/1/16–3/31/16 and Q1 of subsequent Calendar Years.	4/1/2016–8/15/16 ** and 4/1–8/15 of subsequent years.	FY 2018 and subsequent years.**
	CY 16 Q2, 4/1/16–6/30/16 and Q2 of subsequent Calendar Years.	7/1/16–11/15/16 **and 7/1–11/15 of subsequent years.	
	CY 16 Q3, 7/1/16–9/30/16 and Q3 of subsequent Calendar Years.	10/1/16–2/15/17 ** and 10/1–2/15 of subsequent years.	
	CY 16 Q4, 10/1/16–12/31/16 and Q4 of subsequent Calendar Years.	1/1/17–5/15/17 ** and 1/1–5/15 of subsequent years.	

* We refer readers to the Table 14 for an illustration of the data collection/submission quarterly reporting periods and correction and submission deadlines.

** As is illustrated in Table 14: Subsequent years follow the same CY Quarterly Data Collection/submission Quarterly Reporting Periods and Quarterly Review and Correction Periods Deadlines for Payment Determination in which every CY quarter is followed by approximately 135 days for IRFs to review and correct their data until midnight on the final submission deadline dates.

TABLE 15—SUMMARY DETAILS ON DATA COLLECTION PERIOD AND DATA SUBMISSION TIMELINE FOR PREVIOUSLY ADOPTED IRF–PAI QUALITY MEASURES AFFECTING THE FY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS THAT WILL USE 4 CY QUARTERS

Finalized Measures:

- NQF #0678 Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (80 FR 47122)
- NQF #0674 Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (80 FR 47122)
- NQF #2631 Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (80 FR 47122)
- NQF #2633 IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (80 FR 47122)
- NQF #2634 IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (80 FR 47122)
- NQF #2635 IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (80 FR 47122)
- NQF #2636 IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (80 FR 47122)

Submission method	Data Collection/submission Quarterly Reporting Period(s)	Quarterly Review and Correction Periods Data Submission Deadlines for Payment Determination */**	APU determination affected
IRF–PAI/QIES ASAP System	CY 17 Q1, 1/1/17–3/31/17 and Q1 of subsequent Calendar Years.	4/1/2017–8/15/17 *** and 4/1–8/15 of subsequent years.	FY 2019 and subsequent years.***
	CY 17 Q2, 4/1/17–6/30/17 and Q2 of subsequent Calendar Years.	7/1/17–11/15/17 *** and 7/1–11/15 of subsequent years.	
	CY 17 Q3, 7/1/17–9/30/17 and Q3 of subsequent Calendar Years.	10/1/17–2/15/18 *** and 10/1–1/15 of subsequent years.	
	CY 17 Q4, 10/1/17–12/31/17 and Q4 of subsequent Calendar Years.	1/1/18–5/15/18 *** and 1/1–5/15 of subsequent years.	

We refer readers to the Table 15 for an illustration of the data collection/submission quarterly reporting periods and correction and submission deadlines.

** We note that the submission of IRF–PAI data must also adhere to the IRF PPS deadlines.

*** As is illustrated in Table 15: Subsequent years follow the same CY Quarterly Data Collection/submission Quarterly Reporting Periods and Quarterly Review and Correction Periods) and Data Submission Deadlines for Payment Determination in which every CY quarter is followed by approximately 135 days for IRFs to review and correct their data until midnight on the final submission deadline dates.

In the FY 2014 IRF PPS final rule, we adopted the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) measure for the FY 2017 payment determination and subsequent years (78 FR 47910 through 47911). In the FY 2014 IRF PPS final rule (78 FR 47917 through 47919), we finalized the data submission timelines and submission deadlines for the measures for FY 2017 payment determination. Refer to the FY 2014 final rule (78 FR 47917 through 47919) for a more detailed discussion of these timelines and deadlines.

We want to clarify that this measure includes all patients in the IRF one or more days during the influenza vaccination season (IVS) (October 1 of

any given CY through March 31 of the subsequent CY). This includes, for example, a patient is admitted September 15, 2015, and discharged April 1, 2016 (thus, the patient was in the IRF during the 2015–2016 influenza vaccination season). If a patient's stay did not include one or more days in the IRF during the IVS, IRFs must also complete the influenza items. For example, if a patient was admitted after April 1, 2016, and discharged September 30, 2016, and the patient did not receive the influenza vaccine during the IVS, IRFs should code the reason the patient did not receive the influenza vaccination as ''patient was not in the facility during this year's influenza vaccination season.''

Further, we wish to clarify that the data submission timeline for this measure includes 4 calendar quarters and is based on the influenza season (July 1 through June 30 of the subsequent year), rather than on the calendar year. For the purposes of APU determination and for public reporting, data calculation and analysis uses data from an influenza vaccination season that is within the *influenza season* itself. While the influenza vaccination season is October 1 of a given year (or when the vaccine becomes available) through March 31 of the subsequent year, this timeframe rests within a greater time period of the *influenza season* which spans 12 months—that is July 1 of a given year through June 30 of the subsequent year. Thus for this measure, we utilize data from a timeframe of 12 months that mirrors the influenza season which is July 1 of a given year through June 30th of the subsequent year. Additionally, for the APU determination, we review data that has been submitted beginning on July 1 of the calendar year 2 years prior to the calendar year of the APU effective date and ending June 30 of the subsequent calendar year, one year prior to the calendar year of the APU effective date. For example, and as provided in Table 14 for the FY 2019 (October 1, 2018) APU determination, we review data submission beginning July 1 of 2016 through June 30th of June 2017 for the 2016/2017 influenza vaccination season, so as to capture all data that an IRF will have submitted with regard to the 2016/2017 Influenza season itself. We will use assessment data for that time period as well for public reporting. Further, because we enable the opportunity to review and correct data for all assessment based IRF–PAI measures within the IRF QRP, we continue to follow quarterly calendar data collection/submission quarterly reporting period(s) and their subsequent quarterly review and correction periods with data submission deadlines for public reporting and payment determinations. However, rather than using CY timeframe, these quarterly data collection/submission periods and their subsequent quarterly review and correction periods and submission deadlines begin with CY quarter 3, July 1, of a given year and end June 30th, CY quarter 2, of the following year. For further information on data collection for this measure, please refer to section 4 of the IRF–PAI training manual, which is available on the CMS IRF QRP Measures Information Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html*, under the downloads section. For further information on data submission of the IRF–PAI, please refer to the IRF–PAI Data Specifications Version 1.12.1 (FINAL)—in effect on October 1, 2015, available for download at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Software.html*.

Refer to Table 16 for details about the quarterly data collection/submission and the review and correction deadlines for FY 2019 and subsequent years for NQF #0680 Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine.

TABLE 16—SUMMARY DETAILS ON DATA COLLECTION PERIOD AND DATA SUBMISSION TIMELINE FOR PREVIOUSLY ADOPTED IRF–PAI QUALITY MEASURE, NQF #0680 PERCENT OF RESIDENTS OR PATIENTS WHO WERE ASSESSED AND APPROPRIATELY GIVEN THE SEASONAL INFLUENZA VACCINE, AFFECTING THE FY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS *

Finalized Measure:

• NQF #0680 Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (80 FR 47122)

Submission method	Data collection/submission Quarterly Reporting Period(s)	Quarterly review and correction periods data submission deadlines for payment determination **	APU determination affected
IRF–PAI/QIES ASAP System	CY 16 Q3, 7/1/16–9/30/16 and Q3 of subsequent Calendar Years.	10/1/16–2/15/17 ** and 10/1–2/15 of subsequent years.	FY 2019 and subsequent years.**
	CY 16 Q4, 10/1/16–12/31/16 and Q4 of subsequent Calendar Years.	1/1/17–5/15/17 ** and 1/1–5/15 of subsequent years.	
	CY 17 Q1, 1/1/17–3/31/17 and Q1 of subsequent Calendar Years.	4/1/17–8/15/17 ** and 4/1–8/15 of subsequent years.	
	CY 17 Q2, 4/1/17–6/30/17 and Q2 of subsequent Calendar Years.	7/1/17–11/15/17 ** and 7/1–11/15 of subsequent years.	

* We note that the submission of IRF–PAI data must also adhere to the IRF PPS deadlines.

** As is illustrated in Table 16: Subsequent years follow the same CY Quarterly Data Collection/submission Quarterly Reporting Periods and Quarterly Review and Correction Periods (IRF–PAI) and Data Submission (CDC/NHSN) Deadlines for Payment Determination in which every CY quarter is followed by approximately 135 days for IRFs to review and correct their data until midnight on the final submission deadline dates.

We finalized in the FY 2014 IRF PPS final rule (78 FR 47905 through 47906) that for FY 2016 and subsequent years IRFs will submit data on the quality measure Influenza Vaccination Coverage among Healthcare Personnel (NQF

#0431) beginning with data submission starting October 1, 2014 (or when the influenza vaccine becomes available). To clarify that while the data collected by IRFs for this measure includes vaccination information for a flu vaccination season that begins October 1 (or when the vaccine becomes available) of a given year through March 31 of the subsequent year, the CDC/NHSN system only allows for the submission of the corresponding data any time between October 1 of a given year until March 31 of the subsequent year; however, corrections can be made to such data until May 15th of that year. Quality data for this measure are only required to be submitted once per IVS (Oct 1 through March 31), but must be submitted prior to the May 15 deadline for the year in which the IVS ends; quarterly reporting is not required. For example, for FY 2018 payment determinations, while IRFs can begin immunizing their staff when the vaccine is available throughout the influenza vaccination season which ends on March 31, 2016, IRFs can only begin submitting the data for this measure via the CDC/NHSN system starting on October 1, 2015, and may do so up until May 15 of 2016.

TABLE 17—SUMMARY DETAILS ON THE DATA SUBMISSION TIMELINE AND CORRECTION DEADLINE TIMELINE FOR THE PREVIOUSLY ADOPTED INFLUENZA VACCINATION COVERAGE AMONG HEALTHCARE PERSONNEL AFFECTING CY 2018 AND SUBSEQUENT YEARS

Influenza Vaccination Coverage Among Healthcare Personnel Data submission Quarters +	Data submission Period	Review and Correction Periods Data Submission (CDC/NHSN) Deadlines for payment determination ++	
CY QTR 4 through Subsequent CY QTR 1.	10/1/15–3/31/16 and 10/1–3/31 of subsequent years.	4/1/16–5/15/16 and 4/1–5/15 of subsequent years.	Deadline: May 15, 2016 and May 15 of subsequent years.

+ Data on this measure may be submitted via the CDC/NHSN system from October 1 of a given year through May 15 of the subsequent year.
++ A time period of April 1–May 15th is also allotted for the submission, review, and corrections.

TABLE 18—FINALIZED IRF QRP CLAIMS-BASED MEASURE AFFECTING FY 2018 AND SUBSEQUENT YEARS

Quality measure	Data submission method	Performance period
NQF #2502 All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Inpatient Rehabilitation Facilities (80 FR 47087 through 47089).	Medicare FFS Claims	CY 2013 and 2014 for public reporting in 2016. CY 2014 and 2015 for public reporting in 2017.

Although we did not solicit feedback, we received several comments about the previously finalized policy to adopt calendar year data collection time frames, unless there is a clinical reason for an alternative data collection time frame, which are summarized with our responses below.

Comment: Several commenters supported these data collection timelines to simplify the data collection and reporting process, as summarized in the FY 2016 IRF PPS Final Rule (80 FR 47122 through 47123).

Response: We thank these commenters for their support.

Comment: One commenter generally supported the change to calendar year, but was concerned that the IRF–PAI versions aligned with the fiscal year. Several others also commented that since updates are made to the IRF–PAI on a FY basis, this change would create a discrepancy within a single calendar year's data set. Many commenters were concerned that variations in FY 2018 APU data collection periods placed an increased burden on IRFs to maintain compliance and requested that CMS grant some leniency to an IRF the first time it is not compliant with quality reporting due to the new CY-based deadlines.

Response: When we finalized this change in the FY 2016 IRF PPS final rule (80 FR 47122 through 47123), we posited this change would simplify the data collection and submission time frame under the IRF QRP for IRF providers. It would also eliminate the situation in which data collection during a quarter in the same calendar year can affect 2 different years of annual payment update determination (that is, October 1 to December 31 is the first quarter of data collection for quality measures with a FY-based data collection time frame and the last quarter of data collection for quality measures with a CY-based data collection time frame). This change means that when additional quality measures that use IRF–PAI as the data collection mechanism, such as the measure Drug Regimen Review Conducted with Follow-Up for Identified Issues, are adopted for future use in the IRF QRP, the first data collection time frame for those newly-adopted measures will be 3 months (October to December) and subsequent data collection time frames would follow a calendar year data collection time frame. This policy only affects IRFs insofar as for these newly adopted measures, compliance determinations for the applicable FY APU will only reflect data collection and submission for Q4 of the CY in which data collection begins. This does not create a discrepancy in the data set, as stated by the commenter, as we would use the following CY of data for APU analysis and public reporting purposes, should state measures be proposed and finalized for public display in the future.

With regard to concerns about increased burden with the change in data collection periods and requests for leniency regarding submission deadlines, we disagree that leniency is warranted, given that there is no discrepancy in the data set and the policy only affects the first quarter of data collection for newly adopted measures. We have ongoing education regarding data submission deadlines, including quarterly email reminders of upcoming deadlines. We also remind the reader of the availability of the reconsideration process, in which IRFs may file for reconsideration if they believe the finding of non-compliance is in error, or they have evidence of the impact of extraordinary circumstances which prevented timely submission of data.

b. Timeline and Data Submission Mechanisms for the FY 2018 Payment Determination and Subsequent Years for the IRF QRP Resource Use and Other Measures Claims-Based Measures

The MSPB PAC IRF QRP measure; Discharge to Community PAC IRF QRP measure; Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP; and Potentially Preventable Within Stay Readmission Measure for IRFs, which we are finalizing in this final rule, are Medicare FFS claims-based measures. Because claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes, no additional information collection will be required from IRFs. As discussed in section VIII.F of this final rule, these measures will use 2 years of claims-based data beginning with CY 2015 and CY 2016 claims to inform confidential feedback reports for IRFs, and CYs 2016 and 2017 claims data for public reporting.

We invited public comments on this proposal. We did not receive comments related to data submission mechanisms for these measures. For comments related to the measures, please see section VIII.F of this final rule. For comments related to the future public display of these measures, please see section VIII.N of this final rule.

We finalize the timeline and data submission mechanisms for FY 2018 payment determination and subsequent years as proposed.

c. Timeline and Data Submission Mechanisms for the IRF QRP Quality Measure for the FY 2020 Payment Determination and Subsequent Years

As discussed in section VIII.F of this final rule, we proposed that the data for the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC IRF QRP, affecting FY 2020 payment determination and subsequent years, be collected by completing data elements that will be added to the IRF–PAI with submission through the QIES–ASAP system. Data collection will begin on October 1, 2018. More information on IRF reporting using the QIES–ASAP system is located at the Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAI.html*.

For the FY 2020 payment determinations, we proposed to use CY 2018 4th quarter data, that is, beginning with discharges on October 1, 2018, through discharges on December 31, 2018, to remain consistent with the usual October release schedule for the IRF–PAI, to give IRFs sufficient time to update their systems so that they can comply with the new data reporting requirements, and to give us sufficient time to determine compliance for the FY 2020 program. The proposed use of 1 quarter of data for the initial year of assessment data reporting in the IRF QRP, to make compliance determinations related to the applicable FY APU, is consistent with the approach we used previously for the SNF, LTCH, and Hospice QRPs.

Table 18 presents the proposed data collection period and data submission timelines for the new IRF QRP quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC IRF QRP, for the FY 2020 Payment Determination. We invited public comments on this proposal.

TABLE 19—DETAILS ON THE PROPOSED DATA COLLECTION PERIOD AND DATA SUBMISSION TIMELINE FOR RESOURCE USE AND OTHER MEASURES AFFECTING THE FY 2020 PAYMENT DETERMINATION

Quality measure	Submission method	Data collection period	Data correction deadlines *	APU determination affected
Drug Regimen Review Conducted with Follow-Up for Identified Issues PAC IRF QRP.	IRF–PAI/QIES ASAP	CY 2018 Q4, 10/1/18–12/31/18; Quarterly for each subsequent calendar year.	5/15/19 Quarterly approximately 135 days after the end of each quarter for subsequent years..	FY 2020.

* We note that the submission of IRF–PAI data must also adhere to the IRF PPS deadlines.

Following the close of the reporting quarter, October 1, 2018, through December 31, 2018, for the FY 2020 payment determination, IRFs will have the already established additional 4.5 months to correct their quality data and that the final deadline for correcting data for the FY 2020 payment determination will be May 15, 2019 for these measures. We further proposed that for the FY 2021 payment determination and subsequent years, we will collect data using the calendar year reporting cycle as described in section VIII.I.c of this final rule, and illustrated in Table 20. We invited public comments on this proposal.

We did not receive any comments on the proposed data collection periods and data submission timelines for the new proposed IRF QRP quality measure for the FY 2020 and FY 2021 payment determination and subsequent years.

Final Decision: We finalize the timeline and data submission mechanisms for FY 2020 and FY2021 payment determinations and subsequent years as proposed, as described in Table 19. For comments related to the measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues PAC IRF QRP, please see section VIII.G of final rule.

TABLE 20—PROPOSED DATA COLLECTION PERIOD AND DATA CORRECTION DEADLINES * AFFECTING THE FY 2021 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Quality measure	Submission method	Proposed CY data collection quarter	Proposed data collection period	Proposed quarterly review and data correction periods * deadlines for payment determination
Drug Regimen Review Conducted with Follow-Up for Identified Issues PAC IRF QRP.	IRF–PAI/QIES ASAP	Quarter 1	January 1–March 31	April 1– August 15.
		Quarter 2	April 1–June 30	July 1–November 15.
		Quarter 3	July 1–September 30	October 1–February 15.
		Quarter 4	October 1–December 31	January 1–May 15.

* We note that the submission of IRF–PAI data must also adhere to the IRF PPS deadlines.

J. IRF QRP Data Completion Thresholds for the FY 2016 Payment Determination and Subsequent Years

In the FY 2015 IRF PPS final rule (79 FR 45921 through 45923), we finalized IRF QRP thresholds for completeness of IRF data submissions. To ensure that IRFs are meeting an acceptable standard for completeness of submitted data, we finalized the policy that, beginning with the FY 2016 payment determination and for each subsequent year, IRFs must meet or exceed two separate data completeness thresholds: One threshold set at 95 percent for completion of quality measures data collected using the IRF–PAI submitted through the QIES and a second threshold set at 100 percent for quality measures data collected and submitted using the CDC NHSN.

Additionally, we stated that we will apply the same thresholds to all measures adopted as the IRF QRP expands and IRFs begin reporting data on previously finalized measure sets. That is, as we finalize new measures through the regulatory process, IRFs will be held accountable for meeting the previously finalized data completion threshold requirements for each measure until such time that updated threshold requirements are proposed and finalized through a subsequent regulatory cycle.

Further, we finalized the requirement that an IRF must meet or exceed both thresholds to avoid receiving a 2 percentage point reduction to their annual payment update for a given fiscal year, beginning with FY 2016 and for all subsequent payment updates. For a detailed discussion of the finalized IRF QRP data completion requirements, please refer to the FY 2015 IRF PPS final rule (79 FR 45921 through 45923). We proposed to codify the IRF QRP Data Completion Thresholds at § 412.634. We invited public comments on this proposal.

We received several comments with concerns about the proposal to codify the IRF QRP Data Completion Thresholds at § 412.634, which are summarized below.

Comment: One commenter supported the 100 percent standard, but had concerns regarding technical errors with the NHSN that IRFs have experienced in the past year. Several commenters expressed concern about the threshold set at 100 percent for quality measures data collected and submitted using the CDC NHSN, citing significant burden on infection preventionists to review and complete reports in NHSN. One commenter expressed concern that the data completion threshold would be applied to data collected in FY 2014, having a retroactive impact on payment. One commenter recommended changes to the NHSN that could alleviate the reporting requirement, including minimize the reporting of elements outside of CMS regulatory requirements, as well as altering the system to remove monthly reporting plans or allowing them to be submitted electronically.

Response: We wish to clarify that the IRF QRP thresholds for completeness of IRF data submissions were finalized in the FY 2015 IRF PPS final rule (79 FR 45921 through 45923), beginning with FY 2016, which considered quality data submitted during CY 2014. We have continually maintained that providers should be submitting complete and accurate data, and the adoption of the data completion thresholds in the FY 2015 IRF PPS final rule did not change this policy. We believe that both data completion thresholds are achievable, as evidenced by the 91 percent of IRFs that were able to achieve these thresholds for purposes of the FY 2016 payment determination. We have also taken strides to assist providers achieve compliance, including regular notification of upcoming deadlines, updated guidance documents, increased outreach to providers with incomplete data submissions, and the development of several reports which will help providers better determine where they stand with respect to compliance throughout the year. We appreciate the commenters' concerns related to burden and have taken this into consideration when issuing data completion thresholds.

Final Decision: We are finalizing our proposal to codify the IRF QRP data completion thresholds at § 412.634.

K. IRF QRP Data Validation Process for the FY 2016 Payment Determination and Subsequent Years

Validation is intended to provide added assurance of the accuracy of the data that will be reported to the public as required by sections 1886(j)(7)(E) and 1899B(g) of the Act. In the FY 2015 IRF PPS rule (79 FR 45923), we finalized, for the FY 2016 adjustments to the IRF PPS annual increase factor and subsequent years, a process to validate the data submitted for quality purposes. However, in the FY 2016 IRF PPS final rule (80 FR 47124), we finalized our decision to temporarily suspend the implementation of this policy. We did not propose a data validation policy in the FY 2017 IRF PPS proposed rule, as we are developing a policy that could be applied to several PAC QRPs. We intend to propose a data validation policy through future rulemaking.

L. Previously Adopted and Codified IRF QRP Submission Exception and Extension Policies

Refer to § 412.634 for requirements pertaining to submission exception and extension for the FY 2017 payment determination and subsequent years. We proposed to revise § 412.634 to change the timing for submission of these exception and extension requests from 30 days to 90 days from the date of the qualifying event which is preventing an IRF from submitting their quality data for the IRF QRP. We proposed the increased time allotted for the submission of the requests from 30 to 90 days to be consistent with other quality reporting programs; for example, the Hospital Inpatient Quality Reporting (IQR) Program also proposed to extend the deadline to 90 days in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25205). We believe that this increased time will assist providers experiencing

an event in having the time needed to submit such a request. We believe that allowing only 30 days was insufficient. With the exception of this one change, we did not propose any additional changes to the exception and extension policies for the IRF QRP at this time.

We invited public comments on the proposal to revise § 412.634 to change the timing for submission of these exception and extension requests from 30 days to 90 days from the date of the qualifying event which is preventing an IRF from submitting their quality data for the IRF QRP. We received one comment on this proposal, which is summarized and addressed below in this section.

Comment: One commenter supported changing the timing for submission of exception and extension requests from 30 days to 90 days from the date of the qualifying event preventing an IRF from submitting their IRF QRP data.

Response: We thank the commenter for their support.

Final Decision: After careful consideration of the public comments, we are finalizing our proposal to revise § 412.634 to change the timing for submission of these exception and extension requests from 30 days to 90 days from the date of the qualifying event which is preventing an IRF from submitting their quality data for the IRF QRP.

M. Previously Adopted and Finalized IRF QRP Reconsideration and Appeals Procedures

Refer to § 412.634 for a summary of our finalized reconsideration and appeals procedures for the IRF QRP for FY 2017 payment determination and subsequent years. We did not propose any changes to this policy. However, we wish to clarify that in order to notify IRFs found to be non-compliant with the reporting requirements set forth for a given payment determination, we may include the QIES mechanism in addition to U.S. Mail, and we may elect to utilize the MACs to administer such notifications.

We received several comments about the previously adopted and finalized IRF QRP reconsideration and appeals procedures, which are summarized below.

Comment: One commenter requested that the notification also include the reason for non-compliance. Multiple commenters appreciated that CMS is using both U.S. Mail and the QIES system to notify IRFs found to be non-compliant. Another commenter recommended that CMS continue using the U.S. Mail method, noting that QIES may not be a reliable way to distribute time-sensitive information. Several commenters were concerned about the possibility of using MACs to administer notifications, citing their lack of expertise in quality reporting, and requested that CMS clarify the authority that MACs would have to consider IRF QRP compliance and levy corrective action.

Response: We intend to retain this method of notification in addition to the use of QIES. We wish to clarify that the role of the MACs is for notification purposes only. They do not have a role in determining provider compliance in meeting the IRF QRP reporting requirements. We intend to include the reason for non-compliance in the notifications distributed via the CASPER folders; however, we wish to remind facilities that there are reports available in QIES (more information at: *https://www.qtso.com/irfpai.html*) and NHSN (more information at: *http://www.cdc.gov/nhsn/cms/*) that can be utilized to confirm quality measure data submissions. Additional information regarding non-compliance is also available on the IRF QRP Reconsiderations Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Reconsideration-and-Exception-and-Extension.html*.

N. Public Display of Measure Data for the IRF QRP & Procedures for the Opportunity to Review and Correct Data and Information

1. Public Display of Measures

Section 1886(j)(7)(E) of the Act requires the Secretary to establish procedures for making the IRF QRP data available to the public. In the FY 2016 IRF PPS final rule (80 FR 47126 through 47127), we finalized our proposals to display performance data for the IRF QRP quality measures by Fall 2016 on a CMS Web site, such as the *Hospital Compare,* after a 30-day preview period, and to give providers an opportunity to review and correct data submitted to the QIES–ASAP system or to the CDC NHSN. The procedures for the opportunity to review and correct data are provided in section VIII.N.2 of this final rule. In addition, we finalized the proposal to publish a list of IRFs that successfully meet the reporting requirements for the applicable payment determination on the IRF QRP Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Spotlights-Announcements.html*. In the FY 2016 IRF PPS final rule, we finalized that we will update the list after the reconsideration requests are processed on an annual basis.

Also, in the FY 2016 IRF PPS final rule (80 FR 47126 through 47127), we also finalized that the display of information for fall 2016 contains performance data on three quality measures:

- Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678);
- NHSN CAUTI Outcome Measure (NQF #0138); and
- All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502).

The measures Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) and NHSN CAUTI Outcome Measure (NQF #0138) are based on data collected beginning with the first quarter of 2015 or discharges beginning on January 1, 2015. With the exception of the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502), rates are displayed based on 4 rolling quarters of data and will initially use discharges from January 1, 2015, through December 31, 2015 (CY 2015) for Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) and data collected from January 1, 2015, through December 31, 2015 (CY 2015) for NHSN CAUTI Outcome Measure (NQF #0138). For the readmissions measure, data will be publicly report beginning with data collected for discharges beginning January 1, 2013, and rates will be displayed based on 2 consecutive years of data. For IRFs with fewer than 25 eligible cases, we proposed to assign the IRF to a separate category: ''The number of cases is too small (fewer than 25) to reliably tell how well the IRF is performing.'' If an IRF has fewer than 25 eligible cases, the IRF's readmission rates and interval estimates will not be publicly reported for the measure.

Calculations for all three measures are discussed in detail in the FY 2016 IRF PPS final rule (80 FR 47126 through 47127).

Pending the availability of data, we proposed to publicly report data in CY 2017 on 4 additional measures beginning with data collected on these measures for the first quarter of 2015, or discharges beginning on January 1, 2015: (1) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716) ; (2) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717) and, beginning with the 2015–16

influenza vaccination season, these two measures; (3) Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431); and (4) Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (NQF #0680).

Standardized infection ratios (SIRs) for the Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716) and Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717) will be displayed based on 4 rolling quarters of data and will initially use MRSA bacteremia and CDI events that occurred from January 1, 2015 through December 31, 2015 (CY 2015), for calculations. We proposed that the display of these ratios will be updated quarterly. Rates for the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) will initially be displayed for personnel working in the reporting facility October 1, 2015 through March 31, 2016. Rates for the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (NQF #0680) will also initially be displayed for patients in the IRF during the influenza vaccination season, from October 1, 2015, through March 31, 2016. We proposed that the display of these rates will be updated annually for subsequent influenza vaccination seasons.

Calculations for the MRSA and CDI Healthcare Associated Infection (HAI) measures adjust for differences in the characteristics of hospitals and patients using a SIR. The SIR is a summary measure that takes into account differences in the types of patients that a hospital treats. For a more detailed discussion of the SIR, please refer to the FY 2016 IRF PPS final rule (80 FR 47126 through 47127). The MRSA and CDI SIRs may take into account the laboratory methods, bed size of the hospital, and other facility-level factors. It compares the actual number of HAIs in a facility or state to a national benchmark based on previous years of reported data and adjusts the data based on several factors. A confidence interval with a lower and upper limit is displayed around each SIR to indicate that there is a high degree of confidence that the true value of the SIR lies within that interval. A SIR with a lower limit that is greater than 1.0 means that there were more HAIs in a facility or state than were predicted, and the facility is classified as ''Worse than the U.S. National Benchmark.'' If the SIR has an upper limit that is less than 1, the facility had fewer HAIs than were predicted and is classified as ''Better than the U.S. National Benchmark.'' If the confidence interval includes the value of 1, there is no statistical difference between the actual number of HAIs and the number predicted, and the facility is classified as ''No Different than U.S. National Benchmark.'' If the number of predicted infections is less than 1.0, the SIR and confidence interval are not calculated by CDC.

Calculations for the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) are based on reported numbers of personnel who received an influenza vaccine at the reporting facility or who provided written documentation of influenza vaccination outside the reporting facility. The sum of these two numbers is divided by the total number of personnel working at the facility for at least 1 day from October 1 through March 31 of the following year, and the result is multiplied by 100 to produce a compliance percentage (vaccination coverage). No risk adjustment is applicable to these calculations. More information on these calculations and measure specifications is available at *http://www.cdc.gov/nhsn/pdfs/hps-manual/vaccination/4-hcp-vaccination-module.pdf*. We proposed that this data will be displayed on an annual basis and will include data submitted by IRFs for a specific, annual influenza vaccination season. A single compliance (vaccination coverage) percentage for all eligible healthcare personnel will be displayed for each facility.

We invited public comment on our proposal to begin publicly reporting in CY 2017, pending the availability of data, on Facility-wide Inpatient Hospital-onset MRSA Bacteremia Outcome Measure (NQF #1716); Facility-wide Inpatient Hospital-onset CDI Outcome Measure (NQF #1717); and Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431). These comments are summarized and addressed below.

Comment: Several commenters, including MedPAC, supported public reporting of quality measures. MedPAC encouraged ongoing development and public reporting of cross-cutting measures for all provider settings.

Response: We will continue to move forward with cross-setting measure development and public reporting of these measures to meet the mandate of the IMPACT Act.

Comment: Several commenters stated CMS should risk-adjust IRFs' publicly displayed data for Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) for the number of patients that have pressure ulcers.

Response: We refer commenters to the FY 2016 IRF PPS final rule (80 FR 47126 through 47127) that finalized public display of the risk-adjusted quality measure, the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678)

Comment: One commenter expressed concerns that CMS will utilize data from the CARE Tool or IRF–PAI for public reporting of the quality measures and that such data is subjective and non-evidence based and there is a lack of ability to access the competency of staff completing the tool either within or across PAC settings. Therefore, the commenter is concerned that the publicly reported data will not represent the quality of care provided in IRFs and comparing across IRFs.

Response: We appreciate the comment expressing concern regarding the CARE Tool and IRF–PAI data for public reporting. We would like to clarify that quality measures set for public display have already been finalized, and the Secretary has a statutory obligation under sections 1886(j)(7)(E) and 1899B(g) of the Act to establish procedures to make the data publicly available.

Comment: Several commenters expressed concern that the public display of quality measure information is based on measures that do not exemplify the IRF experience, target very small populations of cases, and are not a good indicator of the overall quality of IRFs. Many commenters conveyed that the goals of IRFs are to provide medically necessary rehabilitation therapies to bring about recovery and improved function and the measures fail to assess IRFs success at achieving these goals.

Response: Section 3004 of the Affordable Care Act and the IMPACT Act require the Secretary of Health and Human Services to publish the data on the quality measures implemented in the IRF QRP through rulemaking. The public reporting of the three measures finalized for public reporting in the FY 2016 IRF PPS final rule and the four measures proposed for public reporting in the FY 2017 IRF PPS proposed rule supports the goals of the National Quality Strategy, the CMS Quality Strategy, the HHS HAI Action Plan, and the Hospital Acquired Condition Reduction Program. It is both a CMS and an HHS priority to ensure the delivery of high quality, patient-centered, and safe care across all care settings. While the main focus of care in

an IRF may be centered on restoration of a patient's functional status, we believe that this cannot be achieved without attention to the basic tenants of patient care, which speak to prevention and patient safety, and believe that our quality measures reflect these aspects of quality. The IMPACT Act requires us to address the domain of functional status and requires the public reporting of this data within 2 years of a finalized quality, resource use, and other measure's specified application date. We believe that the addition of these measures to the public display of IRF quality data will help to address any concerns relayed by the commenter.

Comment: One commenter expressed concerns that the NHSN Facility-Wide Inpatient Hospital-Onset MRSA Bacteremia Outcome Measure (NQF #1716) does not reflect care provided in an IRF, specifically, rehabilitation provided to promote functional recovery and achievement of goals. The commenter also noted that the incidence of MRSA is rare, and generally, if a patient in rehabilitation has MRSA, the infection is present upon admission to the rehabilitation facility following transfer from the acute care facility. Finally, the commenter noted that the inclusion of the NHSN Facility-Wide Inpatient Hospital-Onset MRSA Bacteremia Outcome Measure (NQF #1716) within the IRF QRP may cause rehabilitation facilities to inappropriately screen for this condition, resulting in unnecessary costs to the Medicare program.

Response: Section 3004 of the Affordable Care Act and the IMPACT Act requires the Secretary of Health and Human Services to publish the data on the quality measures implemented in the IRF QRP through rulemaking. The public reporting of the NHSN Facility-Wide Inpatient Hospital-Onset MRSA Bacteremia Outcome Measure (NQF #1716) support the goals of the National Quality Strategy, the CMS Quality Strategy, the HHS HAI Action Plan, and the Hospital Acquired Condition Reduction Program. It is both a CMS and an HHS priority to ensure the delivery of high quality, patient-centered, and safe care across all care settings.

According to the CDC, the steward of this quality measure, cases defined by NHSN as Community-onset MRSA Bacteremia are excluded from the data that is provided by NHSN to CMS. Only those cases that meet the NHSN definition of Incident and Healthcare Facility-onset are reported as a part of the CMS IRF QRP. For IRF units within a hospital that participate in the CMS IRF QRP will be given a single MRSA bacteremia LabID SIR for each type of CMS-certified IRF unit (adult and pediatric) mapped within the hospital according to CMS Certification Number (CCN). The MRSA Bacteremia LabID SIR is calculated as: Number of all incident blood source MRSA LabID events identified >3 days after admission to an IRF unit and where the patient had no positive MRSA bacteremia LabID events in the prior 14 days in any CMS-certified IRF unit of that type divided by the total number of predicted incident healthcare facility-onset blood source MRSA LabID events. Clinicians should base decisions about diagnostic testing on the needs and clinical picture of the patient. Patients with MRSA bacteremia would be expected to be symptomatic. Routine collection of blood cultures on patients not suspected of being bacteremic would be outside of the standards of medical care. For additional information on the specifications for this measure, please refer to the CDC reference: *http://www.cdc.gov/nhsn/pdfs/cms/irfs/linelists_irfunits_indicators.pdf*.

Comment: Several commenters recommended that CMS revise the Facility-wide Inpatient Hospital-onset CDI Outcome Measure (NQF #1717) because there are multiple *C. difficile* quality measures for Medicare providers across the continuum of care (acute care hospitals, IRFs, etc.) and one incident of *C. difficile* onset may be reported by three providers and effectively, and unreasonably, be a ''triple hit'' for multiple providers so that it is only reported at the first site of discovery.

Response: The Facility-wide Inpatient Hospital-onset CDI Outcome Measure (NQF #1717) was adopted in the IRF QRP and finalized in the FY 2015 IRF PPS final rule (79 FR 45913 through 45914). The CDC, the steward of this measure, noted that the measure specifications for NQF #1717, by design, align with the NHSN LabID Event protocol, which was developed to require minimal investigation on the part of healthcare facilities and to provide a proxy measure of infection. Dates of admission and specimen collection are required and can easily be collected via electronic methods. These dates enable differentiation of healthcare-associated and community-onset events. To require a facility to determine if a CDI LabID Event had been identified in another facility would call for manual review of medical records and potential communication with transferring facilities. The design of LabID event reporting via NHSN is by single facility, which means that events are reported for the facility where they occur. Analysis is by single facility identifier (NHSN organizational ID) and does not cross admissions to a different NHSN facility (or a different type reporting facility such as nursing home to acute care facility) or transfer from facility A to facility B. Cases defined by NHSN as community-onset *Clostridium difficile* are excluded from the data that is provided by NHSN to CMS. Only those cases that meet the NHSN definitions of an Incident (non-duplicate) Healthcare Facility-onset are reported as a part of the CMS IRF QRP. Therefore, cases that are identified during the first 3 days of admission to a facility, and which may be related to a discharge from another hospital, will not be included in the *Clostridium difficile* LabID Event data reported for the admitting facility.

Comment: The commenter was concerned that the public display of these measures will provide misleading interpretations of quality, as almost all the measures will be based on different time frames and will use different minimum patient thresholds and potentially varying patient populations. The commenter recommends that CMS suspend public display of IRF QRP data until (1) all IMPACT Act domains are implemented and (2) the patient populations for each measure are standardized.

Response: The Secretary has a statutory obligation under section 1899B(g) and 1886(j)(7)(E) of the Act to make the data available to the public. We are transitioning towards aligning the data collection periods to follow the calendar year. Once this is achieved, the only measure that will not be in alignment is the influenza measure since these measures require taking into account the influenza season and vaccination season for the data collection period.

Minimum patient thresholds and populations are dependent on the specific measure. Each measure is specifically applied in public reporting so that there is enough volume of cases reported to protect anonymity and provide meaningful results with representative sample size. Public reporting must comply with applicable privacy laws and provide minimum sample sizes in order for facilities to compare their performance with other IRFs. If the sample size is too small, the results will not reflect their facility performance for comparison purposes.

Final Decision: After careful consideration of the public comments, we are finalizing our proposal to begin publicly reporting in CY 2017, pending the availability of data, on Facility-wide Inpatient Hospital-onset MRSA Bacteremia Outcome Measure (NQF

#1716); Facility-wide Inpatient Hospital-onset CDI Outcome Measure (NQF #1717); and Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431).

For the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680), we proposed to display rates annually based on the influenza season to avoid reporting for more than one influenza vaccination within a CY. For example, in 2017 we will display rates for the patient vaccination measure based on discharges starting on July 1, 2015, to June 30, 2016. This is proposed because it includes the entire influenza vaccination season (October 1, 2015, to March 31, 2016).

Calculations for Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) will be based on patients meeting any one of the following criteria: Patients who received the influenza vaccine during the influenza season, patients who were offered and declined the influenza vaccine, and patients who were ineligible for the influenza vaccine due to contraindication(s). The facility's summary observed score will be calculated by combining the observed counts of all the criteria. This is consistent with the publicly reported patient influenza vaccination measure for Nursing Home Compare. Additionally, for the patient influenza measure, we will exclude IRFs with fewer than 20 stays in the measure denominator. For additional information on the specifications for this measure, please refer to the IRF Quality Reporting Measures Information Web page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html*.

We invited public comments on our proposal to begin publicly reporting the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) measure on discharges from July 1st of the previous calendar year to June 30th of the current calendar year. We invited comments on the public display of the measure Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (NQF #0680) in 2017 pending the availability of data.

We received several comments, which are summarized below.

Comment: Several commenters expressed concern that the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680) is not a true indicator of the quality of care provided in IRFs, which focuses on functional recovery so that patients are able to function to their maximum potential in the least restrictive environment. Commenters expressed concern that the influenza vaccination rates do not adequately assess whether quality care was provided and that CMS has not provided any evidence in the IRF QRP that differences in influenza vaccination rates between facilities affect the quality of outcomes or the patient experience.

Response: We appreciate the concerns by several commenters in regard to the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680). However, this quality measure was adopted in the IRF QRP and finalized in the FY 2014 IRF PPS final rule (78 FR 47906 through 47911).

Final Decision: After careful consideration of the public comments, we are finalizing our proposal to begin publicly reporting the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) measure, pending the availability of data, on discharges from July 1st of the previous calendar year to June 30th of the current calendar year.

Additionally, we requested public comments on whether to include, in the future, public display comparison rates based on CMS regions or US census regions for Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678); All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502); and Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) for CY 2017 public display.

We did not receive any comments about whether to include, in the future, public display comparison rates based on CMS regions or US census regions for CY 2017 public display.

2. Procedures for the Opportunity To Review and Correct Data and Information

Section 1899B(g) of the Act requires the Secretary to establish procedures for public reporting of IRFs' performance, including the performance of individual IRFs, on quality measures specified under section 1899B(c)(1) of the Act and resource use and other measures specified under section 1899B(d)(1) of the Act (collectively, IMPACT Act measures) beginning not later than 2 years after the applicable specified application date under section 1899B(a)(2)(E) of the Act. Under section 1899B(g)(2) of the Act, the procedures must ensure, including through a process consistent with the process applied under section 1886(b)(3)(B)(viii)(VII) of the Act, which refers to public display and review requirements in the Hospital IQR Program, that each IRF has the opportunity to review and submit corrections to its data and information that are to be made public prior to the information being made public.

In the FY 2016 IRF PPS final rule (80 FR 47126 through 47128), and as illustrated in Table 10 in section VIII.I.a of this final rule, we finalized that once the provider has an opportunity to review and correct quarterly data related to measures submitted via the QIES–ASAP system or CDC NHSN, we will consider the provider to have been given the opportunity to review and correct this data. We wish to clarify that although the correction of data (including claims) can occur after the submission deadline, if such corrections are made after a particular quarter's submission and correction deadline, such corrections will not be captured in the file that contains data for calculation of measures for public reporting purposes. To have publicly displayed performance data that is based on accurate underlying data, it will be necessary for IRFs to review and correct this data before the quarterly submission and correction deadline.

We restated and proposed additional details surrounding procedures that will allow individual IRFs to review and correct their data and information on measures that are to be made public before those measure data are made public.

For assessment-based measures, we proposed a process by which we will provide each IRF with a confidential feedback report that will allow the IRF to review its performance on such measures and, during a review and correction period, to review and correct the data the IRF submitted to CMS via the CMS QIES–ASAP system for each such measure. In addition, during the review and correction period, the IRF will be able to request correction of any errors in the assessment-based measure rate calculations.

We proposed that these confidential feedback reports will be available to each IRF using the CASPER system. We

refer to these reports as the IRF Quality Measure (QM) Reports. We proposed to provide monthly updates to the data contained in these reports as data become available. We proposed to provide the reports so that providers will be able to view their data and information at both the facility and patient level for its quality measures. The CASPER facility level QM Reports may contain information such as the numerator, denominator, facility rate, and national rate. The CASPER patient-level QM Reports may contain individual patient information which will provide information related to which patients were included in the quality measures to identify any potential errors for those measures in which we receive patient-level data. Currently, we do not receive patient-level data on the CDC measure data received via the NHSN system. In addition, we will make other reports available in the CASPER system, such as IRF–PAI assessment data submission reports and provider validation reports, which will disclose the IRFs data submission status providing details on all items submitted for a selected assessment and the status of records submitted. We refer providers to the CDC/NHSN system Web site for information on obtaining reports specific to NHSN submitted data at *http://www.cdc.gov/nhsn/inpatient-rehab/index.html*. Additional information regarding the content and availability of these confidential feedback reports will be provided on an ongoing basis on our Web site(s) at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/index.html*.

As previously finalized in the FY 2016 IRF PPS final rule and illustrated in Table 18 in section VIII.I.c of this final rule, IRFs will have approximately 4.5 months after the reporting quarter to correct any errors of their assessment-based data (that appear on the CASPER generated QM reports) and NHSN data used to calculate the measures. During the time of data submission for a given quarterly reporting period and up until the quarterly submission deadline, IRFs could review and perform corrections to errors in the assessment data used to calculate the measures and could request correction of measure calculations. However, as already established, once the quarterly submission deadline occurs, the data is ''frozen'' and calculated for public reporting and providers can no longer submit any corrections. We will encourage IRFs to submit timely assessment data during a given quarterly reporting period and review their data and information early during the review and correction period so that they can identify errors and resubmit data before the data submission deadline.

As noted above, the assessment data will be populated into the confidential feedback reports, and we intend to update the reports monthly with all data that have been submitted and are available. We believe that the data collection/submission quarterly reporting periods plus 4.5 months to review correct and review the data is sufficient time for IRFs to submit, review and, where necessary, correct their data and information. These time frames and deadlines for review and correction of such measures and data satisfy the statutory requirement that IRFs be provided the opportunity to review and correct their data and information and are consistent with the informal process hospitals follow in the Hospital IQR Program.

In FY 2016 IRF PPS final rule (80 FR 47126 through 47128), we finalized the data submission/correction and review period. Also, we afford IRFs a 30-day preview period prior to public display during which IRFs may preview the performance information on their measures that will be made public. We want to clarify that we will provide the *preview* report using the CASPER system, with which IRFs are familiar. The CASPER preview reports inform providers of their performance on each measure which will be publicly reported. Please note that the CASPER *preview* reports for the reporting quarter will be available after the 4.5 month correction period and the applicable data submission/correction deadline have passed and are refreshed on a quarterly basis for those measures publicly reported quarterly, and annually for those measure publicly reported annually. We proposed to give IRFs 30 days to review the preview report beginning from the date on which they can access the report. As already finalized, corrections to the underlying data will not be permitted during this time; however, IRFs may ask for a correction to their measure calculations during the 30-day preview period, should they believe the calculation is inaccurate. We proposed that if we agree that the measure, as it is displayed in the preview report, contains a calculation error, we could suppress the data on the public reporting Web site, recalculate the measure and publish it at the time of the next scheduled public display date. This process will be consistent with informal processes used in the Hospital IQR Program. If finalized, we intend to utilize a subregulatory mechanism, such as our IRF QRP Web site, to provide more information about the preview reports, such as when they will be made available and explain the process for how and when providers may ask for a correction to their measure calculations. We invited public comment on these proposals to provide preview reports using the CASPER system, giving IRFs 30 days review the preview report and ask for a correction, and to use a subregulatory mechanism to explain the process for how and when providers may ask for a correction.

In addition to assessment-based measures and CDC measure data received via the NHSN system, we have also proposed claims-based measures for the IRF QRP. The claims-based measures include those proposed to meet the requirements of the IMPACT Act as well as the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502) which was finalized for public display in the FY 2016 IRF PPS final rule (80 FR 47126 through 47127). As noted in section VII.N.2. of this final rule, section 1899B(g)(2) of the Act requires prepublication provider review and correction procedures that are consistent with those followed in the Hospital IQR Program. Under the Hospital IQR Program's informal procedures, for claims-based measures, we provide hospitals 30 days to preview their claims-based measures and data in a preview report containing aggregate hospital-level data. We proposed to adopt a similar process for the IRF QRP.

Prior to the public display of our claims-based measures, in alignment with the Hospital IQR, HAC and Hospital VBP Programs, we proposed to make available through the CASPER system, a confidential preview report that will contain information pertaining to claims-based measure rate calculations, for example, facility and national rates. The data and information will be for feedback purposes only and could not be corrected. This information will be accompanied by additional confidential information based on the most recent administrative data available at the time we extract the claims data for purposes of calculating the measures. Because the claims-based measures are recalculated on an annual basis, these confidential CASPER QM reports for claims-based measures will be refreshed annually. As previously finalized in the FY 2016 IRF PPS final rule (80 FR 47126 through 47128), IRFs will have 30 days from the date the preview report is made available in which to review this information. The

30-day preview period is the only time when IRFs will be able to see claims-based measures before they are publicly displayed. IRFs will not be able to make corrections to underlying claims data during this preview period, nor will they be able to add new claims to the data extract. However, IRFs may request that we correct our measure calculation if the IRF believes it is incorrect during the 30 day preview period. We proposed that if we agree that the measure, as it is displayed in the preview report, contains a calculation error, we could suppress the data on the public reporting Web site, recalculate the measure, and publish it at the time of the next scheduled public display date. This process will be consistent with informal policies followed in the Hospital IQR Program. If finalized, we intend to utilize a subregulatory mechanism, such as our IRF QRP Web site, to explain the process for how and when providers may contest their measure calculations

The proposed claims-based measures—The MSPB–PAC IRF QRP measure; Discharge to Community—PAC, Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP, and Potentially Preventable Within Stay Readmission Measure for IRFs—use Medicare administrative data from hospitalizations for Medicare FFS beneficiaries. Public reporting of data will be based on 2 consecutive calendar years of data, which is consistent with the specifications of the proposed measures. We proposed to create data extracts using claims data for the proposed claims-based measures–The MSPB–PAC IRF QRP measure; Discharge to Community—PAC, Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP, and Potentially Preventable Within Stay Readmission Measure for IRFs—at least 90 days after the last discharge date in the applicable period, which we will use for the calculations. For example, if the last discharge date in the applicable period for a measure is December 31, 2017, for data collection January 1, 2016, through December 31, 2017, we will create the data extract on approximately March 31, 2018, at the earliest, and use that data to calculate the claims-based measures for that applicable period. Since IRFs will not be able to submit corrections to the underlying claims snapshot nor add claims (for measures that use IRF claims) to this data set at the conclusion of the at least the 90-day period following the last date of discharge used in the applicable period, at that time we will consider IRF claims data to be complete for purposes of calculating the claims-based measures.

We proposed that beginning with data that will be publicly displayed in 2018, claims-based measures will be calculated using claims data at least 90 days after the last discharge date in the applicable period, at which time we will create a data extract or snapshot of the available claims data to use for the measures calculation. This timeframe allows us to balance the need to provide timely program information to IRFs with the need to calculate the claims-based measures using as complete a data set as possible. As noted, under this procedure, during the 30-day preview period, IRFs will not be able to submit corrections to the underlying claims data or to add new claims to the data extract. This is for two reasons: First, for certain measures, the claims data used to calculate the measure is derived not from the IRF's claims, but from the claims of another provider. For example, the proposed measure Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP uses claims data submitted by the hospital to which the patient was readmitted. The claims are not those of the IRF and, therefore, the IRF could not make corrections to them. Second, even where the claims used to calculate the measures are those of the IRF, it will not be not possible to correct the data after it is extracted for the measures calculation. This is because it is necessary to take a static ''snapshot'' of the claims in order to perform the necessary measure calculations.

We seek to have as complete a data set as possible. We recognize that the at least 90-day ''run-out'' period, when we will take the data extract to calculate the claims-based measures, is less than the Medicare program's current timely claims filing policy under which providers have up to 1 year from the date of discharge to submit claims. We considered a number of factors in determining that the proposed at least 90-day run-out period is appropriate to calculate the claims-based measures. After the data extract is created, it takes several months to incorporate other data needed for the calculations (particularly in the case of risk-adjusted or episode-based measures). We then need to generate and check the calculations. Because several months lead time is necessary after acquiring the data to generate the claims-based calculations, if we were to delay our data extraction point to 12 months after the last date of the last discharge in the applicable period, we will not be able to deliver the calculations to IRFs sooner than 18 to 24 months after the last discharge. We believe this will create an unacceptably long delay both for IRFs and for us to deliver timely calculations to IRFs for quality improvement.

We invited public comment on these proposals. We received a number of comments, which are summarized below.

Comment: Several commenters expressed concern that for claims-based measures, CMS proposes to calculate claims-based measures on an annual basis and the CASPER QM provider reports for these measures would only be available annually. Commenters also expressed concern that CMS does not propose to allow providers to correct their metrics on claims-based measures; reports would be for feedback purposes only. Several commenters requested CMS provide claims-based feedback reports at least twice a year as well as providing patient-level data.

Response: We appreciate the commenters' concerns and suggestions to provide feedback reports at least twice a year as well as providing patient-level data for claims-based measures. As discussed previously, the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502) is based on 2 consecutive years of data in order to ensure a sufficient sample size to reliably assess IRFs' performance. The decision to update claims-based measures on an annual basis was to ensure that the amount of data received during the reporting period was sufficient to generate reliable measure rates. However, we will explore the feasibility of providing IRFs with information more frequently. We believe that we are limited in our ability to provide patient level information that stems from claims submitted by providers other than IRF, but we will explore the feasibility of providing patient-level data. With regard to the concern for the correction of claims-based measures and the IRF's ability to correct their metrics, and that the reports we provide will be for feedback purposes only, we interpret the commenter to be referring to both the preview reports and the QM reports we discussed. The limitation on claims-based data and corrections is that the measures are calculated after the claims file has been obtained. If the IRF determines there are errors in the claims data they submitted, then they can correct such data. The corrections to the claims data will be reflected in the subsequent measure calculation. We urge IRFs to submit timely and accurate claims-based data.

Comment: One commenter expressed concern that 30 days is inadequate to

preview and assess the QM reports and recommends 60 days and that CMS should establish a process to discuss and reconcile issues or incongruities between CMS's and the provider's data.

Response: We interpret the commenter to be referring to the preview reports we will provide prior to public reporting and appreciate their concern for the 30-day timeframe for which IRFs have to review and assess the preview reports. The 30-day preview period, previously finalized, is consistent with other public reporting programmatic procedures. As described, this timeframe is for providers to evaluate their data that will be published and alert us to any discrepancies they may find. In addition, as described, IRFs will have an opportunity to review their information and data using various reports, which are provided through the CASPER system and can be used to inform data correction needs on behalf of the IRF. For example, as discussed, we intend to provide IRF QM Reports that will provide monthly reporting on both facility-level and patient-level CMS assessment-based data. Further, we refer the commenter to the discussion we provide in which IRFs will have 4.5 months to review and correct data *prior* to the quarterly freeze dates and posting of the final preview reports in QIES.

Final Decision: After careful consideration of the public comments, we are finalizing our proposals related to procedures for the opportunity to review and correct data and information. We are finalizing as proposed, our policies and procedures pertaining to public reporting and the opportunity to review and correct data and information. We are also finalizing as proposed, our policies and procedures for claims-based measures for public reporting.

O. Mechanism for Providing Feedback Reports to IRFs

Section 1899B(f) of the Act requires the Secretary to provide confidential feedback reports to post-acute care providers on their performance to the measures specified under section 1899B(c)(1) and (d)(1) of the Act, beginning 1 year after the specified application date that applies to such measures and PAC providers. As discussed earlier, the reports we proposed to provide for use by IRFs to review their data and information will be confidential feedback reports that will enable IRFs to review their performance on the measures required under the IRF QRP. We proposed that these confidential feedback reports will be available to each IRF using the CASPER system. Data contained within these CASPER reports will be updated as previously described, on a monthly basis as the data become available except for our claims-based measures, which are only updated on an annual basis.

We intend to provide detailed procedures to IRFs on how to obtain their confidential feedback CASPER reports on the IRF QRP Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/index.html.* We proposed to use the CMS QIES–ASAP system to provide quality measure reports in a manner consistent with how providers obtain various reports to date. The QIES–ASAP system is a confidential and secure system with access granted to providers, or their designees.

We sought public comment on this proposal to satisfy the requirement to provide confidential feedback reports to IRFs. We received several comments, which are summarized are below.

Comment: Several commenters recommended CMS provide more frequent feedback, such as quarterly, for assessment-based measures and every six months reporting for claims-based measures.

Response: We appreciate commenters' suggestion for CMS to provide more frequent feedback, such as quarterly, for assessment-based measures and every 6 months for claims-based measures.

As previously discussed, IRFs will have an opportunity to review and utilize their data using confidential reports provided through the CASPER system. The decision to update claims-based measures on an annual basis was basis was explained previously in response to the comment concerning providing feedback reports at least twice a year.

Comment: One commenter recommended CMS conduct a ''dry run'' in which providers receive confidential preview reports prior to publicly reporting measures so that providers can become familiar with the methodology, understand the measure results, know how well they are performing, and have an opportunity to give CMS feedback on potential technical issues with the measures.

Response: We intend to offer providers information related to their measures so that they become familiar with the measure's methodology and can utilize their confidential *preview* reports which they will receive prior to the public reporting of new IRF QRP measures. IRFs will also receive other confidential reports such as the IRF facility and patient level QM Reports as well as an additional confidential facility-level report to incorporate the quarterly freeze dates, for example, the *Review and Correct* Report. We believe that these various reports will provide an indication on how well the IRF is performing as well as opportunities to provide CMS feedback on technical issues with the measures. Therefore, no additional dry run period is warranted.

Final Decision: After careful consideration of the public comments, we are finalizing our proposal to provide confidential feedback reports to IRFs, as proposed.

P. Method for Applying the Reduction to the FY 2017 IRF Increase Factor for IRFs That Fail To Meet the Quality Reporting Requirements

As previously noted, section 1886(j)(7)(A)(i) of the Act requires the application of a 2-percentage point reduction of the applicable market basket increase factor for IRFs that fail to comply with the quality data submission requirements. In compliance with section 1886(j)(7)(A)(i) of the Act, we proposed to apply a 2-percentage point reduction to the applicable FY 2017 market basket increase factor in calculating a proposed adjusted FY 2017 standard payment conversion factor to apply to payments for only those IRFs that failed to comply with the data submission requirements. As previously noted, application of the 2-percentage point reduction may result in an update that is less than 0.0 for a fiscal year and in payment rates for a fiscal year being less than such payment rates for the preceding fiscal year. Also, reporting-based reductions to the market basket increase factor will not be cumulative; they will only apply for the FY involved.

We invited public comment on the proposed method for applying the reduction to the FY 2017 IRF increase factor for IRFs that fail to meet the quality reporting requirements. We did not receive any comments on this proposal.

Final Decision: We are finalizing our proposed method for applying the reduction to the FY 2017 IRF increase factor for IRFs that fail to meet the quality reporting requirements.

Table 21 shows the calculation of the adjusted FY 2017 standard payment conversion factor that will be used to compute IRF PPS payment rates for any IRF that failed to meet the quality reporting requirements for the applicable reporting period(s).

TABLE 21—CALCULATIONS TO DETERMINE THE ADJUSTED FY 2017 STANDARD PAYMENT CONVERSION FACTOR FOR IRFS THAT FAILED TO MEET THE QUALITY REPORTING REQUIREMENT

Explanation for adjustment	Calculations
Standard Payment Conversion Factor for FY 2016	$15,478.
Market Basket Increase Factor for FY 2017 (2.7 percent), reduced by 0.3 percentage point for the productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act, reduced by 0.75 percentage point in accordance with sections 1886(j)(3)(C) and (D) of the Act and further reduced by 2 percentage points for IRFs that failed to meet the quality reporting requirement.	× 0.9965.
Budget Neutrality Factor for the Wage Index and Labor-Related Share	× 0.9992.
Budget Neutrality Factor for the Revisions to the CMG Relative Weights	× 0.9992.
Adjusted FY 2017 Standard Payment Conversion Factor	= 15,399.

IX. Miscellaneous Comments

Comment: Several commenters were supportive of our continued use of the FY 2014 facility-level adjustments and recommended that CMS continue monitoring the adjustments. Other commenters suggested that CMS be more transparent about the methodology and the factors it utilizes for calculating facility adjustment payments to IRFs. Several commenters suggested that CMS should establish a three-year minimum interval for any change in the IRF provider-level adjustment factors and recommended that if any factor varies by a minimum amount, the factor should be adjusted. Some commenters also recommended that CMS monitor the facility-level adjustment factors annually and adjust them if there is a change in excess of 5 to 10 percent.

Response: As we did not propose any changes to the facility-level adjustments, these comments are outside the scope of the proposed rule. In the FY 2017 IRF PPS proposed rule (81 FR 24177), we noted that, in the FY 2015 IRF PPS final rule (79 FR 45872 at 45882), we froze the facility-level adjustments at FY 2014 levels for FY 2015 and all subsequent years (unless and until we propose to update them again through future notice-and-comment rulemaking). We will continue to monitor the facility-level adjustments and update them as necessary through rulemaking to ensure the continued accuracy of IRF PPS payments.

Comment: Several commenters expressed concerns about the impact of the changes to the 60 percent rule compliance methodology that we finalized in the FY 2014 and FY 2015 IRF PPS final rules on beneficiary access to IRF services, and suggested that we revisit them. These commenters further stated that the translation of International Classification of Diseases, 9th Revision, Clinical Modification (ICD–9–CM) codes to International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) codes using the General Equivalence Mapping (GEMS) tool may have unintentionally caused some diagnoses to now be excluded from counting under the presumptive compliance methodology. In particular, the commenters suggested that we review the codes excluded under the IGCs for traumatic brain injury, hip fracture, and major multiple trauma, and add these cases back in as presumptively compliant cases under the 60 percent rule. Some commenters suggested that we issue clarifications to MACs and CMS Regional Offices that these codes are considered presumptively compliant. Further, one commenter suggested that we revisit our decision on no longer considering presumptively compliant diagnoses codes for rheumatoid myopathy and polyneuropathy, unilateral amputations, and amputation status/aftercare.

Response: As we did not propose any changes to the methodology for determining IRFs' compliance with the 60 percent rule in the FY 2017 IRF PPS proposed rule, these comments are outside the scope of the proposed rule. We appreciate the commenter's suggestions, and will continue to monitor and assess the implications of the changes to the presumptive methodology that we finalized in the FY 2014 and FY 2015 IRF PPS final rules to determine if any further refinements to the methodology are needed. We intend to take a comprehensive look at the ICD–10–CM codes to identify any diagnosis codes that may need to be added to the presumptive compliance methodology, as well as any codes that may need to be removed.

Comment: Several commenters suggested that, as height and weight are now required information on the IRF–PAI (beginning October 1, 2014), CMS should now use this information to identify patients with unilateral joint replacements and body mass indexes (BMI) greater than 50 for presumptive compliance with the 60 percent rule requirements.

Response: As we did not propose any changes to the methodology for determining IRFs' compliance with the 60 percent rule, these comments are outside the scope of the proposed rule. However, we will take these suggestions into consideration.

Comment: One commenter stated that the translation to ICD–10–CM has created a problem with the grouping of rehabilitation diagnosis-related groups (DRGs) in rehabilitation units due to the loss of the ''V code'' under ICD–10–CM. The commenter expressed concern that rehabilitation patients may not be reimbursed appropriately and in many instances would be paid under the Hospital IPPS MS–DRGs.

Response: As payment under the IRF PPS is not based on diagnosis-related groups, this comment is outside the scope of the proposed rule. This final rule only applies to rehabilitation units that are paid under the IRF PPS, not to other types of rehabilitation units which may be present in an acute care hospital but that are paid under other Medicare payment systems.

Comment: One commenter stated that CMS should review its policy regarding the use of ''D-subsequent encounter'' as an eligible 7th character for traumatic injury diagnosis codes as advised by the *AHA Coding Clinic for ICD–10–CM and ICD–10–PCS* Editorial Advisory Board (reference material for this can be found at *http://www.ahacentraloffice.org/codes/Resources.shtml*). The commenter stated that ''subsequent encounter'' is an appropriate option for rehabilitation services and that CMS should allow the ''D'' as an eligible 7th character for traumatic injury diagnosis codes.

Response: IRFs are permitted to use ''D'' as an eligible 7th character for traumatic injury diagnosis codes on both the IRF claim and the IRF–PAI. However, for the reasons indicated in the FY 2015 IRF PPS final rule (79 FR 45872, 45907), effective with discharges occurring on or after October 1, 2015, ICD–10–CM codes with the seventh character extension of ''D'' are not included in the ICD–10–CM versions of the ''List of Comorbidities,'' ''ICD–10–CM Codes That Meet Presumptive Compliance Criteria,'' or ''Impairment

Group Codes That Meet Presumptive Compliance Criteria.'' Whereas the *AHA Coding Clinic for ICD–10–CM and ICD–10 PCS* (Vol. 2, No. 1) guidelines instruct providers to use the 7th character ''D'' for traumatic injury diagnosis codes used in an IRF setting, the guidelines specifically say that the AHA Coding Clinic guidelines only apply to the IRF claim and that providers should refer to the instructions provided in the IRF–PAI training manual, which is available for download from the IRF PPS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAI.html, for instructions on how to code the IRF–PAI.* Thus, ICD–10–CM diagnosis codes with the 7th character ''D,'' if used for traumatic injury diagnosis codes on the IRF–PAI, will not result in a tier payment or result in a case being presumptively compliant with the IRF 60 percent rule for the reasons stated in the FY 2015 IRF PPS final rule (79 FR 45872, 45907).

Comment: Several commenters stated that the FY 2017 update to the standard payment conversion factor does not include additional payment to IRFs for the time and resources needed to complete assessments for quality reporting. These commenters further stated that the additional quality reporting elements in the FY 2016 IRF PPS final rule will add time spent collecting information while decreasing the time available for direct patient care. Several commenters stated that the proposed increase does not cover the costs of medical inflation, or of the technical implementation, training, and data collection related to the quality reporting measures even though costs will be significant. Several commenters stated that the ''minimal increase'' does not adequately take into account the estimated costs of implementing the quality reporting measures and request that CMS add the estimated costs of these measures to the FY 2017 payment update.

Response: We refer readers to the FY 2016 IRF PPS final rule (80 FR 47129 through 47137) for details regarding the Collection of Information Requirements and Regulatory Impact Analysis for the finalized measures. We would also like to clarify that quality program reporting requirements are not included in the standard payment conversion factor. However, in accordance with section 1886(j)(7)(A) of the Act, the applicable annual increase factor for any IRF that does not submit the required data to CMS must be reduced by two percentage points.

Comment: One commenter reiterated MedPAC's March 2016 recommendation that we should analyze patterns of coding across IRFs and reassess the inter-rater reliability of the IRF–PAI.

Response: This comment involves data monitoring activities that are not discussed in the proposed rule, and are therefore outside the scope of the rule. However, we will share this recommendation with the appropriate components within CMS for their consideration of these issues.

X. Provisions of the Final Regulations

In this final rule, we are adopting the provisions set forth in the FY 2017 IRF PPS proposed rule (81 FR 24178). Specifically:

- We will update the FY 2017 IRF PPS relative weights and average length of stay values using the most current and complete Medicare claims and cost report data in a budget-neutral manner, as discussed in section IV of this final rule.
- As established in the FY 2015 IRF PPS final rule (79 FR 45872 at 45882), the facility-level adjustments will remain frozen at FY 2014 levels for FY 2015 and all subsequent years (unless and until we propose to update them again through future notice-and-comment rulemaking), as discussed in section V of this final rule.
- We will update the FY 2017 IRF PPS payment rates by the market basket increase factor, based upon the most current data available, with a 0.75 percentage point reduction as required by sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(v) of the Act and the productivity adjustment required by section 1886(j)(3)(C)(ii)(I) of the Act, as described in section VI of this final rule.
- We will update the FY 2017 IRF PPS payment rates by the FY 2017 wage index and the labor-related share in a budget-neutral manner and continue the phase-out of the rural adjustment as discussed in section VI of this final rule.
- We will calculate the final IRF standard payment conversion factor for FY 2017, as discussed in section VI of this final rule.
- We will update the outlier threshold amount for FY 2017, as discussed in section VII of this final rule.
- We will update the cost-to-charge ratio (CCR) ceiling and urban/rural average CCRs for FY 2017, as discussed in section VII of this final rule.
- We will adopt revisions and updates to quality measures and reporting requirements under the quality reporting program for IRFs in accordance with section 1886(j)(7) of the Act, as discussed in section VIII of this final rule.

XI. Collection of Information Requirements

A. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the OMB for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

This final rule makes reference to associated information collections that are not discussed in the regulation text contained in this document.

B. Collection of Information Requirements for Updates Related to the IRF QRP

Failure to submit data required under section 1886(j)(7)(C) and (F) of the Act will result in the reduction of the annual update to the standard federal rate for discharges occurring during such fiscal year by 2 percentage points for any IRF that does not comply with the requirements established by the Secretary. At the time that this analysis was prepared, 91, or approximately 8 percent, of the 1166 active Medicare-certified IRFs did not receive the full annual percentage increase for the FY 2016 annual payment update determination. Information is not available to determine the precise number of IRFs that will not meet the requirements to receive the full annual percentage increase for the FY 2017 payment determination.

We believe that the burden associated with the IRF QRP is the time and effort associated with data collection and reporting. As of February 1, 2016 there are approximately 1131 IRFs currently reporting quality data to CMS. In this final rule, we are adopting 5 measures. For the FY 2018 payment determinations and subsequent years, we proposed four new measures: (1)

MSPB–PAC IRF QRP; (2) Discharge to Community-PAC IRF QRP, and (3) Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP; (4) Potentially Preventable 30-Day Within Stay Readmission Measure for IRF QRP. These four measures are Medicare claims-based measures. Because claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes, we believe there will be no additional impact.

For the FY 2020 payment determination and subsequent years, we proposed one measure: Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP. Additionally, we proposed that data for this new measure will be collected and reported using the IRF–PAI (version effective October 1, 2018).

Our burden calculations take into account all ''new'' items required on the IRF–PAI (version effective October 1, 2018) to support data collection and reporting for this measure. The addition of the new items required to collect the newly proposed measure is for the purpose of achieving standardization of data elements.

We estimate the additional elements for the newly proposed Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP measure will take 6 minutes of nursing/clinical staff time to report data on admission and 4 minutes of nursing/clinical staff time to report data on discharge, for a total of 10 minutes. We estimate that the additional IRF–PAI items we proposed will be completed by Registered Nurses (RN) for approximately 75 percent of the time required, and Pharmacists for approximately 25 percent of the time required. Individual providers determine the staffing resources necessary. In accordance with OMB control number 0938–0842, we estimate 398,254 discharges from all IRFs annually, with an additional burden of 10 minutes. This will equate to 66,375.67 total hours or 58.69 hours per IRF. We believe this work will be completed by RNs (75 percent) and Pharmacists (25 percent). We obtained mean hourly wages for these staff from the U.S. Bureau of Labor Statistics' May 2014 National Occupational Employment and Wage Estimates (*http://www.bls.gov/oes/current/oes_nat.htm*), and to account for overhead and fringe benefits, we have doubled the mean hourly wage. Per the U.S. Bureau of Labor and Statistics, the mean hourly wage for a RN is $33.55. However, to account for overhead and fringe benefits, we have doubled the mean hourly wage, making it $67.10 for an RN. Per the U.S. Bureau of Labor and Statistics, the mean hourly wage for a pharmacist is $56.98. However, to account for overhead and fringe benefits, we have doubled the mean hourly wage, making it $113.96 for a pharmacist. Given these wages and time estimates, the total cost related to the newly proposed measures is estimated at $4,625.46 per IRF annually, or $5,231,398.17 for all IRFs annually.

For the quality reporting during extraordinary circumstances, in section VIII.L of this final rule, we add a previously finalized process that IRFs may request an exception or extension from the FY 2019 payment determination and that of subsequent payment determinations. The request must be submitted by email within 90 days from the date that the extraordinary circumstances occurred.

While the preparation and submission of the request is an information collection, unlike the aforementioned temporary exemption of the data collection requirements for the new drug regimen review measure, the request is not expected to be submitted to OMB for formal review and approval since we estimate less than two requests (total) per year. Since we estimate fewer than 10 respondents annually, the information collection requirement and associated burden is not subject as stated in 5 CFR 1320.3(c) of the implementing regulations of the Paperwork Reduction Act of 1995.

As discussed in section VIII.M of this final rule, we add a previously finalized process that will enable IRFs to request reconsiderations of our initial non-compliance decision in the event that it believes that it was incorrectly identified as being subject to the 2-percentage point reduction to its annual increase factor due to non-compliance with the IRF QRP reporting requirements. While there is burden associated with filing a reconsideration request, 5 CFR 1320.4 of OMB's implementing regulations for PRA excludes activities during the conduct of administrative actions such as reconsiderations.

We received comments about the collection of information requirements associated with measures being proposed for the IRF QRP, which are summarized and addressed below.

Comment: One commenter appreciated that the claims-based measures being proposed do not place additional burden on the facilities and their staff. Other commenters had concerns about the claims-based measures, noting that while they had no data collection burden, they were associated with time and resources needed to compile and verify data for submission. One commenter expressed concerns that the burden estimate doubles the resources required to collect data but doesn't take into consideration limited resources smaller organizations have.

Response: We recognize the commenter's concern pertaining to burden due to the requirements being added to the IRF Quality Reporting Program. We are very sensitive to the issue of burden associated with data collection and have proposed only the minimal number of additional items (3) needed to calculate the proposed quality measure. Though we recognize that new IRF–PAI items will require additional activities and efforts by providers, we would like to clarify that burden estimates are intended to reflect only the time needed to complete IRF–PAI items, independent of clinical time spent assessing the patient. Similarly, burden estimates are not indented to reflect costs of training and operational processes; these are considered part of the operating costs for an IRF. Time estimates for coding required items being added for the Drug Regimen Review measure were based on a Drug Regimen Review pilot testing conducted in November and December 2015. It should be noted that with each assessment release, we provide free software to our providers that allows for the completion and submission of any required assessment data. Free downloads of the Inpatient Rehabilitation Validation and Entry (IRVEN) software product are available on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Software.html*.

We also wish to note that, as pointed out by one commenter, four of the five measures proposed are claims-based and have no additional data collection burden to providers. Since the data source for these measures is claims data, and is not collected by means of an assessment instrument, the measure does not increase data collection burden on the provider as this data is currently collected by providers. We also note that providers will be given a chance to review their claims-based measure data via feedback provided in the CASPER system. Despite the lack of data collection burden, we appreciate the comments that more education will be required for the public and providers to understand the claims-based measures and the feedback mechanism. We will be providing additional training for the reports that are, and will be, available for providers for reviewing their data.

Although we did not solicit feedback on the burden associated with the measures finalized in the FY 2016 IRF PPS final rule (80 FR 47100 through 47120), including functional status measures, which will be collected via the IRF–PAI Version 1.4 effective October 1, 2016, we received several comments, which are summarized below.

Comment: Several commenters were concerned that the additional 41.5 minutes required to collect new required data elements finalized in the FY 2016 IRF PPS final rule, including training staff and updating medical records, led to increased costs to IRFs that are not covered in the update to the standard payment conversion factor proposed for IRFs. One commenter also noted that delays in training led to additional expenses for preparing staff and electronic health records.

Response: We refer the reader to our discussion of burden due to data set revisions, data collection, or training of staff due to the revisions in the IRF–PAI Version 1.4 in the FY 2016 IRF PPS final rule (80 FR 47086 through 47120). Feedback relating to provider burden will be taken into account as we consider future updates to the IRF QRP.

With regards to comments about the updated SPCF, we refer readers to the IRF PPS FY 2016 final rule (80 FR 47129 through 47137) for details regarding the Collection of Information Requirements and Regulatory Impact Analysis for the measures finalized in FY 2016. We would also like to clarify that QRP requirements are not included in the SPCF, however, per statutory requirements, the applicable annual increase factor for any IRF that does not submit the required data to CMS is reduced by 2 percentage points. Additional responses to these comments are included in sections VI.E and IX. of this final rule.

XII. Regulatory Impact Analysis

A. Statement of Need

This final rule updates the IRF prospective payment rates for FY 2017 as required under section 1886(j)(3)(C) of the Act. It responds to section 1886(j)(5) of the Act, which requires the Secretary to publish in the **Federal Register** on or before the August 1 that precedes the start of each fiscal year, the classification and weighting factors for the IRF PPS's case-mix groups and a description of the methodology and data used in computing the prospective payment rates for that fiscal year.

This final rule also implements sections 1886(j)(3)(C) and (D) of the Act. Section 1886(j)(3)(C)(ii)(I) of the Act requires the Secretary to apply a multi-factor productivity adjustment to the market basket increase factor, and to apply other adjustments as defined by the Act. The productivity adjustment applies to FYs from 2012 forward. The other adjustments apply to FYs 2010 through 2019.

Furthermore, this final rule also adopts policy changes under the statutory discretion afforded to the Secretary under section 1886(j)(7) of the Act. Specifically, we will revise and update the quality measures and reporting requirements under the IRF quality reporting program.

B. Overall Impacts

We have examined the impacts of this final rule as required by Executive Order 12866 (September 30, 1993, Regulatory Planning and Review), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (September 19, 1980, Pub. L. 96–354) (RFA), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for a major final rule with economically significant effects ($100 million or more in any 1 year). We estimate the total impact of the policy updates described in this final rule by comparing the estimated payments in FY 2017 with those in FY 2016. This analysis results in an estimated $145 million increase for FY 2017 IRF PPS payments. As a result, this final rule is designated as economically ''significant'' under section 3(f)(1) of Executive Order 12866, and hence a major rule under the Congressional Review Act. Also, the rule has been reviewed by OMB.

The Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most IRFs and most other providers and suppliers are small entities, either by having revenues of $7.5 million to $38.5 million or less in any 1 year depending on industry classification, or by being nonprofit organizations that are not dominant in their markets. (For details, see the Small Business Administration's final rule that set forth size standards for health care industries, at 65 FR 69432 at *http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf*, effective March 26, 2012 and updated on February 26, 2016.) Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary IRFs or the proportion of IRFs' revenue that is derived from Medicare payments. Therefore, we assume that all IRFs (an approximate total of 1,100 IRFs, of which approximately 60 percent are nonprofit facilities) are considered small entities and that Medicare payment constitutes the majority of their revenues. The HHS generally uses a revenue impact of 3 to 5 percent as a significance threshold under the RFA. As shown in Table 22, we estimate that the net revenue impact of this final rule on all IRFs is to increase estimated payments by approximately 1.9 percent. The rates and policies set forth in this final rule will not have a significant impact (not greater than 3 percent) on a substantial number of small entities. Medicare Administrative Contractors are not considered to be small entities. Individuals and states are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. As discussed in detail below in this section, the rates and policies set forth in this final rule will not have a significant impact (not greater than 3 percent) on a substantial number of rural hospitals based on the data of the 140 rural units and 11 rural hospitals in our database of 1,133 IRFs for which data were available.

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–04, enacted on March 22, 1995) also requires that agencies assess anticipated costs and benefits before

issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2016, that threshold level is approximately $146 million. This final rule will not mandate spending costs on state, local, or tribal governments, in the aggregate, or by the private sector, of greater than $146 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. As stated, this final rule will not have a substantial effect on state and local governments, preempt state law, or otherwise have a federalism implication.

C. Detailed Economic Analysis

1. Basis and Methodology of Estimates

This final rule updates to the IRF PPS rates contained in the FY 2016 IRF PPS final rule (80 FR 47036). Specifically, this final rule updates the CMG relative weights and average length of stay values, the wage index, and the outlier threshold for high-cost cases. This final rule applies a MFP adjustment to the FY 2017 IRF market basket increase factor in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and a 0.75 percentage point reduction to the FY 2017 IRF market basket increase factor in accordance with sections 1886(j)(3)(C)(ii)(II) and (D)(v) of the Act. Further, this final rule contains revisions to the IRF quality reporting requirements that are expected to result in some additional financial effects on IRFs. In addition, section VIII of this final rule discusses the implementation of the required 2 percentage point reduction of the market basket increase factor for any IRF that fails to meet the IRF quality reporting requirements, in accordance with section 1886(j)(7) of the Act.

We estimate that the impact of the changes and updates described in this final rule will be a net estimated increase of $145 million in payments to IRF providers. This estimate does not include the implementation of the required 2 percentage point reduction of the market basket increase factor for any IRF that fails to meet the IRF quality reporting requirements (as discussed in section XII.C.6. of this final rule). The impact analysis in Table 22 of this final rule represents the projected effects of the updates to IRF PPS payments for FY 2017 compared with the estimated IRF PPS payments in FY 2016. We determine the effects by estimating payments while holding all other payment variables constant. We use the best data available, but we do not attempt to predict behavioral responses to these changes, and we do not make adjustments for future changes in such variables as number of discharges or case-mix.

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 forecasting errors because of other changes in the forecasted impact time period. Some examples could be legislative changes made by the Congress to the Medicare program that would impact program funding, or changes specifically related to IRFs. Although some of these changes may not necessarily be specific to the IRF 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 IRFs.

In updating the rates for FY 2017, we are adopting standard annual revisions described in this final rule (for example, the update to the wage and market basket indexes used to adjust the federal rates). We are also implementing a productivity adjustment to the FY 2017 IRF market basket increase factor in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and a 0.75 percentage point reduction to the FY 2017 IRF market basket increase factor in accordance with sections 1886(j)(3)(C)(ii)(II) and (D)(v) of the Act. We estimate the total increase in payments to IRFs in FY 2017, relative to FY 2016, will be approximately $145 million.

This estimate is derived from the application of the FY 2017 IRF market basket increase factor, as reduced by a productivity adjustment in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and a 0.75 percentage point reduction in accordance with sections 1886(j)(3)(C)(ii)(II) and (D)(v) of the Act, which yields an estimated increase in aggregate payments to IRFs of $125 million. Furthermore, there is an additional estimated $20 million increase in aggregate payments to IRFs due to the update of the outlier threshold amount. Outlier payments are estimated to increase from approximately 2.7 percent in FY 2016 to 3.0 percent in FY 2017. Therefore, summed together, we estimate that these updates will result in a net increase in estimated payments of $145 million from FY 2016 to FY 2017.

The effects of the updates that impact IRF PPS payment rates are shown in Table 22. The following updates that affect the IRF PPS payment rates are discussed separately below:

- The effects of the update to the outlier threshold amount, from approximately 2.7 percent to 3.0 percent of total estimated payments for FY 2017, consistent with section 1886(j)(4) of the Act.
- The effects of the annual market basket update (using the IRF market basket) to IRF PPS payment rates, as required by section 1886(j)(3)(A)(i) and sections 1886(j)(3)(C) and (D) of the Act, including a productivity adjustment in accordance with section 1886(j)(3)(C)(i)(I) of the Act, and a 0.75 percentage point reduction in accordance with sections 1886(j)(3)(C)(ii)(II) and (D)(v) of the Act.
- The effects of applying the budget-neutral labor-related share and wage index adjustment, as required under section 1886(j)(6) of the Act.
- The effects of the budget-neutral changes to the CMG relative weights and average length of stay values, under the authority of section 1886(j)(2)(C)(i) of the Act.
- The total change in estimated payments based on the FY 2017 payment changes relative to the estimated FY 2016 payments.

2. Description of Table 22

Table 22 categorizes IRFs by geographic location, including urban or rural location, and location for CMS's 9 Census divisions (as defined on the cost report) of the country. In addition, the table divides IRFs into those that are separate rehabilitation hospitals (otherwise called freestanding hospitals in this section), those that are rehabilitation units of a hospital (otherwise called hospital units in this section), rural or urban facilities, ownership (otherwise called for-profit, non-profit, and government), by teaching status, and by disproportionate share patient percentage (DSH PP). The top row of Table 22 shows the overall impact on the 1,133 IRFs included in the analysis.

The next 12 rows of Table 22 contain IRFs categorized according to their geographic location, designation as either a freestanding hospital or a unit of a hospital, and by type of ownership; all urban, which is further divided into urban units of a hospital, urban freestanding hospitals, and by type of ownership; and all rural, which is further divided into rural units of a hospital, rural freestanding hospitals, and by type of ownership. There are 982 IRFs located in urban areas included in

our analysis. Among these, there are 730 IRF units of hospitals located in urban areas and 252 freestanding IRF hospitals located in urban areas. There are 151 IRFs located in rural areas included in our analysis. Among these, there are 140 IRF units of hospitals located in rural areas and 11 freestanding IRF hospitals located in rural areas. There are 409 for-profit IRFs. Among these, there are 356 IRFs in urban areas and 53 IRFs in rural areas. There are 653 non-profit IRFs. Among these, there are 564 urban IRFs and 89 rural IRFs. There are 71 government-owned IRFs. Among these, there are 62 urban IRFs and 9 rural IRFs.

The remaining four parts of Table 22 show IRFs grouped by their geographic location within a region, by teaching status, and by DSH PP. First, IRFs located in urban areas are categorized for their location within a particular one of the nine Census geographic regions. Second, IRFs located in rural areas are categorized for their location within a particular one of the nine Census geographic regions. In some cases, especially for rural IRFs located in the New England, Mountain, and Pacific regions, the number of IRFs represented is small. IRFs are then grouped by teaching status, including non-teaching IRFs, IRFs with an intern and resident to average daily census (ADC) ratio less than 10 percent, IRFs with an intern and resident to ADC ratio greater than or equal to 10 percent and less than or equal to 19 percent, and IRFs with an intern and resident to ADC ratio greater than 19 percent. Finally, IRFs are grouped by DSH PP, including IRFs with zero DSH PP, IRFs with a DSH PP less than 5 percent, IRFs with a DSH PP between 5 and less than 10 percent, IRFs with a DSH PP between 10 and 20 percent, and IRFs with a DSH PP greater than 20 percent.

The estimated impacts of each policy described in this final rule to the facility categories listed are shown in the columns of Table 22. The description of each column is as follows:

- Column (1) shows the facility classification categories.
- Column (2) shows the number of IRFs in each category in our FY 2016 analysis file.
- Column (3) shows the number of cases in each category in our FY 2016 analysis file.
- Column (4) shows the estimated effect of the adjustment to the outlier threshold amount.
- Column (5) shows the estimated effect of the update to the IRF labor-related share and wage index, in a budget-neutral manner.
- Column (6) shows the estimated effect of the update to the CMG relative weights and average length of stay values, in a budget-neutral manner.
- Column (7) compares our estimates of the payments per discharge, incorporating all of the policies reflected in this final rule for FY 2017 to our estimates of payments per discharge in FY 2016.

The average estimated increase for all IRFs is approximately 1.9 percent. This estimated net increase includes the effects of the IRF market basket increase factor for FY 2017 of 2.7 percent, reduced by a productivity adjustment of 0.3 percentage point in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and further reduced by 0.75 percentage point in accordance with sections 1886(j)(3)(C)(ii)(II) and (D)(v) of the Act. It also includes the approximate 0.3 percent overall increase in estimated IRF outlier payments from the update to the outlier threshold amount. Since we are making the updates to the IRF wage index and the CMG relative weights in a budget-neutral manner, they will not be expected to affect total estimated IRF payments in the aggregate. However, as described in more detail in each section, they will be expected to affect the estimated distribution of payments among providers.

TABLE 22: IRF Impact Table for FY 2017 (Columns 4 through 7 in percentage)

Facility Classification	Number of IRFs	Number of Cases	Outlier	FY 2017 CBSA wage index and labor-share	CMG Weights	Total Percent Change [1]
(1)	(2)	(3)	(4)	(5)	(6)	(7)
Total	1,133	400,781	0.3	0.0	0.0	1.9
Urban unit	730	180,021	0.5	0.0	0.0	2.2
Rural unit	140	23,192	0.4	-0.6	0.0	1.5
Urban hospital	252	193,104	0.1	0.1	0.0	1.8
Rural hospital	11	4,464	0.0	-1.6	0.0	0.0
Urban For-Profit	356	181,789	0.2	-0.1	0.0	1.7
Rural For-Profit	53	10,255	0.3	-0.9	0.0	1.1
Urban Non-Profit	564	172,204	0.4	0.2	0.0	2.3
Rural Non-Profit	89	15,724	0.4	-0.7	0.0	1.4
Urban Government	62	19,132	0.4	-0.4	0.0	1.8
Rural Government	9	1,677	0.3	-1.3	0.1	0.7
Urban	982	373,125	0.3	0.1	0.0	2.0
Rural	151	27,656	0.3	-0.8	0.0	1.2
Urban by region						
Urban New England	31	16,762	0.2	0.2	0.1	2.1
Urban Middle Atlantic	144	57,765	0.2	0.8	0.0	2.7
Urban South Atlantic	146	73,307	0.2	-0.1	0.0	1.8
Urban East North Central	170	50,459	0.3	-0.1	0.1	2.0
Urban East South Central	57	26,179	0.2	-0.5	-0.1	1.4
Urban West North Central	74	20,139	0.3	-0.7	0.0	1.3
Urban West South Central	183	77,887	0.2	-0.1	0.0	1.7
Urban Mountain	77	26,367	0.2	0.0	0.0	1.9
Urban Pacific	100	24,260	0.6	0.3	0.0	2.6
Rural by region						
Rural New England	5	1,321	0.4	-1.6	0.0	0.4
Rural Middle Atlantic	12	1,717	0.3	-2.0	0.1	0.0
Rural South Atlantic	17	4,536	0.2	-0.4	0.0	1.4
Rural East North Central	28	4,906	0.3	0.1	0.0	2.0
Rural East South Central	18	3,515	0.3	-0.5	0.0	1.4
Rural West North Central	21	3,106	0.5	-0.5	0.0	1.7
Rural West South Central	40	7,742	0.3	-1.4	0.0	0.6
Rural Mountain	7	601	1.0	-0.6	0.0	2.1
Rural Pacific	3	212	1.4	0.1	-0.1	3.1
Teaching status						
Non-teaching	1,025	357,005	0.3	0.0	0.0	1.9
Resident to ADC less than 10%	64	31,283	0.3	0.1	0.1	2.1
Resident to ADC 10%-19%	31	10,703	0.4	0.2	0.0	2.3
Resident to ADC greater than 1	13	1,790	0.2	-0.4	-0.1	1.4
Disproportionate share patient percentage (DSH PP)						
DSH PP = 0%	34	7,345	0.4	-0.1	0.0	2.0
DSH PP <5%	157	60,158	0.2	0.4	0.0	2.3
DSH PP 5%-10%	316	129,305	0.2	-0.1	0.0	1.8
DSH PP 10%-20%	371	137,759	0.3	-0.1	0.0	1.8
DSH PP greater than 20%	255	66,214	0.4	0.0	0.0	2.1

[1]This column includes the impact of the updates in columns (4), (5), and (6) above, and of the IRF market basket increase factor for FY 2017 (2.7 percent), reduced by 0.3 percentage point for the productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act, and reduced by 0.75 percentage point in accordance with sections 1886(j)(3)(C)(ii)(II) and -(D)(v) of the Act.

3. Impact of the Update to the Outlier Threshold Amount

The estimated effects of the update to the outlier threshold adjustment are presented in column 4 of Table 22.

For the FY 2017 IRF PPS proposed rule, we used preliminary FY 2015 IRF claims data, and, based on that preliminary analysis, we estimated that IRF outlier payments as a percentage of total estimated IRF payments would be 2.8 percent in FY 2016 (81 FR 24178, 24193). As we typically do between the proposed and final rules each year, we updated our FY 2015 IRF claims data to ensure that we are using the most recent available data in setting IRF payments. Therefore, based on updated analysis of the most recent IRF claims data for this final rule, we now estimate that IRF outlier payments as a percentage of total estimated IRF payments are 2.7 percent in FY 2016. Thus, we are adjusting the outlier threshold amount in this final rule to set total estimated outlier payments equal to 3 percent of total estimated payments in FY 2017. The estimated change in total IRF payments for FY 2017, therefore, includes an approximate 0.3 percent increase in payments because the estimated outlier portion of total payments is estimated to increase from approximately 2.7 percent to 3 percent.

The impact of this outlier adjustment update (as shown in column 4 of Table 22) is to increase estimated overall payments to IRFs by about 0.3 percent. We estimate the largest increase in payments from the update to the outlier threshold amount to be 1.4 percent for rural IRFs in the Pacific region.

4. Impact of the CBSA Wage Index and Labor-Related Share

In column 5 of Table 22, we present the effects of the budget-neutral update of the wage index and labor-related share. The changes to the wage index and the labor-related share are discussed together because the wage index is applied to the labor-related share portion of payments, so the changes in the two have a combined effect on payments to providers. As discussed in section VI.C. of this final rule, we will decrease the labor-related share from 71.0 percent in FY 2016 to 70.9 percent in FY 2017.

5. Impact of the Update to the CMG Relative Weights and Average Length of Stay Values

In column 6 of Table 22, we present the effects of the budget-neutral update of the CMG relative weights and average length of stay values. In the aggregate, we do not estimate that these updates will affect overall estimated payments of IRFs. However, we do expect these updates to have small distributional effects. The largest estimated increase in payments is a 0.1 percent increase for rural IRFs in the Middle Atlantic region, and urban IRFs in the New England and East North Central regions. Rural IRFs in the Pacific region and urban IRFs in the East south Central regions are estimated to experience a 0.1 percent decrease in payments due to the CMG relative weights change.

6. Effects of Requirements for the IRF QRP for FY 2018

In accordance with section 1886(j)(7) of the Act, we will implement a 2 percentage point reduction in the FY 2018 increase factor for IRFs that have failed to report the required quality reporting data to us during the most recent IRF quality reporting period. In section VIII.P of this final rule, we discuss the proposed method for applying the 2 percentage point reduction to IRFs that fail to meet the IRF QRP requirements. At the time that this analysis was prepared, 91, or approximately 8 percent, of the 1166 active Medicare-certified IRFs did not receive the full annual percentage increase for the FY 2016 annual payment update determination. Information is not available to determine the precise number of IRFs that will not meet the requirements to receive the full annual percentage increase for the FY 2017 payment determination.

In section VIII.L of this final rule, we discuss our proposal to suspend the previously finalized data accuracy validation policy for IRFs. While we cannot estimate the change in the number of IRFs that will meet IRF QRP compliance standards at this time, we believe that this number will increase due to the temporary suspension of this policy. Thus, we estimate that the suspension of this policy will decrease impact on overall IRF payments, by increasing the rate of compliance, in addition to decreasing the cost of the IRF QRP to each IRF provider by approximately $47,320 per IRF, which was the estimated cost to each IRF provider to the implement the previously finalized policy.

In section VIII.F of this final rule, we are finalizing four measures for the FY 2018 payment determinations and subsequent years: (1) MSPB–PAC IRF QRP; (2) Discharge to Community-PAC IRF QRP, and (3) Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP; (4) Potentially Preventable Within Stay Readmission Measure IRFs. These four measures are Medicare claims-based measures; because claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes, we believe there will be no additional impact.

In section VIII.G of this final rule, we are also finalizing one measure for the FY 2020 payment determination and subsequent years: Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP. Additionally, data for this measure will be collected and reported using the IRF–PAI (version effective October 1, 2018). While the reporting of data on quality measures is an information collection, we believe that the burden associated with modifications to the IRF–PAI discussed in this final rule fall under the PRA exceptions provided in 1899B(m) of the Act because they are required to achieve the standardization of patient assessment data. Section 1899B(m) of the Act provides that the PRA does not apply to section 1899B and the sections referenced in section 1899B(a)(2)(B) of the Act that require modification to achieve the standardization of patient assessment data. The requirement and burden will, however, be submitted to OMB for review and approval when the modifications to the IRF–PAI or other applicable PAC assessment instrument are not used to achieve the standardization of patient assessment data.

The total cost related to the proposed measures is estimated at $4,625.46 per IRF annually, or $5,231,398.17 for all IRFs annually.

We intend to continue to closely monitor the effects of this new quality reporting program on IRF providers and help perpetuate successful reporting outcomes through ongoing stakeholder education, national trainings, IRF provider announcements, Web site postings, CMS Open Door Forums, and general and technical help desks.

We did not receive any comments related to the Effects of Proposed Requirements for the IRF QRP for FY 2018.

D. Alternatives Considered

The following is a discussion of the alternatives considered for the IRF PPS updates contained in this final rule.

Section 1886(j)(3)(C) of the Act requires the Secretary to update the IRF PPS payment rates by an increase factor that reflects changes over time in the prices of an appropriate mix of goods and services included in the covered IRF services Thus, we did not consider alternatives to updating payments using the estimated IRF market basket

increase factor for FY 2017. However, as noted previously in this final rule, section 1886(j)(3)(C)(ii)(I) of the Act requires the Secretary to apply a productivity adjustment to the market basket increase factor for FY 2017, and sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(v) of the Act require the Secretary to apply a 0.75 percentage point reduction to the market basket increase factor for FY 2017. Thus, in accordance with section 1886(j)(3)(C) of the Act, we update the IRF federal prospective payments in this final rule by 1.65 percent (which equals the 2.7 percent estimated IRF market basket increase factor for FY 2017 reduced by a 0.3 percentage point productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act and further reduced by 0.75 percentage point). We considered maintaining the existing CMG relative weights and average length of stay values for FY 2017. However, in light of recently available data and our desire to ensure that the CMG relative weights and average length of stay values are as reflective as possible of recent changes in IRF utilization and case mix, we believe that it is appropriate to update the CMG relative weights and average length of stay values at this time to ensure that IRF PPS payments continue to reflect as accurately as possible the current costs of care in IRFs.

We considered updating facility-level adjustment factors for FY 2017. However, as discussed in more detail in the FY 2015 final rule (79 FR 45872), we believe that freezing the facility-level adjustments at FY 2014 levels for FY 2015 and all subsequent years (unless and until the data indicate that they need to be further updated) will allow us an opportunity to monitor the effects of the substantial changes to the adjustment factors for FY 2014, and will allow IRFs time to adjust to the previous changes.

We considered maintaining the existing outlier threshold amount for FY 2017. However, analysis of updated FY 2015 data indicates that estimated outlier payments would be lower than 3 percent of total estimated payments for FY 2017, by approximately 0.3 percent, unless we updated the outlier threshold amount. Consequently, we are adjusting the outlier threshold amount in this final rule to reflect a 0.3 percent increase thereby setting the total outlier payments equal to 3 percent, instead of 2.7 percent, of aggregate estimated payments in FY 2017.

E. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/sites/default/files/omb/assets/omb/circulars/a004/a-4.pdf*), in Table 23, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule. Table 23 provides our best estimate of the increase in Medicare payments under the IRF PPS as a result of the updates presented in this final rule based on the data for 1,133 IRFs in our database. In addition, Table 23 presents the costs associated with the new IRF quality reporting program for FY 2017.

TABLE 23—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

Category	Transfers
Change in Estimated Transfers from FY 2016 IRF PPS to FY 2017 IRF PPS	
Annualized Monetized Transfers	$145 million.
From Whom to Whom?	Federal Government to IRF Medicare Providers.
Category	Costs
FY 2017 Cost to Updating the Quality Reporting Program	
Cost for IRFs to Submit Data for the Quality Reporting Program	$5,231,398.17.

F. Conclusion

Overall, the estimated payments per discharge for IRFs in FY 2017 are projected to increase by 1.9 percent, compared with the estimated payments in FY 2016, as reflected in column 7 of Table 22.

IRF payments per discharge are estimated to increase by 2.0 percent in urban areas and 1.2 percent in rural areas, compared with estimated FY 2016 payments. Payments per discharge to rehabilitation units are estimated to increase 2.2 percent in urban areas and 1.5 percent in rural areas. Payments per discharge to freestanding rehabilitation hospitals are estimated to increase 1.8 percent in urban areas and 0.0 percent in rural areas.

Overall, IRFs are estimated to experience a net increase in payments as a result of the proposed policies in this final rule. The largest payment increase is estimated to be a 3.1 percent increase for rural IRFs located in the Pacific region.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 1. The authority citation for part 412 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), sec. 124 of Pub. L. 106–113 (113 Stat. 1501A–332), sec. 1206 of Pub. L. 113–67, and sec. 112 of Pub. L. 113–93.

■ 2. Section 412.634 is amended by revising paragraph (c)(2) and adding paragraph (f) to read as follows:

§ 412.634 Requirements under the Inpatient Rehabilitation Facility (IRF) Quality Reporting Program (QRP).

* * * * *

(c) * * *

(2) An IRF must request an exception or extension within 90 days of the date that the extraordinary circumstances occurred.

* * * * *

(f) *Data Completion Thresholds.* (1) IRFs must meet or exceed two separate data completeness thresholds: One threshold set at 95 percent for completion of quality measures data collected using the IRF–PAI submitted through the QIES and a second threshold set at 100 percent for quality

measures data collected and submitted using the CDC NHSN.

(2) These thresholds will apply to all measures adopted into IRF QRP.

(3) An IRF must meet or exceed both thresholds to avoid receiving a 2 percentage point reduction to their annual payment update for a given fiscal year, beginning with FY 2016 and for all subsequent payment updates.

Dated: July 18, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: July 25, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2016–18196 Filed 7–29–16; 4:15 pm]

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Part IV

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 418

Medicare Program; FY 2017 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 418

[CMS–1652–F]

RIN 0938–AS79

Medicare Program; FY 2017 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule will update the hospice wage index, payment rates, and cap amount for fiscal year (FY) 2017. In addition, this rule changes the hospice quality reporting program, including adopting new quality measures. Finally, this final rule includes information regarding the Medicare Care Choices Model (MCCM).

DATES: These regulations are effective on October 1, 2016.

FOR FURTHER INFORMATION CONTACT: Debra Dean-Whittaker, (410) 786–0848 for questions regarding the CAHPS® Hospice Survey.

Michelle Brazil, (410) 786–1648 for questions regarding the hospice quality reporting program.

Hillary A. Loeffler, (410) 786–0456 for questions regarding hospice payment policy.

SUPPLEMENTARY INFORMATION: Wage index addenda will be available only through the internet on the CMS Web site at: (*http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/index.html*.)

Table of Contents

Acronyms

Because of the many terms to which we refer by acronym in this final rule, we are listing the acronyms used and their corresponding meanings in alphabetical order:

APU Annual Payment Update
ASPE Assistant Secretary of Planning and Evaluation
BBA Balanced Budget Act of 1997
BIPA Benefits Improvement and Protection Act of 2000
BNAF Budget Neutrality Adjustment Factor
BLS Bureau of Labor Statistics
CAHPS® Consumer Assessment of Healthcare Providers and Systems
CBSA Core-Based Statistical Area
CCN CMS Certification Number
CCW Chronic Conditions Data Warehouse
CFR Code of Federal Regulations
CHC Continuous Home Care
CHF Congestive Heart Failure
CMMI Center for Medicare & Medicaid Innovation
CMS Centers for Medicare & Medicaid Services
COPD Chronic Obstructive Pulmonary Disease
CoPs Conditions of Participation
CPI Center for Program Integrity
CPI–U Consumer Price Index—Urban Consumers
CR Change Request
CVA Cerebral Vascular Accident
CWF Common Working File
CY Calendar Year
DME Durable Medical Equipment
DRG Diagnostic Related Group
ER Emergency Room
FEHC Family Evaluation of Hospice Care
FR Federal Register
FY Fiscal Year
GAO Government Accountability Office
GIP General Inpatient Care
HCFA Healthcare Financing Administration
HHS Health and Human Services
HIPAA Health Insurance Portability and Accountability Act
HIS Hospice Item Set
HQRP Hospice Quality Reporting Program
IACS Individuals Authorized Access to CMS Computer Services
ICD–9–CM International Classification of Diseases, Ninth Revision, Clinical Modification
ICD–10–CM International Classification of Diseases, Tenth Revision, Clinical Modification
ICR Information Collection Requirement
IDG Interdisciplinary Group
IMPACT Act Improving Medicare Post-Acute Care Transformation Act of 2014
IOM Institute of Medicine
IPPS Inpatient Prospective Payment System
IRC Inpatient Respite Care

LCD Local Coverage Determination
LOS Length of Stay
MAC Medicare Administrative Contractor
MAP Measure Applications Partnership
MCCM Medicare Care Choices Model
MedPAC Medicare Payment Advisory Commission
MFP Multifactor Productivity
MSA Metropolitan Statistical Area
MSS Medical Social Services
NHPCO National Hospice and Palliative Care Organization
NF Long Term Care Nursing Facility
NOE Notice of Election
NOTR Notice of Termination/Revocation
NP Nurse Practitioner
NPI National Provider Identifier
NQF National Quality Forum
OIG Office of the Inspector General
OACT Office of the Actuary
OMB Office of Management and Budget
PEPPER Program for Evaluating Payment Patterns Electronic Report
PRRB Provider Reimbursement Review Board
PS&R Provider Statistical and Reimbursement Report
Pub. L. Public Law
QAPI Quality Assessment and Performance Improvement
RHC Routine Home Care
RN Registered Nurse
SBA Small Business Administration
SEC Securities and Exchange Commission
SIA Service Intensity Add-on
SNF Skilled Nursing Facility
TEFRA Tax Equity and Fiscal Responsibility Act of 1982
TEP Technical Expert Panel
UHDDS Uniform Hospital Discharge Data Set
U.S.C. United States Code

I. Executive Summary

A. Purpose

This final rule updates the hospice payment rates for fiscal year (FY) 2017, as required under section 1814(i) of the Social Security Act (the Act). This rule also finalizes new quality measures and provides an update on the hospice quality reporting program (HQRP) consistent with the requirements of section 1814(i)(5) of the Act, as added by section 3004(c) of the Patient Protection and Affordable Care Act (Pub. L. 111–148) as amended by the Health Care and Education Reconciliation Act (Pub. L. 111–152) (collectively, the Affordable Care Act). In accordance with section 1814(i)(5)(A) of the Act, starting in FY 2014, hospices that have failed to meet quality reporting requirements receive a 2 percentage point reduction to their payments. Finally, this final rule shares information on the Medicare Care Choices Model developed in accordance with the authorization under section 1115A of the Act for the Center for Medicare and Medicaid Innovation (CMMI) to test innovative payment and service models that have the potential to reduce Medicare, Medicaid, or Children's Health Insurance Program (CHIP) expenditures while maintaining or improving the quality of care.

B. Summary of the Major Provisions

In section III.B.1 of this rule, we update the hospice wage index with updated wage data and make the application of the updated wage data budget-neutral for all four levels of hospice care. In section III.B.2 we discuss the FY 2017 hospice payment update percentage of 2.1 percent. Sections III.B.3 and III.B.4 update the hospice payment rates and hospice cap amount for FY 2017 by the hospice payment update percentage discussed in section III.B.2.

In section III.C of this rule, we discuss updates to HQRP, including two new quality measures as well as of the possibility of utilizing a new assessment instrument to collect quality data. As part of the HQRP, the new measures, effective April 1, 2017, will be: (1) Hospice Visits When Death is Imminent, assessing hospice staff visits to patients and caregivers in the last week of life; and (2) Hospice and Palliative Care Composite Process Measure, assessing the percentage of hospice patients who received care processes consistent with existing guidelines. In section III.C we will also discuss the enhancement of the current Hospice Item Set (HIS) data collection instrument to be more in line with other post-acute care settings. This new data collection instrument will be a comprehensive patient assessment instrument, rather than the current chart abstraction tool. Additionally, in this section we discuss our plans for sharing HQRP data publicly during calendar year (CY) 2016 as well as plans to provide public reporting via a Compare Site in CY 2017.

Finally, in section III.D, we are providing information regarding the Medicare Care Choices Model (MCCM). This model is testing a new option for Medicare and dual eligible beneficiaries with certain advanced diseases who meet the model's other eligibility criteria to receive hospice-like support services from MCCM participating hospices while receiving care from other Medicare providers for their terminal illness. This model is designed to: (1) Increase access to supportive care services provided by hospice; (2) improve quality of life and patient/family/caregiver satisfaction; and (3) inform new payment systems for the Medicare and Medicaid programs.

C. Summary of Impacts

TABLE 1—IMPACT SUMMARY TABLE

Provision description	Transfers
FY 2017 Hospice Wage Index and Payment Rate Update	The overall economic impact of this final rule is estimated to be $350 million in increased payments to hospices during FY 2017.

II. Background

A. Hospice Care

Hospice care is an approach to treatment that recognizes that the impending death of an individual warrants a change in the focus from curative care to palliative care for relief of pain and for symptom management. The goal of hospice care is to help terminally ill individuals continue life with minimal disruption to normal activities while remaining primarily in the home environment. A hospice uses an interdisciplinary approach to deliver medical, nursing, social, psychological, emotional, and spiritual services through use of a broad spectrum of professionals and other caregivers, with the goal of making the beneficiary as physically and emotionally comfortable as possible. Hospice is compassionate beneficiary and family-centered care for those who are terminally ill. It is a comprehensive, holistic approach to treatment that recognizes that the impending death of an individual necessitates a transition from curative to palliative care.

Medicare regulations define ''palliative care'' as ''patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, intellectual, emotional, social, and spiritual needs and to facilitate patient autonomy, access to information, and choice.'' (42 CFR 418.3) Palliative care is at the core of hospice philosophy and

care practices, and is a critical component of the Medicare hospice benefit. Also, see Hospice Conditions of Participation final rule (73 FR 32088 June 5, 2008). The goal of palliative care in hospice is to improve the quality of life of beneficiaries, and their families, facing the issues associated with a life-threatening illness through the prevention and relief of suffering by means of early identification, assessment, and treatment of pain and other issues that may arise. This is achieved by the hospice interdisciplinary group working with the beneficiary and family to develop a comprehensive care plan focused on coordinating care services, reducing unnecessary diagnostics, or ineffective therapies, and offering ongoing conversations with individuals and their families about changes in their condition. The beneficiary's comprehensive care plan will shift over time to meet the changing needs of the individual, family, and caregiver(s) as the individual approaches the end of life.

Medicare hospice care is palliative care for individuals with a prognosis of living 6 months or less if the terminal illness runs its normal course. When a beneficiary is terminally ill, many health problems are brought on by underlying condition(s), as bodily systems are interdependent. In the 2008 Hospice Conditions of Participation final rule, we stated that the medical director or physician designee must consider the primary terminal condition, related diagnoses, current subjective and objective medical findings, current medication and treatment orders, and information about unrelated conditions when considering the initial certification of the terminal illness. (73 FR 32176). As referenced in our regulations at § 418.22(b)(1), to be eligible for Medicare hospice services, the patient's attending physician (if any) and the hospice medical director must certify that the individual is ''terminally ill,'' as defined in section 1861(dd)(3)(A) of the Act and our regulations at § 418.3; that is, the individual's prognosis is for a life expectancy of 6 months or less if the terminal illness runs its normal course. The certification of terminal illness must include a brief narrative explanation of the clinical findings that supports a life expectancy of 6 months or less as part of the certification and recertification forms, as set out at § 418.22(b)(3).

While the goal of hospice care is to allow the beneficiary to remain in his or her home environment, circumstances during the end-of-life may necessitate short-term inpatient admission to a hospital, skilled nursing facility (SNF), or hospice facility for treatment necessary for pain control or acute or chronic symptom management that cannot be managed in any other setting. These acute hospice care services are to ensure that any new or worsening symptoms are intensively addressed so that the beneficiary can return to his or her home environment. Limited, short-term, intermittent, inpatient respite services are also available to the family/caregiver of the hospice patient to relieve the family or other caregivers. Additionally, an individual can receive continuous home care during a period of crisis in which an individual requires primarily continuous nursing care to achieve palliation or management of acute medical symptoms so that the individual can remain at home. Continuous home care may be covered on a continuous basis for as much as 24 hours a day, and these periods must be predominantly nursing care, in accordance with our regulations at § 418.204. A minimum of 8 hours of nursing care, or nursing and aide care, must be furnished on a particular day to qualify for the continuous home care rate (§ 418.302(e)(4)).

Hospices are expected to comply with all civil rights laws, including the provision of auxiliary aids and services to ensure effective communication with patients and patient care representatives with disabilities consistent with section 504 of the Rehabilitation Act of 1973 and the Americans with Disabilities Act, and to provide language access for such persons who are limited in 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/civil-rights.*

B. History of the Medicare Hospice Benefit

Before the creation of the Medicare hospice benefit, hospice programs were originally operated by volunteers who cared for the dying. During the early development stages of the Medicare hospice benefit, hospice advocates were clear that they wanted a Medicare benefit that provided all-inclusive care for terminally-ill individuals, provided pain relief and symptom management, and offered the opportunity to die with dignity in the comfort of one's home rather than in an institutional setting.[1] As stated in the August 22, 1983 proposed rule titled ''Medicare Program; Hospice Care'' (48 FR 38146), ''the hospice experience in the United States has placed emphasis on home care. It offers physician services, specialized nursing services, and other forms of care in the home to enable the terminally ill individual to remain at home in the company of family and friends as long as possible.'' The concept of a beneficiary ''electing'' the hospice benefit and being certified as terminally ill were two key components of the legislation responsible for the creation of the Medicare Hospice Benefit (section 122 of the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA), (Pub. L. 97–248)). Section 122 of TEFRA created the Medicare Hospice benefit, which was implemented on November 1, 1983. Under sections 1812(d) and 1861(dd) of the Act, we provide coverage of hospice care for terminally ill Medicare beneficiaries who elect to receive care from a Medicare-certified hospice. Our regulations at § 418.54(c) stipulate that the comprehensive hospice assessment must identify the beneficiary's physical, psychosocial, emotional, and spiritual needs related to the terminal illness and related conditions, and address those needs in order to promote the beneficiary's well-being, comfort, and dignity throughout the dying process. The comprehensive assessment must take into consideration the following factors: The nature and condition causing admission (including the presence or lack of objective data and subjective complaints); complications and risk factors that affect care planning; functional status; imminence of death; and severity of symptoms (§ 418.54(c)). The Medicare hospice benefit requires the hospice to cover all reasonable and necessary palliative care related to the terminal prognosis, as described in the beneficiary's plan of care. The December 16, 1983 Hospice final rule (48 FR 56008) requires hospices to cover care for interventions to manage pain and symptoms. Additionally, the hospice Conditions of Participation (CoPs) at § 418.56(c) require that the hospice must provide all reasonable and necessary services for the palliation and management of the terminal illness, related conditions, and interventions to manage pain and symptoms. Therapy and interventions must be assessed and managed in terms of providing palliation and comfort without undue symptom burden for the hospice patient or family.[2] In the December 16, 1983 Hospice final rule (48 FR 56010), regarding what is related versus

[1] Connor, Stephen. (2007). Development of Hospice and Palliative Care in the United States. OMEGA. 56(1), p. 89–99.

[2] Paolini, DO, Charlotte. (2001). Symptoms Management at End of Life. JAOA. 101(10). p. 609–615.

unrelated to the terminal illness, we stated: ''. . . we believe that the unique physical condition of each terminally ill individual makes it necessary for these decisions to be made on a case by case basis. It is our general view that hospices are required to provide virtually all the care that is needed by terminally ill patients.'' Therefore, unless there is clear evidence that a condition is unrelated to the terminal prognosis, all conditions are considered to be related to the terminal prognosis and the responsibility of the hospice to address and treat.

As stated in the December 16, 1983 Hospice final rule, the fundamental premise upon which the hospice benefit was designed was the ''revocation'' of traditional curative care and the ''election'' of hospice care for end-of-life symptom management and maximization of quality of life (48 FR 56008). After electing hospice care, the beneficiary typically returns to the home from an institutionalized setting or remains in the home, to be surrounded by family and friends, and to prepare emotionally and spiritually, if requested, for death while receiving expert symptom management and other supportive services. Election of hospice care also requires waiving the right to Medicare payment for curative treatment for the terminal prognosis, and instead receiving palliative care to manage pain or other symptoms.

The benefit was originally designed to cover hospice care for a finite period of time that roughly corresponded to a life expectancy of 6 months or less. Initially, beneficiaries could receive three election periods: Two 90-day periods and one 30-day period. Currently, Medicare beneficiaries can elect hospice care for two 90-day periods and an unlimited number of subsequent 60-day periods; however, at the beginning of each period, a physician must certify that the beneficiary has a life expectancy of 6 months or less if the terminal illness runs its normal course.

C. Services Covered by the Medicare Hospice Benefit

One requirement for coverage under the Medicare Hospice benefit is that hospice services must be reasonable and necessary for the palliation and management of the terminal illness and related conditions. Section 1861(dd)(1) of the Act establishes the services that are to be rendered by a Medicare certified hospice program. These covered services include: Nursing care; physical therapy; occupational therapy; speech-language pathology therapy; medical social services; home health aide services (now called hospice aide services); physician services; homemaker services; medical supplies (including drugs and biologicals); medical appliances; counseling services (including dietary counseling); short-term inpatient care in a hospital, nursing facility, or hospice inpatient facility (including both respite care and procedures necessary for pain control and acute or chronic symptom management); continuous home care during periods of crisis, and only as necessary to maintain the terminally ill individual at home; and any other item or service which is specified in the plan of care and for which payment may otherwise be made under Medicare, in accordance with Title XVIII of the Act.

Section 1814(a)(7)(B) of the Act requires that a written plan for providing hospice care to a beneficiary who is a hospice patient be established before care is provided by, or under arrangements made by, that hospice program and that the written plan be periodically reviewed by the beneficiary's attending physician (if any), the hospice medical director, and an interdisciplinary group (described in section 1861(dd)(2)(B) of the Act). The services offered under the Medicare hospice benefit must be available to beneficiaries as needed, 24 hours a day, 7 days a week (section 1861(dd)(2)(A)(i) of the Act). Upon the implementation of the hospice benefit, Congress expected hospices to continue to use volunteer services, though these services are not reimbursed by Medicare (see section 1861(dd)(2)(E) of the Act and 48 FR 38149). As stated in the August 22, 1983 Hospice proposed rule, the hospice interdisciplinary group should comprise paid hospice employees as well as hospice volunteers (48 FR 38149). This expectation supports the hospice philosophy of holistic, comprehensive, compassionate, end-of-life care.

Before the Medicare hospice benefit was established, Congress requested a demonstration project to test the feasibility of covering hospice care under Medicare. The National Hospice Study was initiated in 1980 through a grant sponsored by the Robert Wood Johnson and John A. Hartford Foundations and the Centers for Medicare & Medicaid Services (CMS) (then, the Health Care Financing Administration (HCFA)). The demonstration project was conducted between October 1980 and March 1983. The project summarized the hospice care philosophy and principles as the following:

- Patient and family know of the terminal condition.
- Further medical treatment and intervention are indicated only on a supportive basis.
- Pain control should be available to patients as needed to prevent rather than to just ameliorate pain.
- Interdisciplinary teamwork is essential in caring for patient and family.
- Family members and friends should be active in providing support during the death and bereavement process.
- Trained volunteers should provide additional support as needed.

The cost data and the findings on what services hospices provided in the demonstration project were used to design the Medicare hospice benefit. The identified hospice services were incorporated into the service requirements under the Medicare hospice benefit. Importantly, in the August 22, 1983 Hospice proposed rule, we stated ''the hospice benefit and the resulting Medicare reimbursement is not intended to diminish the voluntary spirit of hospices'' (48 FR 38149).

D. Medicare Payment for Hospice Care

Sections 1812(d), 1813(a)(4), 1814(a)(7), 1814(i), and 1861(dd) of the Act, and our regulations in part 418, establish eligibility requirements, payment standards and procedures, define covered services, and delineate the conditions a hospice must meet to be approved for participation in the Medicare program. Part 418, subpart G, provides for a per diem payment in one of four prospectively-determined rate categories of hospice care (Routine Home Care (RHC), Continuous Home Care (CHC), 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 to include all of the hospice services needed to manage the beneficiary's care, as required by section 1861(dd)(1) of the Act. There has been little change in the hospice payment structure since the benefit's inception. The per diem rate based on level of care was established in 1983, and this payment structure remains today with some adjustments, as noted below:

1. Omnibus Budget Reconciliation Act of 1989

Section 6005(a) of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239) amended section 1814(i)(1)(C) of the Act and provided for the following two changes in the methodology concerning updating the daily payment rates: (1) Effective January 1, 1990, the daily payment rates for RHC and other services included in

hospice care were increased to equal 120 percent of the rates in effect on September 30, 1989; and (2) the daily payment rate for RHC and other services included in hospice care for fiscal years (FYs) beginning on or after October 1, 1990, were the payment rates in effect during the previous Federal FY increased by the hospital market basket percentage increase.

2. Balanced Budget Act of 1997

Section 4441(a) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) amended section 1814(i)(1)(C)(ii)(VI) of the Act to establish updates to hospice rates for FYs 1998 through 2002. Hospice rates were updated by a factor equal to the hospital market basket percentage increase, minus 1 percentage point. Payment rates for FYs from 2002 have been updated according to section 1814(i)(1)(C)(ii)(VII) of the Act, which states that the update to the payment rates for subsequent FYs will be the hospital market basket percentage increase for the FY. The Act requires us to use the inpatient hospital market basket to determine hospice payment rates.

3. FY 1998 Hospice Wage Index Final Rule

In the August 8, 1997 FY 1998 Hospice Wage Index final rule (62 FR 42860), we implemented a new methodology for calculating the hospice wage index based on the recommendations of a negotiated rulemaking committee. The original hospice wage index was based on 1981 Bureau of Labor Statistics hospital data and had not been updated since 1983. In 1994, because of disparity in wages from one geographical location to another, the Hospice Wage Index Negotiated Rulemaking Committee was formed to negotiate a new wage index methodology that could be accepted by the industry and the government. This Committee was composed of representatives from national hospice associations; rural, urban, large and small hospices, and multi-site hospices; consumer groups; and a government representative. The Committee decided that in updating the hospice wage index, aggregate Medicare payments to hospices would remain budget neutral to payments calculated using the 1983 wage index, to cushion the impact of using a new wage index methodology. To implement this policy, a Budget Neutrality Adjustment Factor (BNAF) was computed and applied annually to the pre-floor, pre-reclassified hospital wage index when deriving the hospice wage index, subject to a wage index floor.

4. FY 2010 Hospice Wage Index Final Rule

Inpatient hospital pre-floor and pre-reclassified wage index values, as described in the August 8, 1997 Hospice Wage Index final rule, are subject to either a budget neutrality adjustment or application of the wage index floor. Wage index values of 0.8 or greater are adjusted by the BNAF. Starting in FY 2010, a 7-year phase-out of the BNAF began (FY 2010 Hospice Wage Index final rule, (74 FR 39384, August 6, 2009)), with a 10 percent reduction in FY 2010, an additional 15 percent reduction for a total of 25 percent in FY 2011, an additional 15 percent reduction for a total 40 percent reduction in FY 2012, an additional 15 percent reduction for a total of 55 percent in FY 2013, and an additional 15 percent reduction for a total 70 percent reduction in FY 2014. The phase-out continued with an additional 15 percent reduction for a total reduction of 85 percent in FY 2015, an additional, and final, 15 percent reduction for complete elimination in FY 2016. We note that the BNAF was an adjustment which increased the hospice wage index value. Therefore, the BNAF phase-out reduced the amount of the BNAF increase applied to the hospice wage index value. It was not a reduction in the hospice wage index value itself or in the hospice payment rates.

5. The Affordable Care Act

Starting with FY 2013 (and in subsequent FYs), the market basket percentage update under the hospice payment system referenced in sections 1814(i)(1)(C)(ii)(VII) and 1814(i)(1)(C)(iii) of the Act is subject to annual reductions related to changes in economy-wide productivity, as specified in section 1814(i)(1)(C)(iv) of the Act. In FY 2013 through FY 2019, the market basket percentage update under the hospice payment system will be reduced by an additional 0.3 percentage point (although for FY 2014 to FY 2019, the potential 0.3 percentage point reduction is subject to suspension under conditions specified in section 1814(i)(1)(C)(v) of the Act).

In addition, sections 1814(i)(5)(A) through (C) of the Act, as added by section 3132(a) of the Affordable Care Act, require hospices to begin submitting quality data, based on measures to be specified by the Secretary of the Department of Health and Human Services (the Secretary), for FY 2014 and subsequent FYs. Beginning in FY 2014, hospices which fail to report quality data will have their market basket update reduced by 2 percentage points.

Section 1814(a)(7)(D)(i) of the Act, as added by section 3132(b)(2) of the Affordable Care Act, requires, effective January 1, 2011, that a hospice physician or nurse practitioner have a face-to-face encounter with the beneficiary to determine continued eligibility of the beneficiary's hospice care prior to the 180th-day recertification and each subsequent recertification, and to attest that such visit took place. When implementing this provision, we finalized in the CY 2011 Home Health Prospective Payment System final rule (75 FR 70435) that the 180th-day recertification and subsequent recertifications would correspond to the beneficiary's third or subsequent benefit periods. Further, section 1814(i)(6) of the Act, as added by section 3132(a)(1)(B) of the Affordable Care Act, authorizes the Secretary to collect additional data and information determined appropriate to revise payments for hospice care and other purposes. The types of data and information suggested in the Affordable Care Act could capture accurate resource utilization, which could be collected on claims, cost reports, and possibly other mechanisms, as the Secretary determined to be appropriate. The data collected could be used to revise the methodology for determining the payment rates for RHC and other services included in hospice care, no earlier than October 1, 2013, as described in section 1814(i)(6)(D) of the Act. In addition, we were required to consult with hospice programs and the Medicare Payment Advisory Commission (MedPAC) regarding additional data collection and payment revision options.

6. FY 2012 Hospice Wage Index Final Rule

When the Medicare Hospice benefit was implemented, Congress included an aggregate cap on hospice payments, which limits the total aggregate payments any individual hospice can receive in a year. Congress stipulated that a ''cap amount'' be computed each year. The cap amount was set at $6,500 per beneficiary when first enacted in 1983 and has been adjusted annually by the change in the medical care expenditure category of the consumer price index for urban consumers from March 1984 to March of the cap year (section 1814(i)(2)(B) of the Act). The cap year was defined as the period from November 1st to October 31st. In the August 4, 2011 FY 2012 Hospice Wage Index final rule (76 FR 47308 through 47314) for the 2012 cap year and

subsequent cap years, we announced that subsequently, the hospice aggregate cap would be calculated using the patient-by-patient proportional methodology. We allowed existing hospices the option of having their cap calculated via the original streamlined methodology. As of FY 2012, new hospices have their cap determinations calculated using the patient-by-patient proportional methodology. The patient-by-patient proportional methodology and the streamlined methodology are two different methodologies for counting beneficiaries when calculating the hospice aggregate cap. A detailed explanation of these methods is found in the August 4, 2011 FY 2012 Hospice Wage Index final rule (76 FR 47308 through 47314). If a hospice's total Medicare reimbursement for the cap year exceeds the hospice aggregate cap, then the hospice must repay the excess back to Medicare.

7. FY 2015 Hospice Wage Index and Payment Rate Update Final Rule

When electing hospice, a beneficiary waives Medicare coverage for any care for the terminal illness and related conditions except for services provided by the designated hospice and attending physician. The FY 2015 Hospice Wage Index and Payment Rate Update final rule (79 FR 50452) finalized a requirement that requires the Notice of Election (NOE) be filed within 5 calendar days after the effective date of hospice election. If the NOE is filed beyond this 5-day period, hospice providers are liable for the services furnished during the days from the effective date of hospice election to the date of NOE filing (79 FR 50474). Similar to the NOE, the claims processing system must be notified of a beneficiary's discharge from hospice or hospice benefit revocation. This update to the beneficiary's status allows claims from non-hospice providers to be processed and paid. Late filing of the NOE can result in inaccurate benefit period data and leaves Medicare vulnerable to paying non-hospice claims related to the terminal illness and related conditions and beneficiaries possibly liable for any cost-sharing associated costs. Upon live discharge or revocation, the beneficiary immediately resumes the Medicare coverage that had been waived when he or she elected hospice. The FY 2015 Hospice Wage Index and Payment Rate Update final rule also finalized a requirement that requires hospices to file a notice of termination/revocation within 5 calendar days of a beneficiary's live discharge or revocation, unless the hospices have already filed a final claim. This requirement helps to protect beneficiaries from delays in accessing needed care (§ 418.26(e)).

A hospice ''attending physician'' is described by the statutory and regulatory definitions as a medical doctor, osteopath, or nurse practitioner whom the beneficiary identifies, at the time of hospice election, as having the most significant role in the determination and delivery of his or her medical care. We received reports of problems with the identification of the person's designated attending physician and a third of hospice patients had multiple providers submit Part B claims as the ''attending physician,'' using a claim modifier. The FY 2015 Hospice Wage Index and Payment Rate Update final rule finalized a requirement that the election form include the beneficiary's choice of attending physician and that the beneficiary provide the hospice with a signed document when he or she chooses to change attending physicians (79 FR 50479).

Hospice providers are required to begin using a Hospice Experience of Care Survey for informal caregivers of hospice patients surveyed in 2015. The FY 2015 Hospice Wage Index and Payment Rate Update final rule provided background and a description of the development of the Hospice Experience of Care Survey, including the model of survey implementation, the survey respondents, eligibility criteria for the sample, and the languages in which the survey is offered. The FY 2015 Hospice Rate Update final rule also set out participation requirements for CY 2015 and discussed vendor oversight activities and the reconsideration and appeals process for entities that failed to win CMS approval as vendors (79 FR 50496).

Finally, the FY 2015 Hospice Wage Index and Payment Rate Update final rule required providers to complete their aggregate cap determination not sooner than 3 months after the end of the cap year, and not later than 5 months after, and remit any overpayments. Those hospices that fail to timely submit their aggregate cap determinations will have their payments suspended until the determination is completed and received by the Medicare Administrative Contractor (MAC) (79 FR 50503).

8. IMPACT Act of 2014

The Improving Medicare Post-Acute Care Transformation Act of 2014 (Pub. L. 113–185) (IMPACT Act) became law on October 6, 2014. Section 3(a) of the IMPACT Act mandated that all Medicare certified hospices be surveyed every 3 years beginning April 6, 2015 and ending September 30, 2025. In addition, section 3(c) of the IMPACT Act requires medical review of hospice cases involving beneficiaries receiving more than 180 days care in select hospices that show a preponderance of such patients; section 3(d) of the IMPACT Act contains a new provision mandating that the cap amount for accounting years that end after September 30, 2016, and before October 1, 2025 be updated by the hospice payment update rather than using the consumer price index for urban consumers (CPI–U) for medical care expenditures.

9. FY 2016 Hospice Wage Index and Payment Rate Update Final Rule

In the FY 2016 Hospice Rate Update final rule, we created two different payment rates for RHC that resulted in a higher base payment rate for the first 60 days of hospice care and a reduced base payment rate for all subsequent days of hospice care (80 FR 47172). We also created a Service Intensity Add-on (SIA) payment payable for services during the last 7 days of the beneficiary's life, equal to the CHC hourly payment rate multiplied by the amount of direct patient care provided by a registered nurse (RN) or social worker that occurs during the last 7 days (80 FR 47177).

In addition to the hospice payment reform changes discussed, the FY 2016 Hospice Wage Index and Payment Rate Update final rule implemented changes mandated by the IMPACT Act, in which the cap amount for accounting years that end after September 30, 2016 and before October 1, 2025 is updated by the hospice payment update percentage rather than using the CPI–U. This was applied to the 2016 cap year, starting on November 1, 2015 and ending on October 31, 2016. In addition, we finalized a provision to align the cap accounting year for both the inpatient cap and the hospice aggregate cap with the FY, for FY 2017 and later (80 FR 47186). This allows for the timely implementation of the IMPACT Act changes while better aligning the cap accounting year with the timeframe described in the IMPACT Act.

Finally, the FY 2016 Hospice Wage Index and Payment Rate Update final rule clarified that hospices must report all diagnoses of the beneficiary on the hospice claim as a part of the ongoing data collection efforts for possible future hospice payment refinements. Reporting of all diagnoses on the hospice claim aligns with current coding guidelines as

well as admission requirements for hospice certifications (80 FR 47142).

E. Trends in Medicare Hospice Utilization

Since the implementation of the hospice benefit in 1983, and especially within the last decade, there has been substantial growth in hospice benefit utilization. The number of Medicare beneficiaries receiving hospice services has grown from 513,000 in FY 2000 to nearly 1.4 million in FY 2015. Similarly, Medicare hospice expenditures have risen from $2.8 billion in FY 2000 to an estimated $15.5 billion in FY 2015.[3] Under the economic assumptions from the 2017 Mid-Session Review,[4] our Office of the Actuary (OACT) projects that hospice expenditures are expected to continue to increase, by approximately 7 percent annually, reflecting an increase in the number of Medicare beneficiaries, more beneficiary awareness of the Medicare Hospice Benefit for end-of-life care, and a growing preference for care provided in home and community-based settings.

There have also been changes in the diagnosis patterns among Medicare hospice enrollees. Specifically, as described in Table 2, there have been notable increases between 2002 and 2015 in neurologically-based diagnoses, including various dementia and Alzheimer's diagnoses. Additionally, there had been significant increases in the use of non-specific, symptom-classified diagnoses, such as ''debility'' and ''adult failure to thrive.'' In FY 2013, ''debility'' and ''adult failure to thrive'' were the first and sixth most common hospice claims-reported diagnoses, respectively, accounting for approximately 14 percent of all diagnoses. Effective October 1, 2014, hospice claims are returned to the provider if ''debility'' and ''adult failure to thrive'' are coded as the principal hospice diagnosis as well as other ICD–9–CM (and as of October 1, 2015, ICD–10–CM) codes that are not permissible as principal diagnosis codes per ICD–9–CM (or ICD–10–CM) coding guidelines. In the FY 2015 Hospice Wage Index and Payment Rate Update final rule (79 FR 50452), we reminded the hospice industry that this policy would go into effect and claims would start to be returned to the provider effective October 1, 2014. As a result of this, there has been a shift in coding patterns on hospice claims. For FY 2015, the most common hospice principal diagnoses were Alzheimer's disease, Congestive Heart Failure, Lung Cancer, Chronic Airway Obstruction, and Senile Dementia which constituted approximately 35 percent of all claims-reported principal diagnosis codes reported in FY 2015. In Table 2 we have updated the information initially presented in the FY 2017 proposed rule (81 FR 25504–06).

TABLE 2—THE TOP TWENTY PRINCIPAL HOSPICE DIAGNOSES, FY 2002, FY 2007, FY 2013, FY 2015

Rank	ICD–9	Reported principal diagnosis	Count	Percentage
		Year: FY 2002		
1	162.9	Lung Cancer	73,769	11
2	428.0	Congestive Heart Failure	45,951	7
3	799.3	Debility Unspecified	36,999	6
4	496	COPD	35,197	5
5	331.0	Alzheimer's Disease	28,787	4
6	436	CVA/Stroke	26,897	4
7	185	Prostate Cancer	20,262	3
8	783.7	Adult Failure To Thrive	18,304	3
9	174.9	Breast Cancer	17,812	3
10	290.0	Senile Dementia, Uncomp	16,999	3
11	153.0	Colon Cancer	16,379	2
12	157.9	Pancreatic Cancer	15,427	2
13	294.8	Organic Brain Synd Nec	10,394	2
14	429.9	Heart Disease Unspecified	10,332	2
15	154.0	Rectosigmoid Colon Cancer	8,956	1
16	332.0	Parkinson's Disease	8,865	1
17	586	Renal Failure Unspecified	8,764	1
18	585	Chronic Renal Failure (End 2005)	8,599	1
19	183.0	Ovarian Cancer	7,432	1
20	188.9	Bladder Cancer	6,916	1
		Year: FY 2007		
1	799.3	Debility Unspecified	90,150	9
2	162.9	Lung Cancer	86,954	8
3	428.0	Congestive Heart Failure	77,836	7
4	496	COPD	60,815	6
5	783.7	Adult Failure To Thrive	58,303	6
6	331.0	Alzheimer's Disease	58,200	6
7	290.0	Senile Dementia Uncomp	37,667	4
8	436	CVA/Stroke	31,800	3
9	429.9	Heart Disease Unspecified	22,170	2
10	185	Prostate Cancer	22,086	2
11	174.9	Breast Cancer	20,378	2
12	157.9	Pancreas Unspecified	19,082	2
13	153.9	Colon Cancer	19,080	2

[3] FY2000 figures from MedPAC analysis of the denominator file, the Medicare Beneficiary Database, and the 100 percent hospice claims standard analytic file from CMS (*http://www.medpac.gov/documents/reports/chapter-11-hospice-services-(march-2012-report).pdf?sfvrsn=4*). FY 2015 hospice claims data from the Chronic Conditions Data Warehouse (CCW), accessed on June 20, 2016.

[4] ''Mid-Session Review: Budget of the US Government.'' *Office of Management and Budget.* July 15, 2016. *https://www.whitehouse.gov/sites/default/files/omb/budget/fy2017/assets/17msr.pdf.*

TABLE 2—THE TOP TWENTY PRINCIPAL HOSPICE DIAGNOSES, FY 2002, FY 2007, FY 2013, FY 2015—Continued

Rank	ICD–9	Reported principal diagnosis	Count	Percentage
14	294.8	Organic Brain Syndrome NEC	17,697	2
15	332.0	Parkinson's Disease	16,524	2
16	294.10	Dementia In Other Diseases w/o Behav. Dist	15,777	2
17	586	Renal Failure Unspecified	12,188	1
18	585.6	End Stage Renal Disease	11,196	1
19	188.9	Bladder Cancer	8,806	1
20	183.0	Ovarian Cancer	8,434	1
Year: FY 2013				
1	799.3	Debility Unspecified	127,415	9
2	428.0	Congestive Heart Failure	96,171	7
3	162.9	Lung Cancer	91,598	6
4	496	COPD	82,184	6
5	331.0	Alzheimer's Disease	79,626	6
6	783.7	Adult Failure to Thrive	71,122	5
7	290.0	Senile Dementia, Uncomp	60,579	4
8	429.9	Heart Disease Unspecified	36,914	3
9	436	CVA/Stroke	34,459	2
10	294.10	Dementia In Other Diseases w/o Behavioral Dist	30,963	2
11	332.0	Parkinson's Disease	25,396	2
12	153.9	Colon Cancer	23,228	2
13	294.20	Dementia Unspecified w/o Behavioral Dist	23,224	2
14	174.9	Breast Cancer	23,059	2
15	157.9	Pancreatic Cancer	22,341	2
16	185	Prostate Cancer	21,769	2
17	585.6	End-Stage Renal Disease	19,309	1
18	518.81	Acute Respiratory Failure	15,965	1
19	294.8	Other Persistent Mental Dis.-classified elsewhere	14,372	1
20	294.11	Dementia In Other Diseases w/Behavioral Dist	13,687	1
Year: FY 2015				
1	331.0	Alzheimer's disease	196,705	13
2	428.0	Congestive heart failure, unspecified	115,111	8
3	162.9	Lung Cancer	88,404	6
4	496	COPD	80,655	6
5	331.2	Senile degeneration of brain	46,843	3
6	332.0	Parkinson's Disease	34,957	2
7	429.9	Heart disease, unspecified	31,906	2
8	436	CVA/Stroke	29,172	2
9	437.0	Cerebral atherosclerosis	26,887	2
10	174.9	Breast Cancer	23,969	2
11	153.9	Colon Cancer	23,844	2
12	185	Prostate Cancer	23,293	2
13	157.9	Pancreatic Cancer	23,127	2
14	585.6	End stage renal disease	22,990	2
15	491.21	Obstructive chronic bronchitis with (acute) exacerbation	21,493	1
16	518.81	Acute respiratory failure	20,214	1
17	429.2	Cardiovascular disease, unspecified	16,937	1
18	434.91	Cerebral artery occlusion, unspecified with cerebral infarction	15,841	1
19	414.00	Coronary atherosclerosis of unspecified type of vessel	15,689	1
20	188.9	Bladder Cancer	11,648	1

Note(s): The frequencies shown represent beneficiaries that had a least one claim with the specific ICD–9–CM code reported as the principal diagnosis. Beneficiaries could be represented multiple times in the results if they have multiple claims during that time period with different principal diagnoses.

Source: FY 2002 and 2007 hospice claims data from the Chronic Conditions Data Warehouse (CCW), accessed on February 14 and February 20, 2013. FY 2013 hospice claims data from the CCW, accessed on June 26, 2014, and FY 2015 hospice claims data from the CCW, accessed on June 20, 2016.

While there has been a shift in the reporting of the principal diagnosis as a result of diagnosis clarifications, a significant proportion of hospice claims (49 percent) in FY 2014 only reported a single principal diagnosis, which may not fully explain the characteristics of Medicare beneficiaries who are approaching the end of life. To address this pattern of single diagnosis reporting, the FY 2015 Hospice Wage Index and Payment Rate Update final rule (79 FR 50498) reiterated ICD–9–CM coding guidelines for the reporting of the principal and additional diagnoses on the hospice claim. We reminded providers to report all diagnoses on the hospice claim for the terminal illness and related conditions, including those that affect the care and clinical management for the beneficiary. Additionally, in the FY 2016 Hospice Wage Index and Payment Rate Update final rule (80 FR 47201), we provided further clarification regarding diagnosis reporting on hospice claims. We clarified that hospices will report *all*

diagnoses identified in the initial and comprehensive assessments on hospice claims, whether related or unrelated to the terminal prognosis of the individual, effective October 1, 2015. Analysis of FY 2015 hospice claims show that only 37 percent of hospice claims include a single, principal diagnosis, with 63 percent submitting at least two diagnoses and 46 percent including at least three.

F. Use of Health Information Technology

The Department of Health and Human Services (HHS) believes that the use of certified health IT by hospices can help providers improve internal care delivery practices and advance the interoperable exchange of health information across care partners to improve communication and care coordination. HHS has a number of initiatives designed to encourage and support the adoption of health information technology and promote nationwide health information exchange to improve health care. The Office of the National Coordinator for Health Information Technology (ONC) leads these efforts in collaboration with other agencies, including CMS and the Office of the Assistant Secretary for Planning and Evaluation (ASPE). In 2015, ONC released a document entitled ''Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap'' (available at: *https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf*), which includes a near-term focus on actions that will enable a majority of individuals and providers across the care continuum to send, receive, find and use a common set of electronic clinical information at the nationwide level by the end of 2017. The 2015 Edition Health IT Certification Criteria (2015 Edition) builds on past rulemakings to facilitate greater interoperability for several clinical health information purposes and enables health information exchange through new and enhanced certification criteria, standards, and implementation specifications. The 2015 Edition also focuses on the establishment of an interoperable nationwide health information infrastructure. More information on the 2015 Edition Final Rule is available at: *https://www.healthit.gov/policy-researchers-implementers/2015-edition-final-rule*

III. Provisions of the Proposed Regulations

The proposed rule, titled ''Medicare Program; FY 2017 Hospice Payment Rate Update'' (81 FR 25497 through 25538), was published in the **Federal Register** on April 28, 2016, with a comment period that ended on June 20, 2016. In that proposed rule, we proposed to update the hospice wage index, payment rates, and cap amount for fiscal year (FY) 2017. In addition, the proposed rule proposed changes to the hospice quality reporting program, including new quality measures. The proposed rule also solicited feedback on an enhanced data collection instrument and described plans to publicly display quality measures and other hospice data beginning in the middle of 2017. Finally, the proposed rule included information regarding the Medicare Care Choices Model (MCCM). We received approximately 56 public comments on the proposed rule, including comments from MedPAC, hospice agencies, national provider associations, patient organizations, nurses, and advocacy groups.

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the FY 2017 Hospice Payment Rate Update. Comments related to the paperwork burden are addressed in the ''Collection of Information Requirements'' section in this final rule. Comments related to the impact analysis are addressed in the ''Economic Analyses'' section in this final rule.

A. Monitoring for Potential Impacts—Affordable Care Act Hospice Reform

In the FY 2017 Hospice Wage Index and Rate Update proposed rule (81 FR 25497), we provided a summary of analysis conducted on pre-hospice spending, non-hospice spending, live discharge rates, and skilled visits in the last days of life. In addition, we also provided a summary of our plans to monitor for impacts of hospice payment reform. We will continue to monitor the impact of future payment and policy changes and will provide the industry with periodic updates on our analysis in future rulemaking and/or announcements on the Hospice Center Web page at: *https://www.cms.gov/Center/Provider-Type/Hospice-Center.html.*

We received several comments on the analysis and CMS's plans for future monitoring efforts with regards to hospice payment reform outlined in the proposed rule, which are summarized below.

Comment: A few commenters expressed concerns regarding whether pre-hospice spending is an appropriate standard for comparison for post-hospice spending for any diagnosis, including dementia. The commenters noted the illness trajectory of dementia is marked by a slow, progressive decline, differs from the illness trajectories of other hospice appropriate diagnoses, and results in care needs increasing and extending over longer periods of time. In turn, it may require higher spending. The commenters asked us to recognize the overall care needs of patients with dementia and other progressive neurological conditions, and the costs associated with these patients and their caregivers. Additionally, several commenters highlighted the challenges of and intensive resources required for short-stay patients, noting that the current payment system may not address the unique needs of that population.

Several commenters suggested that CMS consider payment refinements that help to incentivize appropriate timing on enrollment for hospice. Additional commenters noted their concern regarding a potential case-mix payment system for hospice, as the commenters believe that the hospice benefit differs from all other Medicare payment systems, as it is designed to account for the patient's full scope of Medicare needs.

With regards to non-hospice spending during a hospice election, several commenters suggested that CMS take action to educate other Medicare provider types in order to increase understanding of benefits coverage and claims processing after a beneficiary has elected hospice. Several commenters also suggested that CMS investigate options for preventing other Medicare providers from billing without checking the Common Working File and notifying the hospice for a determination as to whether or not the care is related to the terminal prognosis. Several commenters requested that a greater level of specificity for Part D data be supplied to hospice providers, such that they can track where the billing issues originate and begin to address them. The commenters suggested that a coordinated system would help address the non-hospice spending.

With regards to hospice live discharge rates, a few commenters noted concerns about the difference between two types of live discharges: A patient-initiated discharge or revocation versus a hospice-initiated discharge. The commenters suggested that analysis of live discharge rates should exclude the patient-initiated discharges or revocations. Commenters suggested that for hospice-initiated discharges, the reasons for such discharges should be reported so that hospice providers can

make adjustments in their admission and discharge practices.

With regards to skilled visits during the last days of life, the number of visits by RNs and social workers is anticipated to increase during the last 7 days of a beneficiary's life as a result of the service intensity add-on payment, implemented on January 1, 2016. A few commenters stated that hospices take their cues from patients and families, who should always have the option to decline a visit. As such, decisions regarding visits made by the patient and family ought to be considered and/or reflected in the data.

Finally, most commenters supported our planned analysis to monitor the impact of hospice payment reform and would like to use the monitoring results to target program integrity efforts to those aberrant individual providers.

Although the analysis and monitoring efforts described in the proposed rule did not relate to the timely filing requirement for the hospice Notice of Election (NOE), nevertheless a few commenters expressed concern about the timely filing requirement and lost revenue due to data entry errors that cannot be immediately corrected. Commenters encouraged CMS to continue to explore the possibility of transmitting NOEs through Electronic Data Interchange rather than through direct data entry and recommended that, in the meantime, when the hospice files the NOE in good faith within the 5-day requirement, but the MAC does not accept the NOE within 5 days, the payment for hospice services should be allowed back to the date of election, once the MAC has accepted the NOE.

Response: We appreciate these comments on the ongoing analysis presented and will continue to monitor hospice trends and vulnerabilities within the hospice benefit while also investigating means by which we can educate the larger provider community regarding appropriate billing practices. Additionally, we continue to explore options and strategies for addressing and responding to concerning behavior in the provider community. We will also consider these suggestions in any potential future policy and payment refinements.

With regards to the comments received regarding the NOE timely filing requirement, we recognize that inadvertent NOE errors, such as transposed numbers or incorrect admission dates, will not trigger the NOE to return to the hospice for correction. The hospice must wait until the incorrect information is fully processed by Medicare systems before they can correct it, and this could cause the NOE to be late. We strongly encourage hospices to have quality assurance measures in place regarding the accuracy of the NOE information to mitigate any potential untimely NOEs. Our expectation is that the information provided on the hospice NOE is accurate and free of transcribing errors. To aid in reducing the impact of these situations on hospices, CMS is currently conducting an analysis that aims to redesign the hospice benefit period data in our systems.

B. FY 2017 Hospice Wage Index and Rate Update

1. FY 2017 Hospice Wage Index

a. Background

The hospice wage index is used to adjust payment rates for hospice agencies under the Medicare program to reflect local differences in area wage levels, based on the location where services are furnished. The hospice wage index utilizes the wage adjustment factors used by the Secretary for purposes of section 1886(d)(3)(E) of the Act for hospital wage adjustments. Our regulations at § 418.306(c) require each labor market to be established using the most current hospital wage data available, including any changes made by the Office of Management and Budget (OMB) to the Metropolitan Statistical Areas (MSAs) definitions.

We use the previous FY's hospital wage index data to calculate the hospice wage index values. For FY 2017, the hospice wage index will be based on the FY 2016 pre-floor, pre-reclassified hospital wage index. This means that the hospital wage data used for the hospice wage index is not adjusted to take into account any geographic reclassification of hospitals including those in accordance with section 1886(d)(8)(B) or 1886(d)(10) of the Act. The appropriate wage index value is applied to the labor portion of the payment rate based on the geographic area in which the beneficiary resides when receiving RHC or CHC. The appropriate wage index value is applied to the labor portion of the payment rate based on the geographic location of the facility for beneficiaries receiving GIP or Inpatient Respite Care (IRC).

In the FY 2006 Hospice Wage Index final rule (70 FR 45130), we adopted the changes discussed in the OMB Bulletin No. 03–04 (June 6, 2003). This bulletin announced revised definitions for MSAs and the creation of micropolitan statistical areas and combined statistical areas. The bulletin is available online at *http://www.whitehouse.gov/omb/bulletins/b03-04.html.* When adopting OMB's new labor market designations in FY 2006, we identified some geographic areas where there were no hospitals, and thus, no hospital wage index data, on which to base the calculation of the hospice wage index. In the FY 2010 Hospice Wage Index final rule (74 FR 39386), we adopted the policy that for urban labor markets without a hospital from which hospital wage index data could be derived, all of the CBSAs within the state would be used to calculate a statewide urban average pre-floor, pre-reclassified hospital wage index value to use as a reasonable proxy for these areas. In FY 2016, the only CBSA without a hospital from which hospital wage data could be derived is 25980, Hinesville-Fort Stewart, Georgia.

In the FY 2008 Hospice Wage Index final rule (72 FR 50214), we implemented a new methodology to update the hospice wage index for rural areas without a hospital, and thus no hospital wage data. In cases where there was a rural area without rural hospital wage data, we used the average pre-floor, pre-reclassified hospital wage index data from all contiguous CBSAs to represent a reasonable proxy for the rural area. The term ''contiguous'' means sharing a border (72 FR 50217). Currently, the only rural area without a hospital from which hospital wage data could be derived is Puerto Rico. However, our policy of imputing a rural pre-floor, pre-reclassified hospital wage index value based on the pre-floor, pre-reclassified hospital wage index (or indices) of CBSAs contiguous to a rural area without a hospital from which hospital wage data could be derived does not recognize the unique circumstances of Puerto Rico. In this final rule, for FY 2017, we will continue to use the most recent pre-floor, pre-reclassified hospital wage index value available for Puerto Rico, which is 0.4047.

As described in the August 8, 1997 Hospice Wage Index final rule (62 FR 42860), the pre-floor and pre-reclassified hospital wage index is used as the raw wage index for the hospice benefit. These raw wage index values are then subject to application of the hospice floor to compute the hospice wage index used to determine payments to hospices. Pre-floor, pre-reclassified hospital wage index values below 0.8 are adjusted by a 15 percent increase subject to a maximum wage index value of 0.8. For example, if County A has a pre-floor, pre-reclassified hospital wage index value of 0.3994, we would multiply 0.3994 by 1.15, which equals 0.4593. Since 0.4593 is not greater than 0.8, then County A's hospice wage index would be 0.4593. In another example, if County B has a pre-floor,

pre-reclassified hospital wage index value of 0.7440, we would multiply 0.7440 by 1.15 which equals 0.8556. Because 0.8556 is greater than 0.8, County B's hospice wage index would be 0.8.

b. FY 2016 Implementation of New Labor Market Delineations

OMB has published subsequent bulletins regarding CBSA changes. On February 28, 2013, OMB issued OMB Bulletin No. 13–01, announcing revisions to the delineation of MSAs, Micropolitan Statistical Areas, and Combined Statistical Areas, and guidance on uses of the delineation in these areas. A copy of this bulletin is available online at: *http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13-01.pdf.* This bulletin states that it ''provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on June 28, 2010, in the **Federal Register** (75 FR 37246 through 37252) and Census Bureau data.'' In the FY 2016 Hospice Wage Index final rule (80 FR 47178), we adopted the OMB's new area delineations using a 1-year transition. In the FY 2016 Hospice Wage Index and Payment Rate Update final rule (80 FR 47178), we stated that beginning October 1, 2016, the wage index for all hospice payments would be fully based on the new OMB delineations.

A summary of the comments we received regarding the wage index and our responses to those comments appears below.

Comment: Several commenters noted their support for the full adoption of the new labor market delineations.

Response: We appreciate the comments in support of the CBSA delineations finalized in last year's FY 2016 Hospice Wage Index and Payment Rate Update final rule (80 FR 47142).

Comment: One commenter disagreed with fully basing hospice geographic area wage adjustments on the new OMB delineations. The commenter was particularly concerned with the New York City CBSA and the fact that the CBSA contains counties from New Jersey.

Response: In the FY 2016 Hospice Wage Index and Rate Update final rule (80 FR 47178), we stated that a 1-year transition policy would apply to the FY 2016 payment rates and that, beginning in FY 2017, hospice payments would be fully-based on the new OMB delineations. In addition, we believe that the OMB's CBSA designations reflect the most recent available geographic classifications and are a reasonable and appropriate method of defining geographic areas for the purposes of wage adjusting the hospice payment rates. We do not see any compelling reason to deviate from the OMB designations.

Comment: A commenter was concerned with the continued use of the pre-floor, pre-reclassified hospital wage index to adjust the hospice payment rates, because this causes continuing volatility of the hospice wage index from one year to the next. The commenter believes that this volatility is often based on inaccurate or incomplete hospital cost report data.

Response: We believe that annual changes in the wage index reflect real variations in costs of providing care in various geographic locations. The wage index values are based on data submitted on the inpatient hospital cost reports. We utilize efficient means to ensure and review the accuracy of the hospital cost report data and resulting wage index. The hospice wage index is derived from the pre-floor, pre-reclassified wage index, which is calculated based on cost report data from hospitals paid under the Inpatient Prospective Payment System (IPPS). All IPPS hospitals must complete the wage index survey (Worksheet S–3, Parts II and III) as part of their Medicare cost reports. Cost reports will be rejected if Worksheet S–3 is not completed. In addition, our Medicare contractors perform desk reviews on all hospitals' Worksheet S–3 wage data, and we run edits on the wage data to further ensure the accuracy and validity of the wage data. We believe that our review processes result in an accurate reflection of the applicable wages for the areas given.

In addition, we believe that finalizing our proposal to adopt a hospice wage index standardization factor will provide a safeguard to the Medicare program as well as to hospices because it will mitigate fluctuations in the wage index by ensuring that wage index updates and revisions are implemented in a budget neutral manner.

Comment: A commenter was concerned with the lack of parity between different health care sectors, each of which utilizes some form of a hospital wage index, that experience differing wage index values for specific geographic areas. The commenter also stated that hospital reclassifications create labor market distortions in areas in which hospice costs are not reclassified.

Response: Several post-acute care payment systems utilize the pre-floor, pre-reclassified hospital wage index as the basis for their wage indexes (for example, the Home Health Prospective Payment System (HH PPS), the Skilled Nursing Facility Prospective Payment System (SNF PPS) and the Inpatient Rehabilitation Facility Prospective Payment System (IRF PPS)). The statutes that govern hospice payment do not provide any discretion to permit a mechanism for allowing hospices to seek geographic reclassification. The reclassification provision is found in section 1886(d)(10) of the Act. Section 1886(d)(10)(C)(i) of the Act states, ''The Board shall consider the application of any subsection (d) hospital requesting that the Secretary change the hospital's geographic classification . . .'' This provision is only applicable to hospitals, as defined at section 1886(d) of the Act. In addition, we do not believe that using hospital reclassification data would be appropriate as these data are specific to the requesting hospitals and the data may or may not apply to a given hospice in a given instance.

Comment: One commenter requested that CMS modify the wage index so that the area wage index applicable to any hospice that is located in an urban area of a state may not be less than the area wage index applicable to hospices located in rural areas in that State.

Response: Section 4410(a) of the Balanced Budget Act of 1997 (Pub. L. 105–33) provides that the area wage index applicable to any hospital that is located in an urban area of a state may not be less than the area wage index applicable to hospitals located in rural areas in that state. This rural floor provision is specific to hospitals. Because the hospital rural floor applies only to hospitals, and not to hospices, we continue to believe the use of the previous year's pre-floor and pre-reclassified hospital wage index results in the most appropriate adjustment to the labor portion of the hospice payment rates. This position is longstanding and consistent with other Medicare payment systems (SNF PPS, IRF PPS, HH PPS, etc.).

Comment: A commenter requested that CMS explore a wholesale revision and reform of the hospice wage index.

Response: We are exploring other methodologies for future reform of the Medicare wage index. CMS' ''Report to Congress: Plan to Reform the Medicare Wage Index'' was submitted by the Secretary on April 11, 2012 and is available on our Wage Index Reform Web page at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-*

Payment/AcuteInpatientPPS/Wage-Index-Reform.html.

Final Action: After considering the comments received in response to the proposed rule and for the reasons discussed above, we are finalizing our proposal to use the pre-floor, pre-reclassified hospital inpatient wage index as the wage adjustment to the labor portion of the hospice rates. For FY 2017, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2011 and before October 1, 2012 (FY 2012 cost report data).

The wage index applicable for FY 2017 is available on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/index.html.* As of FY 2012, the wage index values applicable for the upcoming fiscal year and subsequent fiscal years are no longer published in the **Federal Register** (77 FR 44242). The hospice wage index for FY 2017 will be effective October 1, 2016 through September 30, 2017.

2. Hospice Payment Update Percentage

Section 4441(a) of the Balanced Budget Act of 1997 (BBA) amended section 1814(i)(1)(C)(ii)(VI) of the Act to establish updates to hospice rates for FYs 1998 through 2002. Hospice rates were to be updated by a factor equal to the inpatient hospital market basket index set out under section 1886(b)(3)(B)(iii) of the Act, minus 1 percentage point. Payment rates for FYs since 2002 have been updated according to section 1814(i)(1)(C)(ii)(VII) of the Act, which states that the update to the payment rates for subsequent FYs must be the inpatient market basket percentage for that FY. The Act requires us to use the inpatient hospital market basket to determine the hospice payment rate update. In addition, section 3401(g) of the Affordable Care Act mandates that, starting with FY 2013 (and in subsequent FYs), the hospice payment update percentage will be annually reduced by changes in economy-wide productivity as specified in section 1886(b)(3)(B)(xi)(II) of the Act. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period) (the ''MFP adjustment''). A complete description of the MFP projection methodology is available on our Web site at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html.*

In addition to the MFP adjustment, section 3401(g) of the Affordable Care Act also mandates that in FY 2013 through FY 2019, the hospice payment update percentage will be reduced by an additional 0.3 percentage point (although for FY 2014 to FY 2019, the potential 0.3 percentage point reduction is subject to suspension under conditions specified in section 1814(i)(1)(C)(v) of the Act). The hospice payment update percentage for FY 2017 is based on the estimated inpatient hospital market basket update of 2.7 percent (based on IHS Global Insight, Inc.'s second quarter 2016 forecast with historical data through the first quarter of 2016). Due to the requirements at sections 1886(b)(3)(B)(xi)(II) and 1814(i)(1)(C)(v) of the Act, the estimated inpatient hospital market basket update for FY 2017 of 2.7 percent must be reduced by a MFP adjustment as mandated by Affordable Care Act (currently estimated to be 0.3 percentage point for FY 2017). The estimated inpatient hospital market basket update for FY 2017 is reduced further by 0.3 percentage point, as mandated by the Affordable Care Act. In effect, the hospice payment update percentage for FY 2017 is 2.1 percent.

Currently, the labor portion of the hospice payment rates is as follows: For RHC, 68.71 percent; for CHC, 68.71 percent; for General Inpatient Care, 64.01 percent; and for Respite Care, 54.13 percent. The non-labor portion is equal to 100 percent minus the labor portion for each level of care. Therefore, the non-labor portion of the payment rates is as follows: For RHC, 31.29 percent; for CHC, 31.29 percent; for General Inpatient Care, 35.99 percent; and for Respite Care, 45.87 percent.

A summary of the comments we received regarding the payment rates and our responses to those comments appear below.

Comment: Several commenters noted their support of the hospice payment update percentage.

Response: We appreciate the comments in support of the hospice payment update percentage.

Comment: One commenter suggested the CMS eliminate the hospice payment update percentage to hospice payments for FY 2017, as the commenter maintains that payment adequacy for hospice providers is generally positive. Other commenters noted that the proposed hospice payment update percentage is not sufficient to keep pace with rising costs of providing hospice care and suggested that CMS revisit the proposed hospice payment update percentage for potential increase.

Response: The payment update percentage to the hospice rates is required by statute, as previously described in detail in this section, and we do not have regulatory authority to alter the payment update.

Final Action: We are implementing the hospice payment update percentage as discussed in the proposed rule. Based on IHS Global Insight, Inc.'s updated forecast, the hospice payment update percentage for FY 2017 will be 2.1 percent for hospices that submit the required quality data and 0.1 percent for hospices that do not submit the required quality data.

3. FY 2017 Hospice Payment Rates

There are four payment categories that are distinguished by the location and intensity of the services provided. The base payments are adjusted for geographic differences in wages by multiplying the labor share, which varies by category, of each base rate by the applicable hospice wage index. A hospice is paid the RHC rate for each day the beneficiary is enrolled in hospice, unless the hospice provides continuous home care, IRC, or general inpatient care. CHC is provided during a period of patient crisis to maintain the person at home; IRC is short-term care to allow the usual caregiver to rest and be relieved from caregiving; and General Inpatient Care (GIP) is to treat symptoms that cannot be managed in another setting.

As discussed in the FY 2016 Hospice Wage Index and Payment Rate Update final rule (80 FR 47172), we implemented two different RHC payment rates, one RHC rate for the first 60 days and a second RHC rate for days 61 and beyond. In addition, in the final rule, we adopted a Service Intensity Add-on (SIA) payment, when direct patient care is provided by a RN or social worker during the last 7 days of the beneficiary's life. The SIA payment is equal to the CHC hourly rate multiplied by the hours of nursing or social work provided (up to 4 hours total) that occurred on the day of service. In order to maintain budget neutrality, as required under section 1814(i)(6)(D)(ii) of the Act, the new RHC rates were adjusted by a SIA budget neutrality factor.

As discussed in the FY 2016 Hospice Wage Index and Payment Rate Update final rule (80 FR 47177), we will continue to make the SIA payments budget neutral through an annual determination of the SIA budget neutrality factor (SBNF), which will then be applied to the RHC payment

rates. The SBNF will be calculated for each FY using the most current and complete FY utilization data available at the time of rulemaking. For FY 2017, the budget neutrality adjustment that applies to days 1 through 60 is calculated to be 1.0000. The budget neutrality adjustment that applies to days 61 and beyond is calculated to be 0.9999.

For FY 2017, we are applying a wage index standardization factor to the FY 2017 hospice payment rates in order to ensure overall budget neutrality when updating the hospice wage index with more recent hospital wage data. Wage index standardization factors are applied in other payment settings such as under home health Prospective Payment System (PPS), IRF PPS, and SNF PPS. Applying a wage index standardization factor to hospice payments will eliminate the aggregate effect of annual variations in hospital wage data. We believe that adopting a hospice wage index standardization factor will provide a safeguard to the Medicare program as well as to hospices because it will mitigate fluctuations in the wage index by ensuring that wage index updates and revisions are implemented in a budget neutral manner. To calculate the wage index standardization factor, we simulated total payments using the FY 2017 hospice wage index and compared it to our simulation of total payments using the FY 2016 hospice wage index. By dividing payments for each level of care using the FY 2017 wage index by payments for each level of care using the FY 2016 wage index, we obtain a wage index standardization factor for each level of care (RHC days 1–60, RHC days 61+, CHC, IRC, and GIP).

Lastly, the hospice payment rates for hospices that submit the required quality data will be increased by the full FY 2017 hospice payment update percentage of 2.1 percent as discussed in section III.C.3 of this final rule. The FY 2017 RHC rates are shown in Table 11. The FY 2017 payment rates for CHC, IRC, and GIP are shown in Table 12.

TABLE 11—FY 2017 HOSPICE RHC PAYMENT RATES

Code	Description	FY 2016 payment rates	SBNF	Wage index standardization factor	FY 2017 hospice payment update percentage	FY 2017 payment rates
651	Routine Home Care (days 1–60)	$186.84	× 1.0000	× 0.9989	× 1.021	$190.55
651	Routine Home Care (days 61+)	146.83	× 0.9999	× 0.9995	× 1.021	149.82

TABLE 12—FY 2017 HOSPICE CHC, IRC, AND GIP PAYMENT RATES

Code	Description	FY 2016 payment rates	Wage index standardization factor	FY 2017 hospice payment update percentage	FY 2017 payment rates
652	Continuous Home Care Full Rate = 24 hours of care. $40.19 = FY 2017 hourly rate.	$944.79	× 1.0000	× 1.021	$964.63
655	Inpatient Respite Care	167.45	× 1.0000	× 1.021	170.97
656	General Inpatient Care	720.11	× 0.9996	× 1.021	734.94

Sections 1814(i)(5)(A) through (C) of the Act require that hospices begin submitting quality data, based on measures to be specified by the Secretary. In the FY 2012 Hospice Wage Index final rule (76 FR 47320 through 47324), we implemented a Hospice Quality Reporting Program (HQRP), as required by section 3004 of the Affordable Care Act. Hospices were required to begin collecting quality data in October 2012, and submit that quality data in 2013. Section 1814(i)(5)(A)(i) of the Act requires that beginning with FY 2014 and for each subsequent FY, the Secretary shall reduce the market basket update by 2 percentage points for any hospice that does not comply with the quality data submission requirements with respect to that FY. The FY 2017 rates for hospices that do not submit the required quality data will be updated by the FY 2017 hospice payment update percentage of 2.1 percent minus 2 percentage points. These rates are shown in Tables 13 and 14.

TABLE 13—FY 2017 HOSPICE RHC PAYMENT RATES FOR HOSPICES THAT *DO NOT* SUBMIT THE REQUIRED QUALITY DATA

Code	Description	FY 2016 payment rates	SBNF	Wage index standardization factor	FY 2017 hospice payment update of 2.1% minus 2 percentage points = 0.1%	FY 2017 payment rates
651	Routine Home Care (days 1–60)	$186.84	× 1.0000	× 0.9989	× 1.001	$186.82
651	Routine Home Care (days 61+)	146.83	× 0.9999	× 0.9995	× 1.001	146.89

TABLE 14—FY 2017 HOSPICE CHC, IRC, AND GIP PAYMENT RATES FOR HOSPICES THAT *DO NOT* SUBMIT THE REQUIRED QUALITY DATA

Code	Description	FY 2016 payment rates	Wage index standardization factor	FY 2017 hospice payment update of 2.1% minus 2 percentage points = 0.1%	FY 2017 payment rates
652	Continuous Home Care Full Rate = 24 hours of care. $39.41 = FY 2017 hourly rate.	$944.79	× 1.0000	× 1.001	$945.73
655	Inpatient Respite Care	167.45	× 1.0000	× 1.001	167.62
656	General Inpatient Care	720.11	× 0.9996	× 1.001	720.54

A summary of the comments we received regarding the payment rates and our responses to those comments appear below.

Comment: A commenter asked if the application of the standardization factor is premature or is it part of the continued progression of hospice reimbursement from hybrid fee-for-service/health maintenance organization to a full case-mix or value-based purchasing (VBP) system.

Response: We believe that applying a wage index standardization factor to the hospice rates is appropriate. The application of the standardization factor will mitigate any potential effects due to the annual variations in hospital wage data. Moreover, this approach creates a level of protection for the Medicare program as well as to hospices, as it minimizes the impacts of any fluctuations in the wage index.

Comment: Several commenters requested that the SIA Payment eligibility requirements be modified to include additional hospice services, including visits from licensed practical nurses (LPNs), music therapists, and other professionals providing care during the last 7 days of life. In addition, several commenters requested that data be collected in order to determine if the SIA Payment increased the number of visits during beneficiaries' most intensive time of need for skilled care (specifically, the last 7 days of life).

Response: CMS finalized the SIA payment policy in the FY 2016 Hospice Wage Index and Payment Update final rule (80 FR 47141) and we did not solicit comments on a proposal to modify these policy parameters in the FY 2017 Hospice Wage Index and Payment Rate update proposed rule (81 FR 25498). However, we will continue to consider and monitor for potential refinements to this policy, including current monitoring efforts that were described in the FY 2017 Hospice Wage Index and Payment Rate Update proposed rule (81 FR 25498) in response to these policy changes, and we will take these comments into account as we continue to do so.

Comment: One commenter noted that there have been issues with the technical implementation of the SIA payment such that payment adjustments are not occurring as originally intended.

Response: While the technical implementations issues with regards to SIA payments have been minimal, we appreciate this comment and are working diligently with appropriate stakeholders to expedite the appropriate system remediation to ensure accurate payment to providers.

Comment: One commenter expressed concern that the RHC rate payment amount for Days 61 and beyond may lead to payment inadequacy for patients with long lengths of stay. One commenter noted that the episode gap required by the two RHC rates policy implemented for FY 2016 could have a negative impact on those hospices that accept patients via transfers. Moreover, the commenter noted that CMS should consider payment adjustments if a patient is transferred from one hospice to another, particularly at or near day 61 of a hospice episode.

Response: We appreciate the comments and the concern for appropriate payment for long stay beneficiaries as well as transfer patients. The creation of the two RHC rates (one for days 1–60 and a another for days 61 and beyond) was finalized in the FY 2016 Hospice Wage Index and Payment Rate Update final rule (80 FR 47141), and we did not propose any changes for FY 2017 nor did we solicit comments on any future changes. In response to public comments, we stated in the FY 2016 Hospice Wage Index and Payment Rate Update final rule that allowing for a higher payment for a new hospice election (or in transfer situations) without a gap in hospice care of greater than 60 days goes against our intent to mitigate the incentive to discharge and readmit patients (or transfer patients) at or around day 60 for the purposes of obtaining a higher payment (80 FR 47168). With regards to the commenter's concern regarding reimbursement for long lengths of stay, we refer the commenter to the FY 2016 Hospice Wage Index and Payment Rate Update final rule (80 FR 47142), where we discuss the rationale for the creation of a higher RHC rate for days 1–60 and a lower rate for days 61 and beyond. In that final rule, we noted that hospice stays manifest in a 'U-Shaped' pattern (that is, the intensity of services provided is higher both at admission and near death and, conversely, is relatively lower during the middle period of the hospice episode). Since hospice care is most profitable during the long, low-cost middle portions of an episode, longer episodes have very profitable, long middle segments (80 FR 47161). Therefore, in order to better align hospice payments with service intensity during a hospice episode of care, we implemented a higher RHC rate for days 1–60 and a lower rate for days 61 and beyond, effective January 1, 2016. We also implemented a service intensity add-on (SIA) payment policy that reimburses hospices for visits performed during the last 7 days of a beneficiary's life (in addition to RHC per diem payments), also effective January 1, 2016. We will continue to monitor for and consider potential refinements to these policies as appropriate.

Comment: A commenter noted that Medicaid agencies have encountered challenges in the implementation of the payment changes due to hospice reform.

Response: We appreciate this comment and are working diligently with appropriate stakeholders and State Agencies to facilitate effective implementation of hospice payment reform.

Final Action: We are implementing the updates to hospice payment rates as discussed in the proposed rule.

4. Hospice Cap Amount for FY 2017

As discussed in the FY 2016 Hospice Wage Index and Payment Rate Update final rule (80 FR 47183), we implemented changes mandated by the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act). Specifically, for accounting years that end after September 30, 2016 and before October 1, 2025, the hospice cap is updated by the hospice payment update percentage rather than using the consumer price index for urban consumers (CPI–U). As required by section 1814(i)(2)(B)(ii) of the Act, the hospice cap amount for the 2016 cap year, starting on November 1, 2015 and ending on October 31, 2016, is equal to the 2015 cap amount ($27,382.63) updated by the FY 2016 hospice payment update percentage of 1.6 percent. As such, the 2016 cap amount is $27,820.75.

In the FY 2016 Hospice Wage Index and Payment Rate Update final rule (80 FR 47142), we finalized aligning the cap accounting year with the federal FY beginning in 2017. Therefore, the 2017 cap year will start on October 1, 2016 and end on September 30, 2017. Table 26 in the FY 2016 Hospice Wage Index and Payment Rate Update final rule (80 FR 47185) outlines the timeframes for counting beneficiaries and payments during the 2017 transition year. The hospice cap amount for the 2017 cap year will be $28,404.99, which is equal to the 2016 cap amount ($27,820.75) updated by the FY 2017 hospice payment update percentage of 2.1 percent.

A summary of public comments and our responses to comments on the hospice cap are summarized below:

Comment: One commenter expressed concerns that the methodology used to calculate the hospice cap creates an incentive for rural hospices to inflate their utilization of the GIP level of care, as some rural hospices may do this to gain higher reimbursement by placing patients at the GIP level of care that may not qualify for that level of care.

Response: The hospice aggregate cap is calculated based on total reimbursement across all levels of care. In addition, the hospice inpatient cap limits total payments to the hospice for inpatient care (general or respite). Total payments are subject to a limitation that total inpatient care days for Medicare patients does not exceed 20 percent of the total days for which patients had elected hospice care. We urge providers to adhere to appropriate guidelines with respect to the hospice levels of care. We note that in a March 2016 Office of Inspector General (OIG) report, OIG found that hospices billed one-third of GIP stays inappropriately, costing Medicare $268 million in 2012. According to the report, ''hospices commonly billed for GIP when the beneficiary did not have uncontrolled pain or unmanaged symptoms.'' (*http://oig.hhs.gov/oei/reports/oei-02-10-00491.asp*) As such, we will continue to monitor the use of the various levels of care in order to identify any aberrant or problematic behavior.

Final Action: We are implementing the changes to the hospice cap amount as discussed in the proposed rule.

C. Proposed Updates to the Hospice Quality Reporting Program (HQRP)

1. Background and Statutory Authority

Section 3004(c) of the Affordable Care Act amended section 1814(i)(5) of the Act to authorize a quality reporting program for hospices. Section 1814(i)(5)(A)(i) of the Act requires that beginning with FY 2014 and each subsequent FY, the Secretary shall reduce the market basket update by 2 percentage points for any hospice that does not comply with the quality data submission requirements for that FY. Depending on the amount of the annual update for a particular year, a reduction of 2 percentage points could result in the annual market basket update being less than 0 percent for a FY and may result in payment rates that are less than payment rates for the preceding FY. Any reduction based on failure to comply with the reporting requirements, as required by section 1814(i)(5)(B) of the Act, would apply only for the particular FY involved. Any such reduction would not be cumulative or be taken into account in computing the payment amount for subsequent FYs. Section 1814(i)(5)(C) of the Act requires that each hospice submit data to the Secretary on quality measures specified by the Secretary. The data must be submitted in a form, manner, and at a time specified by the Secretary.

2. General Considerations Used for Selection of Quality Measures for the HQRP

Any measures selected by the Secretary must be endorsed by the consensus-based entity, which holds a contract regarding performance measurement, including the endorsement of quality measures, with the Secretary under section 1890(a) of the Act. This contract is currently held by the National Quality Forum (NQF). However, section 1814(i)(5)(D)(ii) of the Act provides that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the consensus-based entity, the Secretary may specify measures that are not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus-based organization identified by the Secretary. Our paramount concern is the successful development of an HQRP that promotes the delivery of high quality healthcare services. We seek to adopt measures for the HQRP that promote person-centered, high quality, and safe care. Our measure selection activities for the HQRP take into consideration input from the Measure Applications Partnership (MAP), convened by the NQF, as part of the established CMS pre-rulemaking process required under section 1890A of the Act. The MAP is a public-private partnership comprised of multi-stakeholder groups convened by the NQF for the primary purpose of providing input to CMS on the selection of certain categories of quality and efficiency measures, as required by section 1890A(a)(3) of the Act. By February 1st of each year, the NQF must provide that input to CMS. Input from the MAP is located at *http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx.* We also take into account national priorities, such as those established by the National Priorities Partnership at (*http://www.qualityforum.org/npp/*), the HHS Strategic Plan (*http://www.hhs.gov/secretary/about/priorities/priorities.html*), the National Strategy for Quality Improvement in Healthcare, (*http://www.ahrq.gov/workingforquality/nqs/nqs2013annlrpt.htm*) and the CMS Quality Strategy (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html*). To the extent practicable, we have sought to adopt measures endorsed by member organizations of the National Consensus Project (NCP), recommended by multi-stakeholder organizations, and developed with the input of providers, purchasers and/or payers, and other stakeholders.

3. Policy for Retention of HQRP Measures Adopted for Previous Payment Determinations

For the purpose of streamlining the rulemaking process, we finalized our policy in the FY 2016 Hospice Wage Index final rule (80 FR 47187) that when we adopt measures for the HQRP beginning with a payment

determination year, these measures would automatically be adopted for all subsequent years' payment determinations, unless we proposed to remove, suspend, or replace the measures. Quality measures would be considered for removal by CMS for reasons including, but not limited to:

- Measure performance among hospices was so high and unvarying that meaningful distinction in improvements in performance could no longer be made;
- Performance or improvement on a measure did not result in better patient outcomes;
- A measure did not align with current clinical guidelines or practice;
- A more broadly applicable measure (across settings, populations, or conditions) for the particular topic was available;
- A measure that was more proximal in time to desired patient outcomes for the particular topic was available;
- A measure that was more strongly associated with desired patient outcomes for the particular topic was available; or
- Collection or public reporting of a measure led to negative unintended consequences.

For any such removal, the public would be given an opportunity to comment through the annual rulemaking process. However, if there were reason to believe continued collection of a measure raised potential safety concerns, we would take immediate action to remove the measure from the HQRP and not wait for the annual rulemaking cycle. The measures would be promptly removed, and we would immediately notify hospices and the public of such a decision through the usual CMS HQRP communication channels, including postings and announcements on the CMS HQRP Web site, Medicare Learning Network (MLN) eNews communications, national provider association calls, and announcements on Open Door Forums and Special Open Door Forums. In such instances, the removal of a measure would be formally announced in the next annual rulemaking cycle.

To further streamline the rulemaking process, we proposed to codify that if measures we are using in the HQRP have non-substantive changes in their specifications change as part of their NQF endorsement process, we would continue to utilize the measure with their new endorsed status in the HQRP. As mentioned previously, quality measures selected for the HQRP must be endorsed by the NQF unless they meet the statutory criteria for exception under section 1814(i)(5)(D)(ii) of the Act. The NQF is a voluntary consensus standard-setting organization with a diverse representation of consumer, purchaser, provider, academic, clinical, and other healthcare stakeholder organizations. The NQF was established to standardize healthcare quality measurement and reporting through its consensus measure development process (*http://www.qualityforum.org/About_NQF/Mission_and_Vision.aspx*). The NQF undertakes review of: (a) New quality measures and national consensus standards for measuring and publicly reporting on performance, (b) regular maintenance processes for endorsed quality measures, (c) measures with time-limited endorsement for consideration of full endorsement, and (d) ad hoc review of endorsed quality measures, practices, consensus standards, or events with adequate justification to substantiate the review. Through NQF's measure maintenance process, NQF-endorsed measures are sometimes updated to incorporate changes that we believe do not substantially change the nature of the measure. Examples of such changes could be updated diagnosis or procedure codes, changes to exclusions to a particular patient/consumer population, or definitions. We believe these types of maintenance changes are distinct from more substantive changes to measures. Additionally, since the NQF endorsement and measure maintenance process is one that ensures transparency, public input, and discussion among representatives across the healthcare enterprise,[5] we believe that the NQF measure endorsement and maintenance process itself is transparent, scientifically rigorous, and provides opportunity for public input. Thus, we proposed to codify at § 418.312 that if the NQF makes only non-substantive changes to specifications for HQRP measures in the NQF's re-endorsement process, we would continue to utilize the measure in its new endorsed status. If NQF-endorsed specifications change and we do not adopt those changes, then we would propose the measure as an application. An application of a NQF-endorsed quality measure is utilized in instances when CMS has identified a need to use a NQF-endorsed measure in a QRP but need to use it with one or more modifications to the quality measure's specifications. These modifications pertain to, but are not limited to, one or more of the following aspects of a NQF-endorsed quality measure: (a) Numerator, (b) denominator, (c) setting, (d) look-back period, (e) calculation period, (f) risk adjustment, and (g) revisions to data elements used to collect the data required for the measure, etc. CMS may adopt a quality measure for the HQRP under section 1814(i)(5)(D)(ii) of the Act, which states, ''In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by [the NQF], the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.'' Reasons for not adopting changes in measure specifications to a measure may include any of the aforementioned criteria in this section, including that the new specification does not align with clinical guidelines or practice or that the new specification leads to negative unintended consequences. Finally, we will continue to use rulemaking to adopt substantive updates made by the NQF to the endorsed measures we have adopted for the HQRP. We continue to make these determinations about what constitutes a substantive versus non-substantive change on a measure-by-measure basis. A change would be deemed substantive if the intent of the measure changes, the facility/setting changes, the data sources changes, the level of analysis changes, and/or the measure is removed. We will continue to provide updates about changes to measure specifications as a result of NQF endorsement or maintenance processes through the normal CMS HQRP communication channels, including postings and announcements on the CMS HQRP Web site, MLN eNews communications, national provider association calls, and announcements on Open Door Forums and Special Open Door Forums.

Comment: CMS received two comments on our proposal to codify that if measures used in the HQRP undergo non-substantive changes as part of their NQF re-endorsement process, we would utilize the measure with their new endorsed status without going through a new notice-and-comment rulemaking process. One commenter supported the proposal to codify this policy. Another commenter was concerned that CMS's plan to adopt non-substantive change(s) approved through the NQF re-endorsement process without a notice-and-comment rulemaking process does not allow providers and vendors the

[5] ''NQF: How Endorsement Happens—National Quality Forum.'' 2010. 26 Jan. 2016 *http://www.qualityforum.org/Measuring_Performance/ABCs/How_Endorsement_Happens.aspx.*

opportunity to provide input on changes to measure specifications. Additionally, the commenter also had concerns that adopting non-substantive changes to measures outside of the rulemaking process would limit the ability for hospices and vendors to make necessary changes to data collection systems to implement non-substantive updates to measures.

Response: We thank commenters for their support of this proposal, and for their concerns raised. We agree that the opportunity for the public to provide input on all changes to measure specifications (both substantive and non-substantive) is vital to the measure development, endorsement, and maintenance process. We also agree with the commenter that vendors and the hospice community need ample time to implement changes to measure specifications, especially those that would warrant updates to Hospice Item Set (HIS) items or technical specifications. We would like to reassure commenters that, as stated in this rule, we will still propose substantive changes to measure through rulemaking. With regard to non-substantive measure changes that could occur as a result of the measure maintenance and re-endorsement process, we would like to clarify that the NQF processes for endorsement and maintenance of measures includes review by an expert Standing Committee, public and Member comment periods, Member voting, consideration by the Consensus Standards Approval Committee (CSAC), endorsement by the Board of Directors, and a 30-day appeals period. The NQF endorsement and maintenance (re-endorsement) process allows ample opportunity for NQF member and public input, during the measure development, endorsement and maintenance phases. We encourage hospices to participate in these NQF comment periods to offer their insights about potential impacts of changes to measures and measure specifications. We believe that in instances of non-substantive changes to measure specifications, maximizing the use of NQF opportunities for public input allows us to efficiently and expediently adopt non-substantive, but important changes to measures. Regarding the commenter's concern about whether this policy will allow providers ample time to implement and adopt non-substantive changes, we would like to point out that when non-substantive changes put forth by the NQF are adopted, we are not required to immediately implement those changes on the date of re-endorsement by NQF. Once a non-substantive change is endorsed by NQF, we will consider the time necessary for providers and vendors to implement the change. If newly endorsed non-substantive changes require updates to data collection mechanisms (for example, updates to HIS specifications) or associated training materials, we will allow ample time for providers and vendors to prepare and implement such changes. As noted in the rule, we will communicate the endorsement of non-substantive changes, decisions about whether to adopt non-substantive changes, and timeline for implementation of non-substantive changes through regular HQRP communication channels. Additionally, CMS welcomes comment on any non-substantive changes adopted under this mechanism through the appropriate sub-regulatory communication channels, including but not limited to: NQF public comment periods held as part of endorsement processes, feedback from providers on the Hospice Quality HelpDesk, and feedback from the provider community on ODFs and SODFs. CMS will make such comments and their responses available to the public under the appropriate sub-regulatory communication channels. Finally, we would like to note that this policy is consistent with similar policies in other QRPs.

Comment: We received a few comments on our previously finalized policy for measure retention. These commenters encouraged CMS's continued consideration of whether previously adopted quality measures are appropriate for retention in the HQRP. Commenters encouraged CMS to eliminate measures that are no longer considered to effectively measure quality.

Response: We thank commenters for their suggestions surrounding measure retention and removal. We agree that any quality measures proposed and retained in the HQRP should continue to provide meaningful data to providers and consumers on quality of care. We regularly conduct measure testing activities according to NQF guidelines and the Blueprint for the CMS Measures Management System Version 12.0 (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint-120.pdf*) to ensure that measures continue to demonstrate scientific acceptability (including reliability and validity) and meet the goals of the HQRP, which include distinguishing performance among hospices and contributing to better patient outcomes. As outlined in this section of the rule, we will propose a measure for removal if meaningful distinctions in quality of care can no longer be made from the measure due to high and unvarying performance.

Final Action: After consideration of the comments, we are codifying our policy that once a quality measure is adopted, it be retained for use in the subsequent fiscal year payment determinations until otherwise stated, as proposed.

4. Previously Adopted Quality Measures for FY 2017 and FY 2018 Payment Determination

As stated in the CY 2013 HH PPS final rule (77 FR 67068 through 67133), CMS expanded the set of required measures to include additional measures endorsed by NQF. We also stated that to support the standardized collection and calculation of quality measures by CMS, collection of the needed data elements would require a standardized data collection instrument. In response, CMS developed, tested, and implemented a hospice patient-level item set, the HIS. Hospices are required to submit a HIS-Admission record and a HIS-Discharge record for each patient admission to hospice since July 1, 2014. In developing the standardized HIS, we considered comments offered in response to the CY 2013 HH PPS proposed rule (77 FR 41548 through 41573). In the FY 2014 Hospice Wage Index final rule (78 FR 48257), and in compliance with section 1814(i)(5)(C) of the Act, we finalized the specific collection of data items that support the following 6 NQF-endorsed measures and 1 modified measure for hospice:

- NQF #1617 Patients Treated with an Opioid who are Given a Bowel Regimen,
- NQF #1634 Pain Screening,
- NQF #1637 Pain Assessment,
- NQF #1638 Dyspnea Treatment,
- NQF #1639 Dyspnea Screening,
- NQF #1641 Treatment Preferences,
- NQF #1647 Beliefs/Values Addressed (if desired by the patient) (modified).

To achieve a comprehensive set of hospice quality measures available for widespread use for quality improvement and informed decision making, and to carry out our commitment to develop a quality reporting program for hospices that uses standardized methods to collect data needed to calculate quality measures, we finalized the HIS effective July 1, 2014 (78 FR 48258). To meet the quality reporting requirements for hospices for the FY 2016 payment determination and each subsequent year, we require regular and ongoing

electronic submission of the HIS data for each patient admission to hospice after July 1, 2014, regardless of payer or patient age (78 FR 48234 through 48258). We finalized a requirement in the FY 2014 Hospice Wage Index final rule (78 FR 48258) that hospice providers collect data on all patients to ensure that all patients regardless of payer or patient age are receiving the same care and that provider metrics measure performance across the spectrum of patients.

Hospices are required to complete and submit a HIS-Admission and a HIS-Discharge record for each patient admission. Hospices failing to report quality data via the HIS for patient admissions occurring in 2016 will have their market basket update reduced by 2 percentage points in FY 2018 (beginning in October 1, 2017). In the FY 2015 Hospice Wage Index final rule (79 FR 50485 through 50487), we finalized the proposal to codify the HIS submission requirement at § 418.312. The System of Record (SOR) Notice titled ''Hospice Item Set (HIS) System,'' SOR number 09–70–0548, was published in the **Federal Register** on April 8, 2014 (79 FR 19341).

TABLE 15—PREVIOUSLY FINALIZED QUALITY MEASURES AFFECTING THE FY 2017 PAYMENT DETERMINATION AND SUBSEQUENT YEAR

Quality measure	NQF ID#	Type	Submission method	Data submission deadlines
Treatment Preferences	1641	Process Measure	Hospice Item Set	Within 30 days of patient admission or discharge (Event Date).
Beliefs/Values Addressed	1647			
Pain Screening	1634			
Pain Assessment	1637			
Dyspnea Screening	1639			
Dyspnea Treatment	1638			
Patients Treated with an Opioid who are Given a Bowel Regimen.	1617			

Comment: CMS received a comment regarding the retirement of the seven day length of stay (LOS) exclusion for six of the care process measures currently implemented in the HQRP. This commenter expressed concern that in eliminating the LOS exclusion, provider behavior may shift towards focusing on completing the HIS requirements and compliance at the expense of addressing the needs and preferences of imminently dying patients. Additionally, this commenter recommended that CMS reconsider eliminating the LOS exclusion or risk adjust for hospices with an excessive number of short-stay patients for patients.

Response: We appreciate the commenters' input on the retirement of the LOS exclusion specification for six of the quality measures currently implemented in the HQRP. Developing and adopting measures that are meaningful and do not lead to negative unintended consequences for patients or providers is important to us. At the time the measures were developed, technical experts recommended that short patient stays be excluded from those measures' denominators for assessing quality of care in hospices. However, no national data regarding the implications of the LOS exclusion was available to the Technical Expert Panel (TEP) at that time. CMS's contractor analyzed data from the HIS to examine the implications of the LOS exclusion on hospices' denominator size and quality measure (QM) scores. Additionally, this analysis examined the timing of when hospices perform the care processes assessed in the quality measures. These analyses were conducted using HIS-Admission and HIS-Discharge records for stays in July 1, 2014 through March 31, 2015. The results of these analyses demonstrated that the denominator sizes for the HQRP QMs are largely impacted by the current 7-day LOS exclusion used to calculate the QMs. Excluding stays with LOS less than 7 days prevents some hospices from being included in QM score calculations because they do not have any qualifying patient stays. Therefore, removing the LOS exclusion criteria will increase the number of patients included in the measures, and thus the number of hospices that are included in the QM calculation. The impact of the LOS exclusions on the distribution of hospices' scores is generally small for all of the QMs. In addition, these analyses revealed that the care processes targeted by the QMs are performed on the day of, or within one day of, admission for the vast majority of patient stays. For example, among patient admissions for which a pain screening was administered, approximately 92 percent of screenings occurred on the day of admission and close to 99 percent occurred within 1 day of admission. This suggested that including stays of less than 7 days in QM calculations (that is, removing the QM LOS exclusion) could be appropriate and would not create a burden on hospices. In response to these results, the individual QMs were submitted by the measures' stewards to the NQF Palliative Care and End of Life Project for re-endorsement in February 2016 and received preliminary approval. In sum, 6 of the 7 current HIS measures that were adopted in the FY 2014 Hospice Wage Index final rule excluded beneficiaries with a LOS of <7 days from the denominator. However, since these measures were adopted in the HQRP, they have undergone their endorsement maintenance with the NQF. As part of the maintenance endorsement, the LOS exclusion for the 6 HIS measures was proposed for removal. NQF has indicated initial support for the removal of the LOS exclusion, and pending NQF maintenance endorsement of the previously adopted measures, we anticipate that the entire set of the 7 HIS measures will no longer exclude any patients with LOS <7 days in future public reporting and use in the HQRP. We appreciate the commenters' recommendation to risk adjust these measures and will consider this recommendation for future measure development efforts.

Comment: CMS received one comment requesting additional items or response options on the HIS V1.00.0 to capture instances where data regarding preferences or other care processes captured on the HIS are not available for non-verbal patients admitted to hospice who do not have a formal caregiver or responsible party available.

Response: We thank the commenter for their comment. For additional information on how to respond to current HIS items when the patient is nonverbal and/or a caregiver is unavailable, we refer readers to the HIS Manual V1.02 available on the Hospice

Item Set portion of the CMS HQRP Web site: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Hospice-Item-Set-HIS.html.* Specifically, we refer readers to the HIS Manual Section F Item-Specific Tips, which specifies roles of responsible parties for patients unable to self-report. The HIS Manual states that the ''Responsible party'' refers to the legally responsible or authorized individual, such as the Health Care Power of Attorney or legal guardian. In the rare cases where there is no legal guardian or power of attorney identified, the hospice should use state law guidance to identify the appropriate surrogate decision-maker. Other items that require patient or caregiver input, such as the pain assessment items, can be completed for nonverbal patients using the nonverbal assessment processes described in the HIS Manual.

5. Proposed Removal of Previously Adopted Measures

As mentioned in section III.C.3, a measure that is adopted and implemented in the HQRP will be adopted for all subsequent years, unless the measure is proposed for removal, suspension, or replacement by CMS. Policies and criteria for removing a measure include those mentioned in section III.C.3 of this proposed rule. CMS is not proposing to remove any of the current HQRP measures at this time. Any future proposals regarding removal, suspension, or replacement of measures will be proposed in this section of future rules.

6. Proposed New Quality Measures for FY 2019 Payment Determinations and Subsequent Years and Concepts Under Consideration for Future Years

a. Background and Considerations in Developing New Quality Measures for the HQRP

As noted in section III.C.2 of this proposed rule, CMS's paramount concern is to develop quality measures that promote care that is person-centered, high quality, and safe. In identifying priority areas for future measure enhancement and development, CMS takes into consideration input from numerous stakeholders, including the MAP, the MedPAC, Technical Expert Panels (TEP), and national priorities, such as those established by the National Priorities Partnership, the HHS Strategic Plan, the National Strategy for Quality Improvement in Healthcare, and the CMS Quality Strategy. In addition, CMS takes into consideration vital feedback and input from research published by our payment reform contractor, as well as important observations and recommendations contained in the Institute of Medicine (IOM) report, titled ''Dying in America,'' released in September 2014.[6] Finally, the current HQRP measure set is also an important consideration for future measure development areas; future measure development areas should complement the current HQRP measure set, which includes HIS measures and Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Hospice Survey measures.

As stated in the FY 2016 Hospice Wage Index final rule (80 FR 47188), based on input from stakeholders, CMS identified several high priority areas for future measure development, including: A patient reported pain outcome measure; claims-based measures focused on care practices patterns, including skilled visits in the last days of life; responsiveness of the hospice to patient and family care needs; and hospice team communication and care coordination. Of the aforementioned measure areas, CMS has pursued measure development for two quality measures: Hospice Visits when Death is Imminent Measure Pair, and Hospice and Palliative Care Composite Process Measure-Comprehensive Assessment at Admission. These measures were included in CMS' List of Measures under Consideration (MUC) list for 2015 and discussed at the MAP meeting on December 14 and 15, 2015. All materials related to the MUC list and the MAP's recommendations for each measure can be found on the National Quality Forum Web site, MAP Post-Acute Care/Long-Term Care Workgroup Web page at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75370.* The MAP supported the direction of each proposed measure.

Comment: Many comments were received about the HQRP quality measures and concepts under consideration for future years. Overall, commenters were supportive of CMS's efforts to develop a more robust quality reporting program that includes development of two new quality measures, the Hospice Visits when Death is Imminent Measure Pair, and Hospice and Palliative Care Composite Process Measure-Comprehensive Assessment at Admission. In addition to the two measures we proposed, regarding measure development in future years, commenters urged CMS to focus on meaningful quality measures and encouraged CMS to move towards the development of outcome measures. Several commenters noted the complexities associated with developing outcomes measures. These commenters also recommended that CMS conduct regular measure testing activities to ensure that all measures currently implemented in the HQRP are relevant and meaningful to providers and consumers. Finally, some commenters recommended the development of future measures of hospice live discharge rates. Commenters believe that such measures could contribute to quality information and hospice performance.

Response: We appreciate the commenters' input and recommendations for future measure development areas for the HQRP. We plan to continue developing the HQRP to respond to the measure gaps identified by the MAP and others, and align measure development with the National Quality Strategy and the CMS Quality Strategy. We will take these comments into consideration in developing and implementing measures for future inclusion in the HQRP. We would like to assure commenters that we are pursuing opportunities related to the development of live-discharge measures through environmental scans, public engagement, and participation in special topic panels. We would also like to assure commenters that for all measures implemented in the HQRP, we regularly conduct measure testing activities according to the Blueprint for the CMS Measures Management System Version 12.0 (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint-120.pdf*). This ensures that measures continue to demonstrate scientific acceptability (including reliability and validity) and meet the goals of the HQRP, which include distinguishing performance among hospices and contributing to better patient outcomes. If measure testing activities reveal that a measure meets one of the conditions for removal that is listed in the proposed rule (measure performance among hospices high and unvarying, performance or improvement in a measure does not result in better patient outcomes, etc.), the measure will be considered for removal from the HQRP to avoid unintended consequences and to ensure that providers' data collection efforts are meaningful and are contributing to quality of care. Finally, we would like to assure commenters that we continue to explore opportunities to pursue

[6] IOM (Institute of Medicine). 2014. Dying in America: Improving quality and honoring individual preferences near the end of life. Washington, DC: The National Academies Press.

hospice outcome measures, and we appreciate the commenters' support for such development efforts.

b. New Quality Measures for the FY 2019 Payment Determination and Subsequent Years

We proposed two new quality measures for the HRQP for the FY 2019 payment determination and subsequent years: Hospice Visits when Death is Imminent Measure Pair, and Hospice and Palliative Care Composite Process Measure-Comprehensive Assessment at Admission.

(1) Proposed Quality Measure 1: Hospice Visits When Death Is Imminent Measure Pair

Measure Background. This measure set addresses whether a hospice patient and their caregivers' needs were addressed by the hospice staff during the last days of life. This measure is specified as a set of 2 measures. Measure 1 assesses the percentage of patients receiving at least 1 visit from registered nurses, physicians, nurse practitioners, or physician assistants in the last 3 days of life. Measure 2 assesses the percentage of patients receiving at least 2 visits from medical social workers, chaplains or spiritual counselors, licensed practical nurses, or hospice aides in the last 7 days of life. Measure 1 addresses case management and clinical care, while Measure 2 gives providers the flexibility to provide individualized care that is in line with the patient, family, and caregiver's preferences and goals for care and contributing to the overall well-being of the individual and others important in their life.

Measure Importance. The last week of life is typically the period in the terminal illness trajectory with the highest symptom burden. Particularly during the last few days before death, patients experience myriad physical and emotional symptoms, necessitating close care and attention from the integrated hospice team. Hospice responsiveness during times of patient and caregiver need is an important aspect of care for hospice consumers. In addition, clinician visits to patients at the end of life have been demonstrated to be associated with improved outcomes such as decreased risk of hospitalization, emergency room visits, hospital deaths, decreased distress for caregivers, and higher satisfaction with care.

Several organizations and panels have identified care of the imminently dying patient as an important domain of palliative and hospice care and established guidelines and recommendations related to this high priority aspect of healthcare that affects a large number of people. The NQF 2006 report *A Framework for Preferred Practices for Palliative Care Quality*[7] and the NCP Clinical Practice Guidelines for Quality Palliative Care[8] recommend that signs and symptoms of impending death are recognized, communicated and educated, and care appropriate for the phase of illness is provided. The American College of Physicians Clinical Practice Guidelines[9] recommend that clinicians regularly assess pain, dyspnea, and depression for patients with serious illness at the end of life. These measures address this high priority area by assessing hospice staff visits to patients and caregivers during the final days of life when patients and caregivers typically experience higher symptom and caregiving burdens, and therefore a higher need for care.

Measure Impact. The literature shows that health care providers' practice is responsive to quality measuring and reporting.[10] CMS feels this research, while not specific to hospices, reasonably predicts the effect of measures on hospice provider behavior. Collecting information about hospice staff visits for measuring quality of care, in addition to the requirement of reporting visits from some disciplines on hospice claims, will encourage hospices to visit patients and caregivers and provide services that will address their care needs and improve quality of life during the patients' last days of life.

Performance Gap. The 2014 Abt Medicare Hospice Payment Reform Report indicated that 28.9 percent of Routine Home Care hospice patients did not receive a skilled visit on the last day of life.[11] The Report defines a 'skilled visit' as a visit from a nurse, social worker, or therapist. This percentage could be, in part, a result of rapid decline and unexpected death. The report revealed variation in receipt of visits at the end of life related to multiple factors. Patients who died on a weekday rather than a weekend, patients with a very short length of stay (5 days or less), and patients aged 84 and younger were more likely to receive a skilled visit in the last 2 days of life. Smaller hospices and hospices in operation for 5 years or less were slightly less likely to provide a visit at the end of life. States with the lowest rates of no visits in the last days of life were some of the more rural states (ND, WI, TN, KS, VT), whereas states with the highest rates of no visits were more urban (NJ, MA, OR, WA, MN).

Existing Measures. This quality measure set will fill a gap by addressing hospice care provided at the end of life. No current HQRP measures address care beyond the hospice initial and comprehensive assessment period, nor do any current HQRP measures relate to the assessment of hospice staff visits to patients and caregivers in the last week of life.

Stakeholder Support. A TEP convened by our measure development contractor, RTI International, on May 7 and 8, 2015, provided input on the measure concept. The TEP agreed that hospice visits when death is imminent is an important concept to measure and supported data collection using the HIS. A second TEP was convened October 19 and 21, 2015, to provide input on the technical specifications of this quality measure pair. The TEP supported development of a measure set rather than a single measure, using different timeframes to measure the different types of care provided, and limiting the measures to patients receiving routine home care. The NQF MAP met on December 14 and 15, 2015, and provided input to CMS. The MAP encouraged continued development of the Hospice Visits when Death is Imminent Measure Pair in the HQRP. More information about the MAP's recommendations for this measure is available at *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75370.* While this measure is not currently NQF endorsed, we recognize that the NQF endorsement process is an important part of measure development and plan to submit this measure pair for NQF endorsement.

Form, Manner, and Timing of Data Collection and Submission. Data for this measure would be collected via the existing data collection mechanism, the HIS. CMS has proposed that 4 new items be added to the HIS-Discharge record to collect the necessary data elements for this measure. CMS expects that data collection for this quality

[7] National Quality Forum. *A National Framework and Preferred Practices for Palliative and Hospice Care Quality.* 2006; Available from: *http://www.qualityforum.org/publications/2006/12/A_National_Framework_and_Preferred_Practices_for_Palliative_and_Hospice_Care_Quality.aspx.*

[8] National Consensus Project, *Clinical Practice Guidelines for Quality Palliative Care. 3rd edition.* 2013, National Consensus Project: Pittsburgh, PA.

[9] Qaseem, A., et al., *Evidence-Based Interventions to Improve the Palliative Care of Pain, Dyspnea, and Depression at the End of Life: A Clinical Practice Guideline from the American College of Physicians.* Annals of Internal Medicine, 2008. 148(2): p. 141–146.

[10] Werner, R., E. Stuart, and D. Polsky, *Public reporting drove quality gains at nursing homes.* Health Affairs, 2010. 29(9): p. 1706–1713.

[11] Plotzke, M., et al., *Medicare Hospice Payment Reform: Analyses to Support Payment Reform.* May 2014, Abt Associates Inc. Prepared for Centers for Medicare and Medicaid Services: Cambridge, MA.

measure via the 4 new HIS items would begin no earlier than April 1, 2017. Thus, under current CMS timelines, hospice providers would begin data collection for this measure for patient admissions and discharges occurring after April 1, 2017. Prior to the release of the new HIS data items, CMS will provide education and training to hospice providers to ensure all providers have adequate information and guidance to collect and submit data on this measure to CMS.

Since the data collection mechanism is the HIS, providers would collect and submit data using the same processes that are outlined in sections III.C.7c through III.C.7e of this rule. In brief, processes in section III.C.7c through III.C.7e specify that data for the measure would be submitted to the Quality Improvement and Evaluation System (QIES) Assessment Submission and Processing (ASAP) system, in compliance with the timeliness criterion and threshold set out in sections III.C.7c through III.C.7e.

For more information on the specifications and data elements for the measure set, Hospice Visits when Death is Imminent, we refer readers to the HQRP Specifications for the Hospice Item Set-based Quality Measures document, available on the ''Current Measures'' portion of the CMS HQRP Web site: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Current-Measures.html.* In addition, to facilitate the reporting of HIS data as it relates to the implementation of the new measure, we submitted a request for approval to OMB for the Hospice Item Set version 2.00.0 under the Paperwork Reduction Act (PRA) process. The new HIS data items that would collect this measure data are also available for public viewing in the PRA package available at: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

We received multiple comments pertaining to the Hospice Visits when Death is Imminent Measure Pair. The following is a summary of the comments we received on this topic and our responses:

Comment: We received many comments in support of our proposal to implement the Hospice Visits when Death is Imminent Measure Pair. Commenters emphasized the importance of visits at the end of life, and stated that this measure pair would provide a valuable measure of quality. Commenters also stated that they expect this measure will improve quality of life during patients' final days and that this measure could be useful to patients, families, and the Medicare program. One commenter said that hospice nurses are often aware when death is imminent because they are skilled at recognizing the final stages of a terminal condition, and that most individuals and families are aided and reassured by visits from some disciplines at the end of life.

Response: We thank the commenters for their support of the Hospice Visits when Death is Imminent Measure Pair in the HQRP. We agree that visits at the end of life are an important component of hospice care and that this measure can help to drive holistic, patient centered quality improvement. We believe that this information will be useful to consumers, providers, and payers.

Comment: Some commenters questioned whether the Hospice Visits when Death is Imminent Measure Pair would foster better quality for hospice care patients and requested evidence-based research showing the link between hospice visits and quality. One commenter emphasized the important role that hospices play in helping prepare patients and caregivers for the end of life, and stated that if hospices provide high quality preparation, then patients and families may need fewer visits at the end of life. The commenter stated that a focus on visits at the end of life may take focus away from empowering patients and caregivers. One commenter stated that, as a process measure, this measure pair does not adequately reflect high quality care, and urged CMS to conduct further testing of the measure. One commenter cautioned that, while sociodemographic differences in receipt of visits may appear to indicate differences in quality, one must also take into consideration possible differences in religious beliefs and cultural values that may affect desire for visits. One commenter noted that these measures alone might not be representative of the quality of care that hospice beneficiaries and their families receive.

Response: We thank the commenters for their feedback. We are committed to the ensuring that all quality measures implemented in the HQRP meet the goals of the program, which include distinguishing performance among hospices and contributing to better patient outcomes.

We believe that provision of hospice visits at the end of life is an important component of high quality hospice care for most patients. The last week of life is typically the period in the terminal illness trajectory with the highest symptom burden and the literature supports hospice visits when death is imminent as a high priority in end-of-life care. Clinician visits to patients at the end of life have been demonstrated to be associated with improved outcomes such as decreased risk of hospitalization, emergency room visits, and hospital death; and higher satisfaction with care.[12] [13] [14] Measurements of visits at the end of life are already used in the literature as quality indicators for end of life or hospice care.[15] [16] [17] Studies focusing on the expectations of patients and families also demonstrate the importance of care and attention from the hospice team in the days leading up to death. Caregivers of dying patients agree overwhelmingly with the importance of preparation at the end of life. Hospice assistance, ranging from legal to logistical to emotional, is paramount in preparing hospice patients and their families for imminent death.[18] Bereaved family members and friends from a variety of settings identified the provision of physical comfort and emotional support to dying patients and their families as fundamental aspects of high-quality care.[19]

The literature shows that health care providers' practices are responsive to

[12] Seow, H., Barbera, L., Howell, D., & Dy, S. M. (2010). Using more end-of-life homecare services is associated with using fewer acute care services: a population-based cohort study. *Med Care, 48*(2), 118–124. doi:10.1097/MLR.0b013e3181c162ef.

[13] Almaawiy, U., Pond, G. R., Sussman, J., Brazil, K., & Seow, H. (2014). Are family physician visits and continuity of care associated with acute care use at end-of-life? A population-based cohort study of homecare cancer patients. *Palliat Med, 28*(2), 176–183. doi:10.1177/0269216313493125.

[14] Pivodic, L., Harding, R., Calanzani, N., McCrone, P., Hall, S., Deliens, L. & Gomes, B. (2015). Home care by general practitioners for cancer patients in the last 3 months of life: An epidemiological study of quality and associated factors. *Palliat Med.* doi:10.1177/0269216315589213.

[15] Barbera, L., Seow, H., Sutradhar, R., Chu, A., Burge, F., Fassbender, K., . . . Potapov, A. (2015). Quality Indicators of End-of-Life Care in Patients With Cancer: What Rate Is Right? *J Oncol Pract, 11*(3), e279–287. doi:10.1200/jop.2015.004416.

[16] Gandhi, S. O. (2012). Differences between non-profit and for-profit hospices: patient selection and quality. *Int J Health Care Finance Econ, 12*(2), 107–127. doi:10.1007/s10754–012–9109-y.

[17] Lorenz, K. A., Ettner, S. L., Rosenfeld, K. E., Carlisle, D. M., Leake, B., & Asch, S. M. (2002). Cash and compassion: profit status and the delivery of hospice services. *J Palliat Med, 5*(4), 507–514. doi:10.1089/109662102760269742.

[18] Steinhauser, K. E., Christakis, N. A., Clipp, E. C., McNeilly, M., McIntyre, L., & Tulsky, J. A. (2000). Factors considered important at the end of life by patients, family, physicians, and other care providers. *Jama, 284*(19), 2476–2482.

[19] Steinhauser, K. E., Christakis, N. A., Clipp, E. C., McNeilly, M., McIntyre, L., & Tulsky, J. A. (2000). Factors considered important at the end of life by patients, family, physicians, and other care providers. *Jama, 284*(19), 2476–2482.

quality measurement and reporting.[20] We believe that this research, while not specific to hospices, reasonably predicts the effect of measures on hospice provider behavior. Collecting information about hospice staff visits for measuring quality of care, in addition to the requirement of reporting visits from some disciplines on hospice claims, will encourage hospices to visit patients and caregivers and provide services that will address their care needs and improve quality of life during the patients' last days of life. While we agree that a greater number of visits does not always indicate higher quality care, based on the published literature and expert input, we believe that most patients benefit from some visits near the end of life. For this reason, this measure set is specified to measure receipt of at least 1 clinician visit (Measure 1) and at least 2 visits from other staff (Measure 2), rather than measuring the total number of visits. A TEP held in October 19 and 21, 2015, by our contractor agreed that a measure of patients receiving at least a minimum number of visits would be a better indicator of quality than a measure of the total number of visits provided.

We agree with the commenter that this measure pair alone may not provide a full representation of the quality of care that hospices provide. The previously finalized measures in the HQRP address care processes at admission, and the Hospice CAHPS survey examines caregiver experience retrospectively. This measure pair fills an important gap in the HQRP by providing a measure of quality of care provided near the time of death, and it is intended to be interpreted along with the other measures in the HQRP to reflect quality of care provided by hospices across several domains of care that are important to patients and other stakeholders. CMS also plans to analyze the relationship between this quality measure pair and other quality measures to support the validity of this measure pair (that is, the measure reflects true quality of care).

Comment: One commenter expressed concern that the results of the Hospice Visits when Death is Imminent Measure Pair may be mischaracterized once they are publicly reported, if appropriate disclaimers are absent from the information provided. Another commenter requested that CMS remind measure users that patients/families have the right to decline services and that those declinations should not be considered an ''under-service'' by the hospice provider.

Response: We thank the commenters for their feedback regarding interpreting these measures. We agree that it is important to educate both providers and consumers on how to use and interpret these quality measures. Prior to public reporting of this measure, we will provide resources through the Hospice Compare Web site to aid consumers in interpreting the quality metrics reported there. CMS has carefully considered usability by consumers throughout the measure development process. The measure specifications take into account usability feedback from a TEP, caregiver workgroup, and clinical user panel. We recognize that some patients may decline services and that rapid and unanticipated patient declines do occur; thus, a score of 100% is not the expectation for this measure pair.

Comment: Some commenters stated that it is not always known when a patient's death is imminent. One commenter stated that there is not always an opportunity for hospices to provide the visits specified in this measure set if a patient experiences a rapid and unanticipated decline.

Response: We understand that it is not always possible to accurately predict time of death. However, the last week of life is typically the period in the terminal illness trajectory with the highest symptom burden, especially during the last few days before death. We recognize that rapid and unanticipated patient declines do occur; thus, a score of 100 percent is not the expectation for this measure pair. We do expect that hospices delivering high quality care will be responsive to the patient and caregiver needs that arise during the last days of a patient's life. In order to address performance gaps in this measure, providers may be motivated to proactively assess symptom burden, resulting in improved symptom management and higher quality of life during the final days.

Comment: We received some comments related to the structure of the Hospice Visits when Death is Imminent Measure Pair and intent of each measure. Some comments indicated that commenters might have misinterpreted the intent of this measure pair. For example, one commenter stated that adoption of this measure pair would in fact create three visit metrics, and another commenter referenced the calculation of a composite measure for visits at the end of life. Some commenters interpreted the specifications as not including visits addressing spiritual or psychosocial suffering in the 3 days before death.

Some commenters requested clarification of the calculation of each of these measures and of the disciplines included in each. One commenter recommended that Measure 1 and Measure 2 be combined into one measure in order to streamline data collection. One commenter requested that RN visits be included in both Measure 1 and Measure 2 since some interventions to manage symptoms may only be provided by an RN.

Response: We wish to clarify the intent of this measure pair. The Hospice Visits when Death is Imminent Measure Pair will be calculated and reported as two separate measures. These measures are intended to be interpreted as a set. For more information on the specifications and data elements for the measure set, Hospice Visits when Death is Imminent Measure Pair, we refer readers to the HQRP Specifications for the Hospice Item Set-based Quality Measures document, available on the ''Current Measures'' portion of the CMS HQRP Web site: *https://www.cms.gov/Medicare/Quality-Initiatives-PatientAssessment-Instruments/HospiceQuality-Reporting/CurrentMeasures.html.*

The two measures are intended to capture distinct aspects of hospice care at the end of life. The inclusion of registered nurses, physicians, nurse practitioners, and physician assistants in Measure 1 is intended to capture the range of clinical disciplines that might visit a patient, depending on patient and hospice preferences, and uses a 3-day timeframe to reflect the active dying phase. The inclusion of medical social workers, chaplains or spiritual counselors, licensed practical nurses, and hospice aides in Measure 2 is intended to allow for flexible and individualized care in line with patient, family, and caregiver preferences. The 7-day time frame covers both the active dying phase and the transition period before, and thus could also capture important visits related to preparation for active dying. To clarify, the 7-day time frame is inclusive of the 3 days prior to death. Data collection is conducted at the discipline level in order to provide us with sufficient information to conduct reliability and validity testing and possible future measure refinement.

Comment: We received some comments regarding the types of visits included in the Hospice Visits when Death is Imminent Measure Pair. Some commenters requested that all visits on the date of death be included in the measures, including postmortem visits, as this is an important service that hospices provide. One commenter

[20] Werner, R., E. Stuart, and D. Polsky, Public reporting drove quality gains at nursing homes. *Health Affairs*, 2010. 29(9): p. 1706–1713.

recommended that a new, separate measure could look at postmortem visits. Some commenters requested that phone calls or videoconferencing be included in the measures. One commenter stated that phone calls may be an especially important form of contact in rural areas. A few commenters requested clarification of the definition of a visit counted for quality purposes, and one inquired what visit duration is expected.

Response: We thank the commenters for their feedback regarding the types of visits included in this measure pair. We agree that post mortem and bereavement visits are an important service for hospices to provide. However, we believe that these services are outside the scope of this quality measure pair, which focusses specifically on visits when death is imminent. These visits provided shortly prior to death are intended to address the increased symptom burden many patients experience when death is imminent and provide an opportunity for proactive assessment and communication.

We recognize that some providers use phone calls to supplement care provided in person and that these calls can be helpful in facilitating ongoing care and communication. However, in agreement with a TEP and based on the available evidence, we consider these calls as a supplement to, and not a replacement for, in-person care, particularly when death is imminent. For this reason, phone calls are not included in the definition of a visit for this measure pair. Prior to implementation of the HIS V2.00.0, we will provide hospices with guidance and training materials, including an updated version of the HIS Manual. These training materials will further clarify the types of visits included in this measure pair and other item coding information.

Comment: We received many comments regarding the disciplines included in each of the Hospice Visits when Death is Imminent measures. One commenter stated that this measure pair recognizes the value of the core interdisciplinary team members and maintains a holistic approach to care. Many commenters supported the inclusion of chaplains or spiritual counselors and aides in Measure 2, as they play an important role in the interdisciplinary team. Some commenters encouraged CMS to conduct further research on the types of visits provided at the end of life and present a clear rationale for inclusion or exclusion from this measure. One commenter recommended that both measures be amended to include any member of the hospice's interdisciplinary team.

Many commenters requested that visits from volunteers be included in Measure 2. The commenters pointed out that the use of volunteers is a Medicare requirement for hospices, and that volunteers play an important role in the delivery of hospice care. One commenter indicated that it might be burdensome to report data on volunteer visits, but that inclusion of volunteers would be valuable. A couple of commenters requested that visits from music therapists or massage therapists be included in Measure 2.

Several commenters noted that although physician assistant (PA) visits are included in this quality measure pair, this discipline is not identified by CMS as a core or non-core service of a hospice provider. Some of these commenters requested that PA visits be removed from the measure in order to align with the Conditions of Participation and Medicare payment practices. Some of these commenters supported the inclusion of PAs and recommended that their role be clarified. One commenter stated that since the use of PAs is limited, inclusion of PA visits would negatively skew the data.

One commenter noted that a Licensed Practicing Nurse's (LPN) scope of practice varies from state to state, and asked that CMS consider removing LPN visits from the measure to make the measure more uniform nation-wide. One commenter expressed appreciation for the inclusion of LPNs and stated that the discipline is frequently used.

Some commenters requested that bereavement coordinator or bereavement counselor visits be included in this measure pair. One commenter requested clarification of whether a visit from a provider contracted but not employed by a hospice program would be considered a visit under this measure pair.

Response: We thank the commenters for their support of the disciplines included in this measure, including chaplains or spiritual counselors and aides. This measure pair is designed to allow hospices flexibility to determine the most appropriate discipline or disciplines to visit a patient. The inclusion of registered nurses, physicians, nurse practitioners, and physician assistants in Measure 1 is intended to capture the range of clinical disciplines that might visit a patient, depending on patient and family preferences and emerging care needs in the last days of life. Similarly, the inclusion of medical social workers, chaplains or spiritual counselors, licensed practical nurses, and hospice aides in Measure 2 is intended to allow for flexible and individualized care in line with patient, family, and caregiver preferences. This measure is not intended to require visits from any given discipline, but aims to allow flexibility in the types of visits provided. The Hospice Conditions of Participation state that the interdisciplinary group must include, but is not limited to, a doctor of medicine or osteopathy, a registered nurse, a social worker, and a pastoral or other counselor. Visits from all of these disciplines are included in this measure pair, as well as from some additional disciplines. We have carefully researched the topic of which disciplines to include in this measure pair, including an environmental scan, pilot test of this measure in summer 2015, TEP discussions on May 7 and 8, 2015, and October 19 and 21, 2015, and input from our Clinical Users Panel and Caregiver Workgroup.

Regarding volunteer visits, we agree that volunteers play an important role in high quality hospice care and that their visits are important to patients and families. Visits from volunteers were included in an early version of this measure, which pilot tested for feasibility in summer 2015. Many of the hospices included in the pilot had trouble reporting data on visits from volunteers because the records of volunteer visits were often stored in a separate system and were frequently delayed. The data was unreliable, and hospices reported significant reporting burden. This topic was discussed with the TEP, held October 19 and 21, 2015. After reviewing the results from the pilot test and thoroughly discussing the issues, the TEP members did not support including visits from volunteers in this measure pair. For the same reasons, the TEP advised against including complementary and alternative therapists such as music or massage therapists in this measure pair, though they do provide important services.

Regarding physician assistant visits, although Medicare does not provide separate payments for visits from physician assistants, these services would be covered under the hospice per diem. Additionally, this measure is an all-payer measure and some states and other programs may authorize physician assistants to provide hospice care under separate payments. This measure pair is separate from payment and should focus on services provided by hospices and not be restricted by the terms of payment by Medicare. Therefore, the inclusion of physician assistants in the

measure specifications provides the flexibility for hospices that may have physician assistants to count these clinical visits as part of Measure 1. We wish to clarify that the absence of physician assistant visits will not negatively skew the data reported in this measure. Visits from physician assistants are one of the options included in Measure 1, but patients will also be included in the numerator of the measure if they receive a visit from a registered nurse, physician, or nurse practitioner.

We thank the commenters for their feedback regarding the inclusion of LPNs in Measure 2. Members of our TEP agreed that LPNs provide an important service in hospice care that is distinct from the role of RNs. For this reason, we have included visits from LPNs in Measure 2 of this measure pair.

We appreciate the commenters' recommendations to include bereavement coordinators, and agree that visits from these disciplines are important for many patients and families. However, we believe that bereavement services are outside the scope of this quality measure pair, which focusses specifically on visits, which may address the increased symptom burden many patients experience when death is imminent, and provide an opportunity for proactive assessment and communication.

Regarding contracted hospice staff, we clarify that visits from contracted staff may be included in this measure pair. As defined in the HIS Manual V1.02, hospice staff members may include volunteers, contractors, and affiliates.

Comment: Some commenters recommended changes to the Hospice Visits when Death is Imminent Measure Pair to further align the two measures. A few commenters suggested that both Measure 1 and Measure 2 be measured over a 7-day timeframe in order to improve consistency between the measures and simplify data collection for providers. A few commenters recommended that CMS consider altering Measure 2 such that it includes in the numerator patients who receive one visit from medical social workers, chaplains or spiritual counselors, licensed practical nurses or hospice aides in the final seven days of life.

Response: We thank the commenters for their feedback on the specifications of the two measures in this measure pair. As currently specified, Measure 1 uses a 3-day timeframe and Measure 2 uses a 7-day timeframe. A TEP meeting held October 19 and 21, 2015, provided input on the timeframes. The TEP indicated that the 3-day timeframe would be reflective of the active dying phase, and that it would be appropriate to measure clinical visits provided during the active dying phase. The 7-day time frame covers both the active dying phase and the transition period before, and thus could also capture important visits related to preparation for active dying. An analysis of Medicare claims indicates that most routine home care patients (94 percent) receive at least one skilled visit from a nurse, social worker, therapist or physician in the last four days of life.[21] Because of this, there may be a ceiling effect for these quality measures using a longer time frame.

The current specification of Measure 2 limits the numerator to patients who receive at least two visits from those disciplines in the final 7 days of life. Using two visits rather than one may also serve to reduce the expected ceiling effect that is likely to result from grouping multiple disciplines together in Measure 2.

Comment: Many commenters pointed out that, in keeping with the individualized and patient-centered focus of hospice care, patients and families have the option of declining visits from hospice providers if they deem them unnecessary or unwanted. Commenters indicated that patients and caregivers might decline a visit for various reasons: Desire for privacy at the end of life, adequate preparation for the end of life such that additional visits are not necessary, or patient is receiving receipt of similar services from outside of the hospice provider. Some commenters recommended that revisions be made to the HIS Discharge form to allow a hospice to indicate that a patient or family was offered a visit included in either Measure 1 or Measure 2, but refused or deferred the visit. Some commenters recommended that patients who refuse an offered visit be included in the measure numerator, while others recommended that these patients be excluded from the measure pair, and a few recommended that the measures be risk adjusted to reflect patient refusal of services.

Some commenters cautioned that this measure pair could result in an unintended consequence: Hospices might provide unnecessary or unwanted visits, thus undermining patient and family preferences and choice. One commenter cautioned that specifying when particular staff must visit would undermine the flexibility hospices have in customizing the plan of care. Some commenters pointed out that, by respecting the wishes of some patients to receive fewer visits, a hospice might have lower scores on this measure pair but that it would not reflect an issue with quality of care.

Response: We thank the commenter for their feedback about patients and families that may refuse a visit at the end of life. In a pilot study conducted by our measure development contractor, hospices reported that information on visit refusal is available, but is burdensome for hospices to report. In addition, fewer than 4 percent of patients in the pilot study refused a visit from a given discipline, and no patients refused all visits offered. By including multiple disciplines in each measure, the Hospice Visits when Death is Imminent Measure Pair is designed to allow hospices flexibility to determine the most appropriate discipline or disciplines to visit a patient, and to consider patient and family preferences. A TEP held by our measure development contractor did not expect that there would be wide variation in the rate of visit refusal across hospices. The TEP determined that the burden of data collection would outweigh the benefit of excluding patients who refuse visits. For these reasons, we determined not to require hospices to report data on visit refusals. Hospices may wish to track visit refusals internally for quality improvement purposes. This measure pair will be tested for reliability and validity prior to public reporting. We recognize that some patients may decline services and that rapid and unanticipated patient declines do occur; thus, the expectation is not for hospices to score 100 percent on this measure pair. We will take these comments into account during future measure development.

Comment: Some commenters recommended using risk adjustment or exclusions to account for patient characteristics in the Hospice Visits when Death is Imminent Measure Pair. Some commenters stated that patients with shorter lengths of stay will likely receive different visits than patients with longer lengths of stay. Commenters requested that CMS examine any differences, and some requested that the Hospice Visits when Death is Imminent Measure Pair be risk adjusted or stratified for length of stay in hospice. Another commenter requested that case mix adjustment be used in the calculation of this measure pair.

[21] Plotzke, M. C., T.J.; Axelrod, Elizabeth; Hunt, Meaghan; Muma, Allison; Gozalo, Pedro; Teno, Joan. (2015). *Medicare Hospice Payment Reform: Analysis of How the Medicare Hospice Benefit is Used.* Retrieved from *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Downloads/December-2015-Technical-Report.pdf.*

One commenter recommended that patients with a length of stay shorter than 5 days be excluded from Measure 2. This is the length of time allowed by Hospice Conditions of Participation requirements for the comprehensive assessments to be completed, and the commenter expects that some patients might not receive two visits from a medical social worker, chaplain or spiritual counselor, licensed practical nurse, or hospice aide before Day 5. Another commenter recommended that patients with a length of stay of three days or fewer be excluded from Measure 1 if the only visit received is the initial nursing assessment. The commenter expressed concern that for such short lengths of stay, the measure would function as an indicator of compliance rather than of quality.

Finally, one commenter requested clarification of whether this measure pair would be applied across all levels of care.

Response: We thank the commenters for their feedback. As currently specified, this measure set is not risk adjusted. A TEP convened by our measure development contractor discussed possible risk adjustment of this measure pair, including risk adjustment by diagnosis or length of stay. The TEP determined that diagnosis may not reliably predict symptom burden at the end of life and therefore may not reliably predict need for visits. The TEP members determined that it might be important to take length of stay into account in measure calculations. We will continue to consider this feedback, and will examine measure performance, including the potential need for risk adjustment in the future.

As currently specified, Measure 1 does not include a length of stay exclusion, while Measure 2 excludes patients with a length of stay less than or equal to one day (that is, admitted and discharged on the same day). The rationale for excluding patients with a very short length of stay from Measure 2 is that Measure 2 requires two visits from select hospice staff, and it may be difficult or possibly inappropriate to provide more than one such visit for patients receiving only one day of hospice care. We do not exclude these patients from Measure 1 because Measure 1 specifies at least one clinician visit, and it is reasonable to expect that a hospice would provide at least one such visit, even for patients with a very short length of stay. It is acceptable if this visit is the initial nursing assessment visit. One of the goals of this measure pair is to increase prospective assessment of patient needs and timely management of symptoms prior to death, and this can be accomplished during the initial nursing assessment visit as well as other types of visits provided in the final days to patients with longer length of stay. We do not intend to increase burden on providers or patients by requiring specific types of visits to meet the goals of this measure. Patients with short lengths of stay are expected to have high symptom burden throughout their short stay and can benefit from hospice visits. For these reasons, patients with short lengths of stay are included in this measure.

This measure pair currently includes only patients who received routine home care. It does not include patients who received general inpatient care, respite care, or continuous home care during the measure timeframes. Routine home care patients for whom the hospice receives a service intensity add-on payment are included in this measure, as this payment is an add-on to the routine home care rate.

Comment: Some commenters encouraged CMS to obtain NQF endorsement prior to proposing new measures. One commenter expressed appreciation that this measure development process has included input from the Measure Applications Partnership (MAP).

Response: We appreciate the commenters' input and support of the NQF endorsement process. Our paramount concern is the successful development of a HQRP that promotes the delivery of high quality healthcare services. We seek to adopt measures for the HQRP that promote patient-centered and high quality care. Our measure selection activities for the HQRP take into consideration input from the MAP, convened by the NQF, as part of the established CMS pre-rulemaking process required under section 1890A of the Act. The NQF MAP met on December 14th and 15th, 2015 and encouraged continued development of this measure pair. Additionally, while this measure is not currently NQF-endorsed, we recognize that the NQF endorsement process is an important part of measure development and plan to submit this measure for NQF endorsement. This quality measure will fill a gap by addressing quality of hospice care at the end of life. Furthermore, no current NQF-endorsed measures address hospice care when death is imminent, and this measure is a first step towards that goal. CMS is establishing the timeline for seeking NQF endorsement for this quality measure and will communicate this timeline to the public in future rulemaking cycles.

Comment: One commenter asked whether CMS would correlate the Hospice Visits when Death is Imminent Measure Pair with the Hospice CAHPS results. Another commenter recommended that CMS compare outcomes as measured by the HIS care processes and the CAHPS survey with the data collected on visits at the end of life to guide refinement of this measure pair.

Response: We plan to conduct reliability and validity testing of this measure pair as part of ongoing measure maintenance and refinement and to prepare for NQF endorsement. As part of those efforts, we will examine the correlations of the paired measures with other quality measures calculated from the HIS and possibly from the CAHPS.

Comment: Some commenters indicated that data collection for the Hospice Visits when Death is Imminent Measure Pair would be burdensome for providers, and potentially duplicative of the information about visits reported in Medicare claims. One commenter requested that claims data be used to calculate this measure pair in order to reduce provider burden of data collection. Another commenter encouraged CMS to establish a claims code for spiritual counselor/chaplain visits so that their visits can be reviewed for reimbursement and quality considerations. One commenter indicated that this measure pair would be calculated using claims data.

Response: We wish to clarify the data source for this measure pair. This measure will be calculated using data from the HIS V2.00.0, and will not be a claims-based measure. This HIS-based measure pair will expand upon information that would be available in Medicare hospice claims. The HIS includes data for all hospice patients, regardless of payment source, while claims data capture only Medicare Fee-for-service beneficiaries. Therefore, the use of assessment data allows the measure to be inclusive of all patients regardless of payer. Medicare claims capture visits from certain disciplines, including skilled nursing, medical social services, aides, physical therapy, occupational therapy, and speech therapy—language pathology. HIS items will capture hospice visits by members of additional disciplines that are not included in the Medicare hospice claims (for example, chaplains). Finally, visit information on the HIS can be assessed and reported in a timelier manner than Medicare claims, providing hospices with opportunities to review and improve care.

Comment: Some commenters requested that sufficient time be given

prior to measure implementation of the Hospice Visits when Death is Imminent Measure Pair to ensure time for software vendors to develop new processes, and hospices to upgrade their EMR systems, train staff, and conduct testing. One commenter recommended that CMS delay initiation of data collection for this measure pair until October 1, 2016. One commenter encouraged CMS to solicit feedback from the hospice industry and software vendors to determine whether necessary updates can be made by April 1, 2017. Other commenters recommended a period of data collection on the proposed measures prior to implementation of the measures.

Response: We appreciate the commenters' feedback regarding the timeline for implementation and public reporting of this measure pair. We would like to clarify the implementation date proposed in this rule; data used for calculation of this measure pair will be collected via the HIS V2.00.0. The HIS V2.00.0 is undergoing review as part of a PRA package under OMB number 0938–1153 and will be implemented April 1, 2017. This measure pair is proposed for the FY 2019 payment determination and subsequent years. The HIS V2.00.0 is currently available for review by software vendors and hospice providers. Some of the activities that are necessary prior to implementation can be done concurrently. For example, hospice education and training in the new items and data abstraction can be conducted at the same time as vendor development of software. As stated in section III.C.7.c, providers may also use the Hospice Abstraction Reporting Tool (HART) software, which is free to download and use. HART provides an alternative option for hospice providers to collect and maintain facility, patient, and HIS Record information for subsequent submission to the QIES ASAP system. We agree it is critical to establish the reliability and validity of the quality measures prior to public reporting. We plan to conduct data analysis to demonstrate the ability of the quality measures to distinguish the quality of services provided. More detail on public display is provided in section III.C.11 of this rule.

Comment: Some commenters drew connections between the Hospice Visits when Death is Imminent Measure Pair and the Service Intensity Add-on payment. Some commenters recommended delaying implementation of this measure pair until the impact of the SIA payment is better understood. One commenter recommended that CMS use the data obtained for Measure 2 to update the payment of the SIA payment to include visits by licensed practical nurses and other disciplines. One commenter stated that CMS should align financial payment and quality measures.

Response: We thank the commenters for their feedback regarding the Hospice Visits when Death is Imminent Measure Pair and the SIA. CMS adopted SIA payments to address the observed misalignment between resource use and associated Medicare payments and to improve patient care through the promotion of skilled visits at end of life with minimal claims processing systems changes. While it may be good for payment and quality to align when possible, this measure pair is a measure of quality, not of practice driven by reimbursement structure. We will take into consideration using measure data for further refinement of the SIA.

Final Action: After consideration of the comments, we are finalizing our proposal to implement the Hospice Visits when Death is Imminent Measure Pair effective April 1, 2017. Data will be collected starting on such date, and will, if not reported, affect payments for FY 2019.

(2) Proposed Quality Measure 2: Hospice and Palliative Care Composite Process Measure—Comprehensive Assessment at Admission

Measure Background. The Hospice and Palliative Care Composite Process Measure—Comprehensive Assessment at Admission is a composite measure that assesses whether a comprehensive patient assessment is completed at hospice admission by evaluating the number of individual care processes completed upon admission for each hospice patient stay. A composite measure, as defined by the NQF, is a combination of two or more component measures, each of which individually reflects quality of care, fashioned into a single performance measure with a single score.[22] For more information on composite measure definitions, guiding principles, and measure evaluation criteria, we refer readers to the NQF Composite Performance Measure Evaluation Guidance Publication available at *https://www.qualityforum.org/Publications/2013/04/Composite_Performance_Measure_Evaluation_Guidance.aspx.* A total of 7 individual care processes will be captured in this composite measure, which include the 6 NQF-endorsed quality measures and 1 modified NQF-endorsed quality measure currently implemented in the HQRP. Thus, the Hospice and Palliative Care Composite Process quality measure will use the current HQRP quality measures as its components. These individual component measures address care processes around hospice admission that are clinically recommended or required in the hospice CoPs.[23] This measure calculates the percentage of patients who received all care processes at admission. To calculate this measure, the individual components of the composite measure are assessed separately for each patient and then aggregated into one score for each hospice.

Measure Importance. This composite quality measure for comprehensive assessment at admission addresses high priority aspects of quality hospice care as identified by both leading hospice stakeholders and beneficiaries receiving hospice services. The NCP for Quality Palliative Care Clinical Practice Guidelines for Quality Palliative Care established 8 core palliative care domains, and this composite measure captures 4 of those domains.[24] The 4 domains captured by this composite measure are the Structure and Process of Care Domain; the Physical Aspects of Care Domain; the Spiritual, Religious, and Existential Aspects of Care Domain, and the Ethical and Legal Aspects of Care Domain. The NCP guidelines placed equal weight on both the physical and psychosocial domains, emphasizing a comprehensive approach to patient care. For more information on the NCP domains for palliative care, refer to *http://www.nationalconsensusproject.org/guidelines_download2.aspx.* In addition, the Medicare Hospice CoPs require that hospice comprehensive assessments identify patients' physical, psychosocial, emotional, and spiritual needs and address them to promote the hospice patient's comfort throughout the end-of-life process. Furthermore, the person-centered, family, and caregiver perspective align with the domains identified by the CoPs and NCP, as patients and their families/caregivers also place value on physical symptom management and spiritual/psychosocial care as important factors at the end of

[22] National Quality Forum. (2013). Composite Performance Measure Evaluation Guidance: National Quality Forum.

[23] Medicare and Medicaid Programs: Hospice Conditions of Participation, Part 418 subpart 54. Centers for Medicare and Medicaid Services, June 5, 2008.

[24] The National Consensus Project for Quality Palliative Care Clinical Practice Guidelines for Quality Palliative Care 3rd edition 2013.

life.[25] [26] A composite measure serves to ensure all hospice patients receive a comprehensive assessment for both physical and psychosocial needs at admission.

Measure Impact. The literature indicates that health care providers' practice is responsive to quality measures reported.[27] CMS feels this research, while not specific to hospices, reasonably predicts the effect of measures on hospice provider behavior. Collecting information about the total number of care processes conducted for each patient will incentivize hospices to conduct all desirable care processes for each patient and provide services that will address their care needs and improve quality during the time he or she is receiving hospice care. Additionally, creating a composite quality measure for comprehensive assessment at admission will provide consumers and providers with a single measure regarding the overall quality and completeness of assessment of patient needs at hospice admission, which can then be used to meaningfully and easily compare quality across hospice providers and increase transparency.

Performance Gap. Analyses conducted by our measure development contractor, RTI International, show that hospice performance scores on the current 7 HQRP measures are high (a score of 90 percent or higher on most measures); however, these analyses also revealed that, on average, a much lower percentage of patient stays in a hospice had documentation that all of these desirable care processes were completed at admission. Thus, by assessing hospices' performance of comprehensive assessment, the composite measure sets a higher standard of care for hospices and reveals a larger performance gap. A similar effect has been shown in the literature where facilities are achieving more than 90 percent compliance with individual measures, but compliance numbers decrease when multiple measures are combined as one.[28] [29] The performance gap identified by the composite measure creates opportunities for quality improvement and may motivate providers to conduct a greater number of high priority care processes for as many patients as possible upon admission to hospice.

Existing Measures. The Family Evaluation of Hospice Care (FEHC), NQF #0208, is a precursor of the Hospice CAHPS®. The surveys cover some similar domains. However, a major difference between them is the detailed requirements for survey administration of the CAHPS® Hospice Survey, which allow for comparison of hospice programs, The Hospice CAHPS® survey quality measure is not yet endorsed by NQF. CMS has recently submitted the CAHPS® Hospice Survey (experience of care) measure (NQF #2651) to be considered for endorsement under the Palliative and End-of-Life Care Project 2015–2016. For more information regarding this project and the measure submitted, we refer readers to *https://www.qualityforum.org/ProjectMeasures.aspx?projectID=80663.* In addition, we refer readers to section III.C.9 of this rule for more information on the Hospice CAHPS® survey and associated quality measures. The CAHPS®-based quality measures submitted to NQF include patient and caregiver experience of care outcome measures and CMS plans to propose these measures as part of the HQRP measure set in future rulemaking cycles. A key difference between the FEHC, Hospice CAHPS® and the Hospice and Palliative Care Composite Process Measure is that the FEHC and Hospice CAHPS® focus on the consumer's perspective of their health agency and experience, whereas the Hospice and Palliative Care Composite Process Measure focuses on the clinical care processes that are actually delivered by the hospice to each patient.

Stakeholder Support. A TEP convened by our measure development contractor, RTI International, on December 2, 2015, provided input on this measure concept. The TEP unanimously agreed that a comprehensive hospice composite measure is an important measure and supported data collection using the HIS. The NQF MAP met on December 14th and 15th, 2015 and provided input to CMS. In their final recommendation, the MAP encouraged continued development of the Hospice and Palliative Care Composite Process Measure—Comprehensive Assessment at Admission measure. More information about the MAP's recommendations for this measure is available at *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75370.*

While this measure is not currently NQF-endorsed, we recognize that the NQF endorsement process is an important part of measure development and plan to submit this measure for NQF endorsement. As noted, this quality measure will fill a gap by holding hospices to a higher standard of care and will motivate providers to conduct a greater number of high priority care processes for as many beneficiaries as possible upon admission as hospice patients. Furthermore, no current NQF-endorsed measures address the completion of a comprehensive care assessment at hospice admission.

Form, Manner, and Timing of Data Collection and Submission. The data source for this measure will be currently implemented HIS items that are currently used in the calculation of the 7 component measures. These items and quality measure algorithms for the 7 component measures can be found in the HQRP Specifications for the Hospice Item Set-based Quality Measures document, which is available in the ''Downloads'' section of the ''Current Measures'' portion of the CMS HQRP Web site: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Current-Measures.html.* Since the proposed measure is a composite measure whose components are currently adopted HQRP measures, no new data collection will be required; data for the composite measure will come from existing items from the existing 7 HQRP component measures. CMS proposes to begin calculating this measure using existing data items, beginning April 1, 2017; this means patient admissions occurring after April 1, 2017 would be included in the composite measure calculation.

Since the composite measure components are existing HIS data items, providers are already collecting the data needed to calculate the composite measure. Data collection will continue in accordance with processes outlined in sections III.C.7c through III.C.7e of this rule.

For more information on the specifications and data elements for the measure, Hospice and Palliative Care Composite Process Measure-Comprehensive Assessment at Admission, we refer readers to the *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Current-Measures.html* document, available on the ''Current Measures''

[25] Singer PA, Martin DK, Kelner M. Quality End-of-Life Care: Patients' Perspectives. JAMA. 1999;281(2):163–168. doi:10.1001/jama.281.2.163.

[26] Steinhauser KE, Christakis NA, Clipp EC, McNeilly M, McIntyre L, Tulsky JA. Factors Considered Important at the End of Life by Patients, Family, Physicians, and Other Care Providers. JAMA. 2000;284(19):2476–2482. doi:10.1001/jama.284.19.2476.

[27] Werner, R., E. Stuart, and D. Polsky, *Public reporting drove quality gains at nursing homes.* Health Affairs, 2010. 29(9): p. 1706–1713.

[28] Nolan, T., & Berwick, D. M. (2006). All-or-none measurement raises the bar on performance. JAMA [H.W. Wilson—GS], 295(10), 1168.

[29] Agency for Healthcare Research and Quality. (2004). National Healthcare Quality Report.

portion of the CMS HQRP Web site: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Current-Measures.html.*

We received multiple comments pertaining to the Hospice and Palliative Care Composite Process Measure. The following is a summary of the comments we received on this topic and our responses.

Comment: CMS received many comments in support of the proposed Hospice and Palliative Care Composite Process Measure—Comprehensive Assessment at Admission quality measure. Commenters appreciated that the measure demonstrates greater variation in hospice performance than the individual component measures, and that it can be used to differentiate performance across hospices. Commenters also appreciated that CMS's measure selection activities for the HQRP take into consideration input from stakeholders such as the Measure Applications Partnership (MAP). Several commenters were supportive of CMS's approach to quality measure development in the HQRP, specifically, the use of Technical Expert Panels (TEP) to obtain expert and other stakeholder input.

Response: We thank commenters for their support of the proposed Hospice and Palliative Care Composite Process Measure—Comprehensive Assessment at Admission quality measure, herein after referred to as the 'Composite QM'.

Comment: Many comments were received regarding the retirement of the seven day length of stay exclusion for six of the care process measures that comprise the Composite QM. Commenters' primary concern focused on the impact of removing this exclusion on provider behavior; specifically, commenters suggested that eliminating the LOS exclusion may inappropriately incentivize providers to focus on completion and compliance with the HIS requirements at the expense of addressing the needs and preferences of imminently dying patients. Commenters noted that upon admission for imminently dying patients, a comprehensive assessment is not in the interest of patients and caregivers, nor may it be feasible for hospices to deliver because the focus is on appropriately directed to other priorities. One commenter stated that the level and intensity of hospices services are different for patients with short LOS and that the items captured in this measure are not reflective of quality of care for patients imminently dying. Finally, one commenter indicated that this measure might complicate data collection efforts and processes already in place at hospices, noting that different members of the interdisciplinary team often complete different sections of the HIS at different times. This commenter believed that hospices would therefore need to establish new data collection processes when addressing urgent patient/family needs should be the priority. In response to these concerns, commenters requested that provisions be made to account for patients with short LOS and suggested alternative approaches to do so. Namely, commenters recommended that CMS risk adjust or stratify for patients with a 2-day or less, 3-day or less, or 5-day or less LOS, while other comments recommended that CMS maintain the current 7-day LOS exclusion. Another commenter recommended that a new measure be created to capture data for short LOS patients, rather than including them in this measure. Commenters requested clarification on why the measure was not created with risk adjustment in its current specifications.

Response: We appreciate the commenters' input on the Composite QM LOS exclusion specifications. Developing and adopting measures that benefit patient outcomes and do not lead to negative unintended consequences of the utmost importance to CMS. We would like to take this opportunity to respond to commenters' concerns about the impact of retiring the LOS exclusion, first by describing the history of the LOS exclusion and the reason for retiring it from the individual measures. As many commenters noted, 6 of the 7 component quality measure (QMs) exclude patient stays that are less than 7 days from the measure denominator. At the time the measures were developed, no national data regarding the implications of the LOS exclusion was available at that time, and technical experts recommended that short patient stays be excluded from those measures' denominators for assessing quality of care. Since the implementation of the HIS, we have performed descriptive analyses to examine the implications of the LOS exclusion on hospices' denominator size and QM scores. Additionally, this analysis also examined the timing of when hospices perform the care processes assessed in the quality measures. The results of these analyses demonstrated that the denominator sizes for the HQRP QMs are largely impacted by the current 7 day LOS exclusion used to calculate the QMs. Excluding stays with LOS less than 7 days result in many hospices not having sufficient denominator size to allow for public display of their quality scores. Although the LOS exclusion has a sizable impact on the number of hospices eligible to have their data publicly displayed, the impact of the LOS exclusions on the distribution of hospices' scores is generally small for all of the QMs. Therefore, removing the LOS exclusion criteria will increase the number of hospices eligible for public reporting while having a minimal impact on the QM scores. In addition, these analyses revealed that the care processes targeted by the QMs are performed on the day of or within one day of admission for the vast majority of patient stays. For example, among patient admissions for which a pain screening was administered, approximately 92 percent of screenings occurred on the day of admission and close to 99 percent occurred within 1 day of admission. This suggests that including stays of less than 7 days in QM calculations (that is, removing the QM LOS exclusion) may be appropriate and would not create a burden on hospices. In response to these results, the measure developer and steward submitted the individual QMs to the NQF Palliative Care and End of Life Project for re-endorsement in February 2016 without the LOS exclusion. Because of the anticipated removal of the LOS exclusion for the current HQRP measures (component measures for this Composite QM), this Composite QM was proposed without the LOS exclusion in order to be consistent with the individual measure components. Our contractor convened a TEP in December 2015 to inform the development of the Composite QM. The TEP, presented with the results of the LOS analysis, strongly recommended that the Composite QM maintain the same measure specifications as the individual measures. Additionally, this TEP considered the creation of a separate measure specifically for short LOS patients, as recommended by a commenter, but ultimately agreed that such a measure would not capture comprehensive care for short LOS patients as the current proposed measure would. Furthermore, we remind commenters that because the Composite QM is based on the 7 current HIS measures that are already endorsed by NQF, risk adjustment for the Composite QM will be consistent with any risk adjustment created and applied for the individual measures. Any additional risk adjustment applied to the individual measures will first be developed and tested for in coordination with the NQF prior to

implementation. We will keep the commenters' recommendations and concerns regarding short LOS in mind for future development efforts and data analysis.

Comment: CMS received comments regarding the contribution of this measure to quality of care. While commenters did not object to the development and implementation of this measure, many were concerned whether this measure is truly reflective of comprehensive care at admission and whether it will provide patients and families with meaningful information.

Response: We appreciate the commenters' concern regarding the impact and relevance of the Composite QM. We are committed to the ensuring that all quality measures implemented in the HQRP meet the goals of the HQRP, which include distinguishing performance among hospices and improving patient outcomes. We regularly conduct measure testing and evaluation activities to ensure that measures continue to demonstrate improvements in-patient care. We would like to convey to commenters that a primary motivation in developing the Composite QM is to provide interpretable and meaningful information to consumers. We believe that, above and beyond information provided by the individual component QMs, the Composite QM accomplishes this by providing consumers with a single measure regarding the overall quality and completeness of assessment of patient needs at hospice admission, which can then be used to compare quality across hospice providers and increase transparency, while also accessing information about hospice performance on each of the individual measures that comprise the Composite QM. As also noted in this rule, the Composite QM demonstrates greater variation in hospice performance than individual measures. Hospice performance scores on the current 7 HQRP measures are high (a score of 90 percent or higher on most measures); however, on average, a much lower percentage of patient stays in a hospice had documentation that all 7 of these care processes were completed at admission. Additionally, we would like to reiterate that the Composite QM for comprehensive assessment at admission addresses high priority aspects of comprehensive quality hospice care as identified by both leading hospice stakeholders and beneficiaries receiving hospice services, all of which emphasize attention to physical, psychosocial, emotional, and spiritual needs of patients.

Comment: CMS received a few comments recommending that CMS attain NQF endorsement of the Composite QM prior to implementation.

Response: We appreciate the commenters' input and support of the NQF endorsement process. Our paramount concern is the successful development of a HQRP that promotes the delivery of high quality healthcare services. We seek to adopt measures for the HQRP that promote patient-centered and high quality care. Our measure selection activities for the HQRP take into consideration input from the Measure Applications Partnership (MAP), convened by the NQF, as part of the established CMS pre-rulemaking process required under section 1890A of the Act. The NQF MAP met on December 14th and 15th, 2015 and encouraged continued development of this measure. Additionally, while this measure is not currently NQF-endorsed, we recognize that the NQF endorsement process is an important part of measure development and plan to submit this measure for NQF endorsement. This quality measure will fill a gap by holding hospices to a higher standard of care and will motivate providers to conduct a greater number of high priority care processes for as many beneficiaries as possible upon admission as hospice patients—a unique contribution to hospices. Furthermore, no current NQF-endorsed measures address the completion of a comprehensive care assessment at hospice admission, and this measure is a first step towards that goal. We are establishing the timeline for seeking NQF endorsement for this quality measure and will communicate this timeline to the public in future rulemaking cycles.

Comment: CMS received one comment requesting clarification on the logic behind including NQF #1617 Patients Treated with an Opioid Who Are Given a Bowel Regimen measure as a component measure of the proposed Composite QM. This commenter indicated that the NQF #1617 measure does not collect data representative of comprehensive care on the first day of admission and, therefore, does not serve this measure well as a component.

Response: We would like to clarify that the Composite QM is not designed to focus on care processes completed on the first day of admission; rather, this measure is intended to capture all comprehensive assessment activities around the time of hospice admission. This timeframe is in line with guidelines identified the Medicare Hospice Conditions of Participation (CoPs).[30] The Medicare CoPs mandate that an initial assessment be completed within 48 hours after the election of hospice care and that a comprehensive assessment be completed no later than 5 calendar days after the election of hospice care is in accordance with § 418.24. Therefore, by collecting data beyond the first day of admission, this measure aligns with the practices recommended by the CoPs and with national guidelines and clinical recommendations. The Medicare CoPs require that both the hospice initial and comprehensive assessments identify patients' physical needs and address them to promote the hospice patients' well-being and comfort throughout the dying process. Additionally, the Quality Palliative Care Clinical Practice Guidelines [31] produced by the National Consensus Project (NCP) established eight core palliative care domains, one of which emphasizes the assessment and management of pain and/or other physical symptoms. This measure captures care processes related to bowel management and opioid use. Most patients prescribed opioids to manage pain or other symptoms develop some degree of constipation after opioid initiation or dose increases. Reducing opioid-induced constipation can reduce patient discomfort and improve quality of life. Properly assessing and managing symptoms related to bowel management are critical components of the comprehensive assessment. Therefore, by including the NQF #1617 measure in this comprehensive assessment, we address high priority aspects of quality hospice care as identified by leading hospice stakeholders.

Comment: CMS received one comment recommending that the title of this measure, specifically the term ''at admission'', be clarified or replaced. The commenter believed that the use of the phrase ''at admission'' was misleading since it seemed to imply that the measure captures care processes completed on the day of admission. Since the composite measure in fact captures care processes completed during the initial and/or comprehensive assessment (which, per CoP requirements, must be completed within 2 and 5 days from admission, respectively), the commenter believed the title of the measure could be misleading since care processes that are components of the measure may be completed beyond the day of admission.

[30] Medicare and Medicaid Programs: Hospice Conditions of Participation, Part 418 subpart 54. Centers for Medicare and Medicaid Services (2008).

[31] Clinical Practice Guidelines for Quality Palliative Care. National Consensus Project for Quality Palliative Care (2013).

Response: We would like to thank this commenter for their recommendation. We would like to clarify that this measure title was developed based on the CoP requirement for the comprehensive assessment. While it is true that the CoPs require the first comprehensive assessment to be completed within 5 days of admission, the CoPs also require hospices to update the comprehensive assessment as frequently as the condition of the patient requires, but no less frequently than every 15 days. Thus, we used the phrase Comprehensive Assessment ''at Admission'' to denote that this measure and the data it captures refers to care processes delivered during the *first* comprehensive assessment completed upon admission to hospice and not any subsequent comprehensive assessment updates.

Comment: CMS received a few comments regarding the measure specifications of the Composite QM. Commenters requested clarification on the composite measure score calculation, construction, and components.

Response: The Composite QM is a composite measure that assesses whether a comprehensive patient assessment is completed at hospice admission by evaluating whether seven critical individual care processes were completed upon admission for each hospice patient stay. A composite measure, as defined by the NQF, is a combination of two or more component measures, each of which individually reflects quality of care, into a single performance measure with a single score. For more information on composite measure definitions, guiding principles, and measure evaluation criteria, we refer readers to the NQF Composite Performance Measure Evaluation Guidance Publication available at *https://www.qualityforum.org/Publications/2013/04/Composite_Performance_Measure_Evaluation_Guidance.aspx.* A total of 7 individual care processes will be captured in this Composite QM, which include the 6 NQF endorsed quality measures and 1 modified NQF endorsed quality measure currently implemented in the HQRP. This Composite QM calculates the percentage of patients who received all applicable care processes at admission. For additional details on the draft Composite QM specifications, we refer readers to the HQRP Specifications for HIS-Based QM document, available on the ''Current Measures'' portion of the CMS HQRP Web site: *https://www.cms.gov/Medicare/Quality-Initiatives-PatientAssessment-Instruments/HospiceQuality-Reporting/CurrentMeasures.html.* This measure, therefore, reflects the variation in hospices' performance on all 7 quality measures for each patient at admission. We will continue the development and analyses of the Composite QM. Potential refinement to the measure specifications will be communicated with the public via HQRP communication channels, including postings and announcements on the CMS HQRP Web site, MLN eNews communications, national provider association calls, and announcements on Open Door Forums and Special Open Door Forums.

Comment: CMS received a few comments recommending that CMS be mindful of public awareness of differences between process and outcome measures when creating a composite measure. Two commenters stated that although this measure concept is valuable and consistent with existing clinical guidelines, knowledge about differences in hospice measure types is minimal among the public. The commenter noted that the public might not be able to understand the relationship of hospice performance on the Composite QM to quality of care delivery at the hospice. Additionally, two commenters recommended that to aid consumer understanding of information from the Composite QM, CMS should supplement this data with information from the hospice CAHPS survey.

Response: We appreciate the commenters' feedback on public usability of the Composite QM. We would like to highlight that one primary motivation for creating this Composite QM was to provide interpretable and meaningful information to consumers. We believe the Composite QM may be easier for consumers to understand because it provides the public with a single metric regarding care processes at admission as compared to the individual component QMs. As such, QM scores can be easily used to compare quality across providers and make informed decisions. We are committed to providing all users with the necessary information to understand the intent and application of measures in the HQRP. As with other measures, we will conduct measure testing and reportability analysis to determine if the Composite QM is appropriate for public reporting. Should we determine the Composite QM is appropriate for public reporting, we would take necessary steps to ensure that any data publicly reported is meaningful and understandable by the public. Such steps may include usability testing and cognitive interviewing. We also plan to make hospice CAHPS quality measures publicly available to consumers.

Final Action: After consideration of the comments, we are finalizing our proposal to implement the Hospice and Palliative Care Composite Process Measure—Comprehensive Assessment at Admission effective April 1, 2017.

TABLE 16—PROPOSED QUALITY MEASURES AND DATA COLLECTION PERIOD AFFECTING THE FY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Quality measure	NQF ID No.	Type	Submission method	Data collection to begin
Hospice Visits when Death is Imminent	TBD	Process Measure	Hospice Item Set	04/01/2017
Hospice and Palliative Care Composite Process Measure	TBD.			

7. Form, Manner, and Timing of Quality Data Submission

a. Background

Section 1814(i)(5)(C) of the Act requires that each hospice submit data to the Secretary on quality measures specified by the Secretary. Such data must be submitted in a form and manner, and at a time specified by the Secretary. Section 1814(i)(5)(A)(i) of the Act requires that beginning with the FY 2014 and for each subsequent FY, the Secretary shall reduce the market basket update by 2 percentage points for any hospice that does not comply with the quality data submission requirements for that FY.

b. Previously Finalized Policy for New Facilities To Begin Submitting Quality Data

In the FY 2015 Hospice Wage Index final rule (79 FR 50488), we finalized a policy stating that any hospice that receives its CMS Certification Number (CCN) (also known as the Medicare Provider Number) notification letter

dated on or after November 1 of the preceding year involved is excluded from any payment penalty for quality reporting purposes for the following FY. This requirement was codified at § 418.312.

In the FY 2016 Hospice Wage Index final rule (80 FR 47189), we further clarified and finalized our policy for the timing of new providers to begin reporting data to CMS. The clarified policy finalized in the FY 2016 Hospice Wage Index final rule (80 FR 47189) distinguished between when new hospice providers are required to begin submitting HIS data and when providers will be subject to the potential 2 percentage point annual payment update (APU) reduction for failure to comply with HQRP requirements. In summary, the policy finalized in the FY 2016 Hospice Wage Index final rule (80 FR 47189 through 47190) clarified that providers *must begin submitting HIS* data on the date listed in the letterhead of the CCN Notification letter received from CMS but will be subject to the APU reduction based on whether the CCN Notification letter was dated before or after November 1 of the reporting year involved. Thus, beginning with the FY 2018 payment determination and for each subsequent payment determination, we finalized our policy that a new hospice be responsible for HQRP quality data submission beginning on the date of the CCN notification letter; we retained our prior policy that hospices not be subject to the APU reduction if the CCN notification letter was dated after November 1 of the year involved. For example, if a provider receives their CCN notification letter and the date in the letterhead is November 5, 2016, that provider will begin submitting HIS data for patient admissions occurring after November 5, 2016. However, since the CCN notification letter was dated after November 1st, they would not be evaluated for, or subject to any payment penalties for, the relevant FY APU update (which in this instance is the FY 2018 APU, which is associated with patient admissions occurring 1/1/16–12/31/16).

This policy allows CMS to receive HIS data on all patient admissions on or after the date a hospice receives their CCN notification letter, while at the same time allowing hospices flexibility and time to establish the necessary accounts for data submission before they are subject to the potential APU reduction for a given reporting year. Currently, new hospices may experience a lag between Medicare certification and receipt of their actual CCN Number. Since hospices cannot submit data to the QIES ASAP system without a valid CCN Number, CMS proposed that new hospices begin collecting HIS quality data beginning on the date noted on the CCN notification letter. We believe this policy will provide sufficient time for new hospices to establish appropriate collection and reporting mechanisms to submit the required quality data to CMS. Requiring quality data reporting beginning on the date listed in the letterhead of the CCN notification letter aligns CMS policy for requirements for new providers with the functionality of the HIS data submission system (QIES ASAP).

c. Previously Finalized Data Submission Mechanism, Collection Timelines, and Submission Deadlines for the FY 2017 Payment Determination

In the FY 2015 Hospice Wage Index final rule (79 FR 50486), we finalized our policy requiring that, for the FY 2017 reporting requirements, hospices must complete and submit HIS records for all patient admissions to hospice after July 1, 2014. For each HQRP program year, we require that hospices submit data on each of the adopted measures in accordance with the reporting requirements specified in sections III.C.7c through III.C.7e of that rule for the designated reporting period. This requirement applies to previously finalized and adopted measures, as well as new measures proposed through the rulemaking process. Electronic submission is required for all HIS records. Although electronic submission of HIS records is required, hospices do not need to have an electronic medical record to complete or submit HIS data. In the FY 2014 Hospice Wage Index final rule (78 FR 48258), we finalized a provision requiring that providers can use either the Hospice Abstraction Reporting Tool (HART) (which is free to download and use) or vendor-designed software to complete HIS records. HART provides an alternative option for hospice providers to collect and maintain facility, patient, and HIS Record information for subsequent submission to the QIES ASAP system. Once HIS records are complete, electronic HIS files must be submitted to CMS via the QIES ASAP system. Electronic data submission via the QIES ASAP system is required for all HIS submissions; there are no other data submission methods available. Hospices have 30 days from a patient admission or discharge to submit the appropriate HIS record for that patient through the QIES ASAP system. CMS will continue to make HIS completion and submission software available to hospices at no cost. We provided details on data collection and submission timing under the downloads section of the HIS Web site on the *CMS.gov* Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Hospice-Item-Set-HIS.html*.

The QIES ASAP system provides reports upon successful submission and processing of the HIS records. The final validation report may serve as evidence of submission. This is the same data submission system used by nursing homes, inpatient rehabilitation facilities, home health agencies, and long-term care hospitals for the submission of Minimum Data Set Version 3.0 (MDS 3.0), Inpatient Rehabilitation Facility-patient assessment instrument (IRF–PAI), Outcome Assessment Information Set (OASIS), and Long-Term Care Hospital Continuity Assessment Record & Evaluation Data Set (LTCH CARE), respectively. We have provided hospices with information and details about use of the HIS through postings on the HQRP Web site, Open Door Forums, announcements in the CMS MLN Connects Provider e-News (E-News), and provider training.

d. Previously Finalized Data Submission Timelines and Requirements for FY 2018 Payment Determination and Subsequent Years

Hospices are evaluated for purposes of the quality reporting program based on whether or not they submit data, not on their substantive performance level for the required quality measures. In order for CMS to appropriately evaluate the quality reporting data received by hospice providers, it is essential HIS data be received in a timely manner.

The submission date is the date on which the completed record is submitted and accepted by the QIES ASAP system. In the FY 2016 Hospice Wage Index final rule (80 FR 47191), CMS finalized our policy that beginning with the FY 2018 payment determination hospices must submit all HIS records within 30 days of the event date, which is the patient's admission date for HIS-Admission records or discharge date for HIS-Discharge records.

For HIS-Admission records, the submission date must be no later than the admission date plus 30 calendar days. The submission date can be equal to the admission date, or no greater than 30 days later. The QIES ASAP system will issue a warning on the Final Validation Report if the submission date is more than 30 days after the patient's admission date.

For HIS-Discharge records, the submission date must be no later than the discharge date plus 30 calendar days. The submission date can be equal to the discharge date, or no greater than 30 days later. The QIES ASAP system will issue a warning on the Final Validation Report if the submission date is more than 30 days after the patient's discharge date.

The QIES ASAP system validation edits are designed to monitor the timeliness of submission and ensure that providers' submitted records conform to the HIS data submission specifications. Providers are notified when timing criteria have not been met by warnings that appear on their Final Validation Reports. A standardized data collection approach that coincides with timely submission of data is essential to establish a robust quality reporting program and ensure the scientific reliability of the data received.

In the FY 2016 Hospice Wage Index final rule (80 FR 47191), CMS also clarified the difference between the completion deadlines and the submission deadlines. Current sub-regulatory guidance produced by CMS (for example, HIS Manual, HIS trainings) states that the completion deadlines for HIS records are 14 days from the Event Date for HIS-Admission records and 7 days from the Event Date for HIS-Discharge records. Completion deadlines continue to reflect CMS guidance only; these guidelines are not statutorily specified and are not designated through regulation. These guidelines are intended to offer clear direction to hospice agencies in regards to the timely completion of HIS-Admission and HIS-Discharge records. The completion deadlines define only the latest possible date on which a hospice should complete each HIS record. This guidance is meant to better align HIS completion processes with clinical workflow processes; however, hospices may develop alternative internal policies to complete HIS records. Although it is at the discretion of the hospice to develop internal policies for completing HIS records, CMS continues to recommend that providers complete and attempt to submit HIS records early, prior to the previously finalized submission deadline of 30 days, beginning in FY 2018. Completing and attempting to submit records early allows providers ample time to address any technical issues encountered in the QIES ASAP submission process, such as correcting fatal error messages. Completing and attempting to submit records early will ensure that providers are able to comply with the 30 day submission deadline.

HQRP guidance documents, including the CMS HQRP Web site, HIS Manual, HIS trainings, Frequently Asked Questions, and Fact Sheets, continue to offer the most up-to-date CMS guidance to assist providers in the successful completion and submission of HIS records. Availability of updated guidance will be communicated to providers through the usual CMS HQRP communication channels, including postings and announcements on the CMS HQRP Web site, MLN eNews communications, national provider association calls, and announcements on Open Door Forums and Special Open Door Forums.

e. Previously Finalized HQRP Data Submission and Compliance Thresholds for the FY 2018 Payment Determination and Subsequent Years

To accurately analyze quality reporting data received by hospice providers, it is imperative we receive ongoing and timely submission of all HIS-Admission and HIS-Discharge records. In the FY 2016 Hospice Wage Index final rule (80 FR 47192), CMS finalized the timeliness criteria for submission of HIS-Admission and HIS-Discharge records. The finalized timeliness criteria was in response to input from our stakeholders seeking additional specificity related to HQRP compliance affecting FY payment determinations and, due to the importance of ensuring the integrity of quality data submitted.

Last year, we finalized our policy (80 FR 47191 through 47192) that beginning with the FY 2018 payment determination and subsequent FY payment determinations, all HIS records would have to be submitted within 30 days of the event date, which is the patient's admission date or discharge date. In conjunction with this requirement, we also finalized our policy (80 FR 47192) to establish an incremental threshold for compliance over a 3-year period. To be compliant for the FY 2018 APU determination, hospices must submit no less than 70 percent of their total number of HIS-Admission and HIS-Discharge records by no later than 30 days from the event date. The timeliness threshold is set at 80 percent for the FY 2019 APU determination and at 90 percent for the FY 2020 APU determination and subsequent years. The threshold corresponds with the overall amount of HIS records received from each provider that fall within the established 30 day submission timeframes. Our ultimate goal is to require all hospices to achieve a compliance rate of 90 percent or more.

To summarize, in the FY 2016 Hospice Wage Index final rule (80 FR 47193), we finalized our policy to implement the timeliness threshold requirement beginning with all HIS admission and discharge records that occur after January 1, 2016, in accordance with the following schedule.

- Beginning January 1, 2016 to December 31, 2016, hospices must submit at least 70 percent of all required HIS records within the 30 day submission timeframe for the year or be subject to a 2 percentage point reduction to their market basket update for FY 2018.
- Beginning January 1, 2017 to December 31, 2017, hospices must submit at least 80 percent of all required HIS records within the 30 day submission timeframe for the year or be subject to a 2 percentage point reduction to their market basket update for FY 2019.
- Beginning January 1, 2018 to December 31, 2018, hospices must submit at least 90 percent of all required HIS records within the 30 day submission timeframe for the year or be subject to a 2 percentage point reduction to their market basket update for FY 2020.

Timely submission of data is necessary to accurately analyze quality measure data received by providers. To support the feasibility of a hospice to achieve the compliance thresholds, CMS's measure development contractor conducted some preliminary analyses of Quarter 3 and Quarter 4 HIS data from 2014. According to this analysis, the vast majority of hospices (92 percent) would have met the compliance thresholds at 70 percent. Moreover, 88 percent and 78 percent of hospices would have met the compliance thresholds at 80 percent and 90 percent, respectively. CMS believes this analysis is further evidence that the compliance thresholds are reasonable and achievable by hospice providers.

The current reports available to providers in the Certification and Survey Provider Enhanced Reports (CASPER) system do allow providers to track the number of HIS records that are submitted within the 30 day submission timeframe. Currently, submitting an HIS record past the 30 day submission timeframe results in a non-fatal (warning) error. In April 2015, CMS made available 3 new Hospice Reports in CASPER, which include reports that can list HIS Record Errors by Field by Provider and HIS records with a specific error number. CMS is working on expanding this functionality of CASPER reports to include a timeliness compliance threshold report that

providers could run to determine their preliminary compliance with the timeliness compliance requirement. CMS expects these reports to be available by late fall of 2016.

In the FY 2016 Hospice Wage Index final rule (80 FR 47192 through 47193), CMS provided clarification regarding the methodology used in calculating the 70 percent/80 percent/90 percent compliance thresholds. In general, HIS records submitted for patient admissions and discharges occurring during the reporting period (January 1st to December 31st of the reporting year involved) will be included in the denominator for the compliance threshold calculation. The numerator of the compliance threshold calculation would include any records from the denominator that were submitted within the 30 day submission deadline. In the FY 2016 Hospice Wage Index final rule (80 FR 47192), CMS also stated we would make allowances in the calculation methodology for two circumstances. First, the calculation methodology will be adjusted following the applicable reporting period for records for which a hospice is granted an extension or exemption by CMS. Second, adjustments will be made for instances of modification/inactivation requests (Item A0050. Type of Record = 2 or 3). Additional helpful resources regarding the timeliness compliance threshold for HIS submissions can be found under the downloads section of the Hospice Item Set Web site at CMS.gov at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Hospice-Item-Set-HIS.html.* Lastly, as further details of the data submission and compliance threshold are determined by CMS, we anticipate communicating these details through the regular CMS HQRP communication channels, including postings and announcements on the CMS HQRP Web site, MLN eNews communications, national provider association calls, and announcements on Open Door Forums and Special Open Door Forums.

Comment: A few commenters commented on our previously finalized policies for form, manner, and timing of data collection. One commenter raised concern about the ability of hospices to comply with the incremental 70 percent/80 percent/90 percent timeliness compliance threshold in cases of natural disasters. Specifically, the commenter was concerned that in the case of protracted natural disasters (for example, Hurricane Sandy), hospice organizations may not be able to email CMS within the 30-day timeframe to request an extension or exemption as appropriate, and that, in turn, failure to submit a timely request for extension or exemption may put a hospice at risk of non-compliance with the timeliness threshold. Another commenter stated they believed the process for HIS data collection and submission, which relies heavily on chart abstraction, was error-ridden and outdated. The commenter encouraged CMS to automate data collection and submission processes via electronic submission of HIS data.

Response: We thank the commenters for their comments on our previously finalized policies for form, manner, and timing of data collection. Regarding the first commenter's concern about ability to submit a timely extension or exemption request to maintain compliance with the 70/80/90 timeliness compliance thresholds in the case of extended natural disasters, CMS refers readers to our previously finalized policies for extensions and exemptions, addressed in section III.C.8 of this rule. As noted in section III.C.8, in instances of extraordinary circumstances (like widespread natural disasters), we may grant an extension/exemption to hospices that have not requested them, which may include instances where hospices are unable to make the request within the 30-day timeframe due to extenuating circumstances. Regarding the second commenter's request for electronic data collection and submission processes for the HIS, we would like to clarify that, as noted in section III.C.7.c of this rule, electronic submission of HIS records is already required; no other data submission methods are available. Hospices are required to submit all HIS records through the QIES ASAP system. We also provide electronic software to hospices free of charge that allows hospices to complete HIS records electronically; alternatively, hospices may choose to use vendor-designed software to complete HIS records. As noted by the commenter, we believe this electronic process of data completion and submission minimizes burden on providers and helps ensure data quality through the HIS record validation process. We refer readers to section III.C.7.c for more information on mechanisms of data submission for the HIS.

f. New Data Collection and Submission Mechanisms Under Consideration for Future Years

CMS has made great progress in implementing the objectives set forth in the quality reporting and data collection activities required by sections 3004 of the Affordable Care Act. To date, CMS has established the HQRP, which includes 7 NQF-endorsed quality measures that are collected via the HIS. As stated in this rule, data on these measures are expected to be publicly reported sometime in 2017. Additionally, CMS has also implemented the Hospice CAHPS® as part of the HQRP to gather important input on patient experience of care in hospice. Over the past several years, CMS has conducted data collection and analysis on hospice utilization and trends to help reform the hospice payment system. In the FY 2016 Hospice Wage Index final rule, we finalized payment reform measures, including changes to the RHC payment rate and the implementation of a Service Intensity Add-On (SIA) payment, effective January 1st, 2016. As part of payment reform and ongoing program integrity efforts, we will continue ongoing monitoring of utilization trends for any future refinements.

To facilitate continued progress towards the requirements set forth in section 3004 of the Affordable Care Act, CMS is considering developing a new data collection mechanism for use by hospices. This new data collection mechanism would be a hospice patient assessment instrument, which would serve 2 primary objectives concordant with the Affordable Care Act legislation: (1) To provide the quality data necessary for HQRP requirements and the current function of the HIS; and (2) provide additional clinical data that could inform future payment refinements.

CMS believes that the development of a hospice patient assessment tool could offer several benefits over the current mechanisms of data collection for quality and payment purposes, which include the submission of HIS data and the submission of claims data. For future payment refinements, a hospice patient assessment tool would allow CMS to gather more detailed clinical information, beyond the patient diagnosis and comorbidities that are currently reported on hospice claims. As stated in the FY 2016 Hospice Wage Index final rule (80 FR 47203), detailed patient characteristics are necessary to determine whether a case mix payment system could be achieved. A hospice patient assessment tool would allow CMS to capture information on symptom burden, functional status, and patient, family, and caregiver preferences, all of which will inform future payment refinements.

While systematic assessment is vital throughout the continuum of care, including palliative and end-of-life care, documentation confirming completion

of systematic assessment in hospice settings is often inadequate or absent.[32] The value of the introduction of structured approaches via a clinical assessment is well established, as it enables a more comprehensive and consistent way of identifying and meeting patient needs.[33]

Moreover, symptoms are the leading reason that people seek medical care in the first place and frequently serve as the basis for establishing a diagnosis. Measures of physical function and disease burden have been used to identify older adults at high-risk for excess health care utilization, disability, or mortality.[34] Currently, data collected on claims includes line-item visits by discipline, General Inpatient Care (GIP) visit reporting to hospice patients in skilled nursing facilities or hospitals, post-mortem visits, injectable and non-injectable drugs and infusion pumps. Industry representatives have communicated to CMS that required claims information is not sufficiently comprehensive to accurately reflect the provision and the cost of hospice care.

For quality data collection, a hospice patient assessment instrument would support the goals of the HQRP as new quality measures are developed and adopted. Since the current quality data collection tool (HIS) is a chart abstraction tool, not a hospice patient assessment instrument, CMS is limited in the types of data that can be collected via the HIS. Instead of retrospective data collection elements, a hospice patient assessment tool would include data elements designed to be collected concurrent with provision of care. As such, CMS believes a hospice patient assessment tool would allow for more robust data collection that could inform development of new quality measures that are meaningful to hospice patients, their families and caregivers, and other stakeholders.

Finally, a hospice patient assessment tool that provides clinical data that is used for both payment and quality purposes would align the hospice benefit with other care settings that use similar approaches, such as nursing homes, inpatient rehabilitation facilities, and home health agencies which submit data via the MDS 3.0, IRF–PAI, and OASIS, respectively.

CMS envisions the hospice patient assessment tool itself as an expanded HIS. The hospice patient assessment tool would include current HIS items, as well as additional clinical items that could be used for payment refinement purposes or to develop new quality measures. The hospice patient assessment tool would not replace existing requirements set forth in the Medicare Hospice CoPs (such as the initial nursing and comprehensive assessment), but would be designed to complement data that are collected as part of normal clinical care. If such a patient assessment were adopted, the new data collection effort would replace the current HIS, but would not replace other HQRP data collection efforts (that is, the Hospice CAHPS® survey), nor would it replace regular submission of claims data. CMS envisions that patient assessment data would be collected upon a patient's admission to and discharge from any Medicare-certified hospice provider; additional interim data collection efforts are also possible. Should CMS develop and implement a hospice patient assessment tool, CMS would provide several training opportunities to ensure providers are able to comply with any new requirements.

CMS is not proposing a hospice patient assessment tool at this time; we are still in the early stages of development of an assessment tool to determine if it would be feasible to implement under the Medicare Hospice Benefit. In the development of such a hospice patient assessment tool, CMS will continue to receive stakeholder input from MedPAC and ongoing input from the provider community, Medicare beneficiaries, and technical experts. It is of the utmost importance to CMS to develop a hospice patient assessment tool that is scientifically rigorous and clinically appropriate, thus we believe that continued and transparent involvement of stakeholders is critical. Additionally, it is of the utmost importance to CMS to minimize data collection burden on providers; in the development of any hospice patient assessment tool, CMS will ensure that patient assessment data items are not duplicative or overly burdensome to providers, patients, caregivers, or their families.

We received multiple comments pertaining to a potential hospice patient assessment tool to collect quality, clinical and other data with the ability to be used to inform future payment refinement efforts. The following is a summary of the comments we received on this topic and our responses.

Comment: CMS received many comments about the potential new data collection mechanism—a comprehensive, standardized hospice patient assessment instrument—under consideration for future years. Overall, the vast majority of commenters were supportive of CMS's efforts to develop a patient assessment tool. Commenters believed that a patient assessment tool capturing information on symptom burden, functional status, and patient, family, and caregiver preferences has the potential to more accurately inform future payment refinements and quality measure development based on the needs of the populations served. Commenters noted that the development of a patient assessment tool would be an integral step in improving care management and coordination across settings, providing standardized data on the services that patients and families receive to better understand the complex patient characteristics. One of the commenters, MedPAC, supported the development of a patient assessment instrument, noting its potential value in capturing more meaningful quality data, as well as providing more detailed clinical information that might be useful for payment policy.

Commenters offered several suggestions for CMS to consider in moving forward with the development of a patient assessment tool. Suggestions focused on two main themes: (1) Considerations for the content of any patient assessment tool (2) considerations for the process used by CMS to develop and test a patient assessment tool. Beyond these two themes, commenters also listed other considerations, including cross-setting considerations (experience with other assessment tools and relationship to the IMPACT Act), burden and costs, use for future payment refinements, and general concerns.

Regarding considerations for the content of a patient assessment tool, overall, commenters emphasized the unique nature and care goals of hospice, urging CMS to bear in mind these complexities in the development of a patient assessment. Specifically, commenters stated that the patient assessment tool should reflect the holistic nature of hospice care delivery to the patient and their loved ones and should include physical, psychosocial, and spiritual components. Commenters also noted that the unit of care in hospice is the patient and family, and that the initial and ongoing assessment, as well as care planning and

[32] McMillan, S., Small, B., & Haley, W. (2011). Improving Hospice Outcomes through Systematic Assessment: A Clinical Trial. *Cancer Nursing,* 34(2), 89–97.

[33] Bourbonnais, F.F., Perreault, A., & Bouvette, M. (2004). Introduction of a pain and symptom assessment tool in the clinical setting—lessons learned. *Journal of Nursing Management,* 12(3), 194–200.

[34] Sha, M., Callahan, C., Counsell, S., Westmoreland, G., Stump, T., Kroenke, K. (2005). Physical symptoms as a predictor of health care use and mortality among older adults. 118, 301–306.

interventions, address the holistic care needs of both the patient and family. Commenters urged CMS not to limit the focus of a patient assessment tool to the clinical, ''head-to-toe'' nursing assessment, since care plans in hospice are often ''more personal than medical'' with emphasis on the patient's family and environment. Similarly, commenters pointed out the interdisciplinary nature of hospice, and recommended that any patient assessment tool include information from the entire hospice team. In consideration of all of these factors, commenters ultimately urged CMS to develop data elements that are relevant and meaningful to hospice practice.

In addition to comments about the nature and goals of hospice care, several commenters also had specific content suggestions for CMS to consider in the development of a patient assessment tool:

- Several commenters recommended that the assessment tool recognize the patient's right to refuse or defer offered services and the importance of an individualized plan of care.
- Several commenters recommended that the assessment tool accommodate care delivered in various settings, including nursing homes, assisted living facilities, hospitals, hospice facilities, and the patient's home.
- Several commenters recommended that the assessment tool allow for modified assessment of patients who are imminently dying to facilitate a focus on the urgent and immediate needs of the patient and family. Commenters noted that for imminently dying patients, the focus is the management of symptoms and the family's emotions, not necessarily a detailed medical history and physical assessment of the patient.
- Several commenters noted that the assessment tool should preserve the integrity of the hospice philosophy by allowing hospice interdisciplinary team members to individualize assessments and care based on their best clinical judgment. Additionally, commenters recommended that CMS not place overly restrictive limits on members of the interdisciplinary team that are permitted to complete the assessment tool. Commenters recommended that CMS allow several disciplines to contribute patient information and goals on the assessment, noting that this was a limitation of other assessment tools.
- One commenter recommended that CMS collect assessment data beyond the admission and discharge time points discussed in the proposed rule (81 FR 25528). The commenter noted the importance of measuring care throughout the entire stay, not just at admission and discharge.
- Commenters recommended that any outcome measure derived from the assessment be risk-adjusted.
- A couple of commenters suggested that any ''Reason for Discharge'' item(s) on the assessment tool differentiate the reason behind any live discharges (for example, revoked vs. moved out of service area).
- One commenter recommended CMS consider the International Classification of Function (ICF), in the development of a patient assessment tool. The commenter noted that the ICF provides a scientific basis for understanding health and health-related states as well as outcomes, related to both physical as well as social determinants, and could be a way to determine appropriate outcomes more quickly. Finally, the commenter noted that the ICF is already integrated into the ICD–10 and ICD–11 taxonomy internationally.
- Another commenter recommended that CMS align any new hospice assessment tool with the National Consensus Project for Quality Palliative Care Clinical Practice Guidelines for Quality Palliative Care.

Commenters had several suggestions regarding the process for development of any patient assessment tool. The majority of comments on the process for assessment tool development focused on systematically and comprehensively gathering input from hospice providers and other stakeholders with respect to what is appropriate and relevant to include in the assessment tool. Commenters offered specific suggestions of ways to involve the provider community, including CMS-convened technical expert panels (TEP) that include representation from hospices, physicians, and other members of the hospice Interdisciplinary Team (IDT). In addition to TEPs, one commenter suggested that CMS consider extending opportunities for input beyond TEPs and employ widespread processes for gathering provider input. Commenters also had suggestions for testing and refinement of a patient assessment tool. Commenters recommended piloting the tool with a wide variety of hospices, to ensure that the assessment tool is tested with variation in hospice size, rurality, state regulatory environments, and organization type (that is, hospital based, freestanding, those with inpatient facilities vs. those who contract for inpatient care, etc.). Commenters recommended a pilot testing process that is thorough and includes a dry-run period or phased-in implementation approach. Finally, commenters encouraged CMS to provide thorough and ongoing education and support for hospices as the patient assessment tool is implemented. Commenters specifically requested that educational materials include clear definitions of patient assessment items and data collection procedures.

Several commenters also discussed their experience with assessment tools in other care settings (for example, the OASIS in home health and the MDS in nursing homes). Some commenters expressed concerns about potential overreliance on existing assessment instrument items citing the difference in care goals between hospice and other post-acute care settings. These commenters emphasized the importance of creating an assessment tool tailored to the unique needs of hospice. On the other hand, commenters also urged CMS to create an assessment tool that is aligned and consistent with other assessment tools to facilitate care coordination and planning across the care continuum.

A few commenters offered considerations on potential burden and costs of a new assessment instrument. Commenters urged CMS to pursue efforts that would limit administrative burden, reduce redundancy, and ensure the use of definitions consistent with other assessment tools. Commenters noted that the assessment would likely be completed by different staff than those who are currently completing the HIS-Admission and HIS-Discharge records and that the assessment would likely be more time-intensive than the current HIS. Commenters urged CMS to consider increased costs to providers and to take into consideration the time and resources necessary to complete the assessment.

One commenter suggested that CMS—as appropriate—consider harmonizing measures from the IMPACT Act. The commenter noted that such harmonization would facilitate communication among providers and to measure the care of patient populations across setting measures. With respect to use of the patient assessment for future payment refinements, a few commenters noted the importance of rigorous testing of assessment items for inter-rater reliability and validity.

Beyond the support and suggestions offered, some commenters did raise concerns about a patient assessment tool. Commenters cautioned against a patient assessment tool that would lead to ''checklist'' assessments and undue restrictions on patient eligibility and the freedom to employ clinical judgment. Finally, one commenter had concerns about the flexibility of electronic medical record systems to capture

assessment items in a structured and minimally burdensome manner.

Response: First, we thank the commenters for their support of the development of a patient assessment tool. We agree that development of a patient assessment tool is a critical next step in refining quality data collection efforts and to inform future refinements to the hospice payment system. Second, we greatly appreciate the thoughtful input and recommendations from the hospice community. We believe the initial input from our stakeholders regarding the content and process for development of a patient assessment tool is aligned with our vision and guiding principles for moving forward with developing this new data collection mechanism. We would like to assure the provider community that we wholeheartedly agree with commenters regarding the unique nature of hospice care, and we intended to keep the hospice philosophy as the foundation of the patient assessment tool. We seek to develop an assessment tool that reflects the distinctive aspects of hospice care, including the palliative, rather than curative, focus of hospice care. We agree with the points raised by commenters about the overall focus of an assessment tool and aims to develop a tool that addresses the holistic nature of hospice, incorporating important medical, psychosocial, spiritual, and other aspects of care that are important for patients and their caregivers. We also appreciate commenters' specific suggestions regarding the content of a patient assessment tool including the need for a flexible assessment, which would incorporate input from various members of the IDT and accommodate circumstances unique to hospice such as care of the imminently dying and patient/caregivers' right to decline services or treatment.

With respect to commenters' suggestions about the process for development of a patient assessment tool, we would again like to thank the hospice community for their detailed input and careful consideration. Again, we would like to assure the provider community that it is our intent to use a development process that is transparent and includes multiple opportunities for stakeholder input. Feedback from the provider community is vital to the development of a patient assessment tool that is meaningful and not unduly burdensome on providers. As noted by commenters and discussed in this rule, CMS plans to hold TEPs to inform the development, testing, and refinement of the patient assessment. CMS also plans to provide other opportunities for stakeholders to provide input through venues such as special open door forums and other regular HQRP communication channels. We are committed to a development process that will ensure rigorous and iterative testing of the patient assessment tool in hospices with varying organizational characteristics, patient populations, settings of care delivery, and levels of care. We recognize the emphasis that we will need to place on thorough testing and analysis of items for reliability and validity, particularly for purposes of any future payment refinements. Finally, we agree that ongoing training and education will be vital, and we will ensure access to regular HQRP education and outreach outlets, such as training webinars, manuals and access to various Helpdesks.

We also appreciate commenters' suggestions on cross-setting harmonization and for sharing their experience with assessment tools in other care settings. We would like to assure commenters that we recognize the unique nature of hospice care; it is not our intent to develop an assessment tool that inappropriately relies on items from existing tools, such as the Minimum Data Set (MDS) and Outcome and Information Assessment Information Set (OASIS). We will work diligently with the provider community to gather information on current assessment practices in hospice and to ensure that a hospice assessment tool would capture the goals of hospice care and be complementary to current clinical practice. Regarding the commenters' suggestion to harmonize assessment items and resulting quality measure with the IMPACT Act quality measures, we appreciate the commenter's suggestion and will take it under consideration for future measure and assessment development.

Finally, with respect to concerns raised by commenters about costs and administrative burden, as stated in the rule, it is our goal to minimize data collection burden on providers and ensure that patient assessment items are not duplicative or overly burdensome to providers, patients, or their families. We believe that regular, ongoing input from the provider community will aide in the development of an assessment that is not overly burdensome. We expect that development of the patient assessment will take into account the ongoing movement toward use of certified EHRs and other interoperable health IT across all patient settings. We expect that our consultations with providers and with technical experts including health IT experts will include assessing and taking advantage of opportunities to develop and deploy the instrument in a way that integrates with hospice work flows and with the potential of health IT to help providers improve care, communication and coordination across the interdisciplinary care team while reducing burden on clinicians and other care team members by streamlining data collection and management. In addition, any patient assessment tool would be submitted to OMB as required by the Paperwork Reduction Act, the purpose of which is to ensure that Federally-sponsored data collection efforts pose no undue burden on the public.

We appreciate the input from the public regarding the development of a patient assessment tool for hospice. We will continue to inform our stakeholders on any progress and proposals regarding the patient assessment tool through future rulemaking cycles.

8. HQRP Submission Exemption and Extension Requirements for the FY 2017 Payment Determination and Subsequent Years

In the FY 2015 Hospice Wage Index final rule (79 FR 50488), we finalized our proposal to allow hospices to request, and for CMS to grant, exemptions/extensions for the reporting of required HIS quality data when there are extraordinary circumstances beyond the control of the provider. When an extension/exemption is granted, a hospice will not incur payment reduction penalties for failure to comply with the requirements of the HQRP. For the FY 2016 payment determination and subsequent payment determinations, a hospice may request an extension/exemption of the requirement to submit quality data for a specified time period. In the event that a hospice requests an extension/exemption for quality reporting purposes, the hospice would submit a written request to CMS. In general, exemptions and extensions will not be granted for hospice vendor issues, fatal error messages preventing record submission, or staff error.

In the event that a hospice seeks to request an exemptions or extension for quality reporting purposes, the hospice must request an exemption or extension within 30 days of the date that the extraordinary circumstances occurred by submitting the request to CMS via email to the HQRP mailbox at *HospiceQRPReconsiderations@cms.hhs.gov.* Exception or extension requests sent to CMS through any other channel will not be considered valid. The request for an exemption or extension must contain all of the finalized requirements as outlined on our Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-*

Quality-Reporting/Extensions-and-Exemption-Requests.html.

If a hospice is granted an exemption or extension, timeframes for which an exemption or extension is granted will be applied to the new timeliness requirement so such hospices are not penalized. If a hospice is granted an exemption, we will not require that the hospice submit any quality data for a given period of time. By contrast, if we grant an extension to a hospice, the hospice will still remain responsible for submitting quality data collected during the timeframe in question, although we will specify a revised deadline by which the hospice must submit these quality data.

This process does not preclude us from granting extensions/exemptions to hospices that have not requested them when we determine that an extraordinary circumstance, such as an act of nature, affects an entire region or locale. We may grant an extension/exemption to a hospice if we determine that a systemic problem with our data collection systems directly affected the ability of the hospice to submit data. If we make the determination to grant an extension/exemption to hospices in a region or locale, we will communicate this decision through routine CMS HQRP communication channels, including postings and announcements on the CMS HQRP Web site, MLN eNews communications, national provider association calls, and announcements on Open Door Forums and Special Open Door Forums.

9. Hospice CAHPS® Participation Requirements for the 2019 APU and 2020 APU

National Implementation of the Hospice CAHPS® Survey started January 1, 2015 as stated in the FY 2015 Hospice Wage Index and Payment Rate Update final rule (79 FR 50452). The CAHPS® Hospice Survey is a component of CMS' Hospice Quality Reporting Program that emphasizes the experiences of hospice patients and their primary caregivers listed in the hospice patients' records. Readers who want more information are referred to our extensive discussion of the Hospice Experience of Care Survey in the Hospice Wage Index FY 2015 final rule for a description of the measurements involved and their relationship to the statutory requirement for hospice quality reporting (79 FR 50450 also refer to 78 FR 48261).

a. Background and Description of the Survey

The CAHPS® Hospice Survey is the first national hospice experience of care survey that includes standard survey administration protocols that allow for fair comparisons across hospices. Consistent with many other CMS CAHPS® surveys that are publicly reported on CMS Web sites, CMS will publicly report hospice data when at least 12 months of data are available, so that valid comparisons can be made across hospice providers in the United States, in order to help patients, family, friends, and caregivers choose the right hospice program.

The goals of the CAHPS® Hospice Survey are to:

- Produce comparable data on hospice patients' and caregivers' perspectives of care that allow objective and meaningful comparisons between hospices on domains that are important to consumers.
- Create incentives for hospices to improve their quality of care through public reporting of survey results.
- Hold hospice care providers accountable by informing the public about the providers' quality of care.

Details regarding CAHPS® Hospice Survey national implementation, and survey administration as well as participation requirements, exemptions from the survey requirement, hospice patient and caregiver eligibility criteria, fielding schedules, sampling requirements, and the languages in which is questionnaire, are available on the CAHPS® Web site, *www.HospiceCAHPSsurvey.org* and in the Quality Assurance Guidelines (QAG) manual, which is also on the same site and is available for download. Measures from the survey will be submitted to the NQF for endorsement.

b. Participation Requirements To Meet Quality Reporting Requirements for the FY 2019 APU

To meet participation requirements for the FY 2019 APU, hospices must collect survey data on an ongoing monthly basis from January 2017 through December 2017 (inclusive). Data submission deadlines for the 2019 APU can be found in Table 17. The data must be submitted by the deadlines listed in Table 17 by the hospice's authorized approved CMS vendor.

Hospices provide lists of the patients who died under their care to form the sample for the Hospice CAHPS® Survey. We emphasize the importance of hospices providing complete and accurate information to their vendors in a timely manner. Hospices must contract with an approved Hospice CAHPS® Survey vendor to conduct the survey on their behalf. The hospice is responsible for making sure their vendor meets all data submission deadlines. Vendor failure to submit data on time will be the responsibility of the hospice.

TABLE 17—CAHPS® HOSPICE SURVEY DATA SUBMISSION DATES FY 2018 APU, FY 2019 APU, AND FY 2020 APU

Sample months (that is, month of death) [1]	Quarterly data submission deadlines [2]
FY 2018 APU	
January–March 2016 (Q1)	August 10, 2016.
April–June 2016 (Q2)	November 9, 2016.
July–September 2016 (Q3)	February 8, 2017.
October–December 2016 (Q4)	May 10, 2017.
FY 2019 APU	
January–March 2017 (Q1)	August 9, 2017.
April–June 2017 (Q2)	November 8, 2017.
July–September 2017 (Q3)	February 14, 2018.
October–December 2017 (Q4)	May 9, 2018.
FY 2020 APU	
January–March 2018 (Q1)	August 8, 2018.

TABLE 17—CAHPS® HOSPICE SURVEY DATA SUBMISSION DATES FY 2018 APU, FY 2019 APU, AND FY 2020 APU—Continued

Sample months (that is, month of death) [1]	Quarterly data submission deadlines [2]
April–June 2018 (Q2)	November 14, 2018.
July–September 2018 (Q3)	February 13, 2019.
October–December 2018 (Q4)	May 8, 2019.

[1] Data collection for each sample month initiates 2 months following the month of patient death (for example, in April for deaths occurring in January).

[2] Data submission deadlines are the second Wednesday of the submission months, which are Augst, November, February, and May.

Hospices that have fewer than 50 survey-eligible decedents/caregivers in the period from January 1, 2016 through December 31, 2016 are exempt from CAHPS® Hospice Survey data collection and reporting requirements for the FY 2019 payment determination. To qualify, hospices must submit an exemption request form. This form will be available in first quarter 2017 on the CAHPS® Hospice Survey Web site *http://www.hospiceCAHPSsurvey.org.* Hospices that want to claim the size exemption are required to submit to CMS their total unique patient count for the period of January 1, 2016 through December 31, 2016. The due date for submitting the exemption request form for the FY 2019 APU is August 10, 2017.

CMS proposed that hospices that received their CCN after January 1, 2017 are exempted from the FY 2019 APU Hospice CAHPS® requirements due to newness. This exemption will be determined by CMS. The exemption is for 1 year only.

c. Participation Requirements To Meet Quality Reporting Requirements for the FY 2020 APU

To meet participation requirements for the FY 2020 APU, hospices must collect survey data on an ongoing monthly basis from January 2018 through December 2018 (inclusive). Data submission deadlines for the 2020 APU can be found in Table 17. The data must be submitted by the deadlines in Table 17 by the hospice's authorized approved CMS vendor.

Hospices that have fewer than 50 survey-eligible decedents/caregivers in the period from January 1, 2017 through December 31, 2017 are exempt from CAHPS® Hospice Survey data collection and reporting requirements for the FY 2020 payment determination. To qualify, hospices must submit an exemption request form. This form will be available in first quarter 2018 on the CAHPS® Hospice Survey Web site *http://www.hospiceCAHPSsurvey.org.* Hospices that want to claim the size exemption are required to submit to CMS their total unique patient count for the period of January 1, 2017 through December 31, 2017. The due date for submitting the exemption request form for the FY 2020 APU is August 10, 2018.

CMS proposed that hospices that received their CCN after January 1, 2018 are exempted from the FY 2020 APU Hospice CAHPS® requirements due to newness. This exemption will be determined by CMS. The exemption is for 1 year only.

d. Annual Payment Update

The Affordable Care Act requires that beginning with FY 2014 and each subsequent fiscal year, the Secretary shall reduce the market basket update by 2 percentage points for any hospice that does not comply with the quality data submission requirements for that fiscal year, unless covered by specific exemptions. Any such reduction will not be cumulative and will not be taken into account in computing the payment amount for subsequent fiscal years. In the FY 2015 Hospice Wage Index final rule, we added the CAHPS® Hospice Survey to the Hospice Quality Reporting Program requirements for the FY 2017 payment determination and determinations for subsequent years.

- To meet the HQRP requirements for the FY 2018 payment determination, hospices would collect survey data on a monthly basis for the months of January 1, 2016 through December 31, 2016 to qualify for the full APU.
- To meet the HQRP requirements for the FY 2019 payment determination, hospices would collect survey data on a monthly basis for the months of January 1, 2017 through December 31, 2017 to qualify for the full APU.
- To meet the HQRP requirements for the FY 2020 payment determination, hospices would collect survey data on a monthly basis for the months of January 1, 2018 through December 31, 2018 to qualify for the full APU.

e. Hospice CAHPS® Reconsiderations and Appeals Process

Hospices are required to monitor their respective Hospice CAHPS® Survey vendors to ensure that vendors submit their data on time. The hospice CAHPS® data warehouse provides reports to vendors and hospices, including reports on the status of their data submissions. Details about the reports and emails received after data submission should be referred to the Quality Assurance Guidelines Manual. If a hospice does not know how to retrieve their reports, or lacks access to the reports, they should contact Hospice CAHPS® Technical Assistance at *hospiceCAHPSsurvey@hcqis.org* or call them at 1–844 –472 –4621. Additional information can be found on page 113 of the Hospice CAHPS® Quality Assurance Guidelines manual Version 2.0 which is available on the Hospice CAHPS® Web site, *www.hospicecahpssurvey.org.*

In the FY 2017 payment determination and subsequent years, reporting compliance is determined by successfully fulfilling both the Hospice CAHPS® Survey requirements and the HIS data submission requirements. Providers would use the same process for submitting a reconsideration request that are outlined in section III.C.10 of this rule.

We received multiple comments pertaining to the Hospice CAHPS® Survey. The following is a summary of the comments we received on this topic and our responses.

Comment: One commenter expressed concern about the length of the survey and described it as a tool that is 36 pages in length and fraught with arduous stipulations of its delivery. In addition, the commenter stated that it would be very difficult for CMS to monitor compliance with how hospices are portraying the survey and described the survey as cumbersome for bereaved families to complete.

Response: The Hospice CAHPS Survey consists of a total of 47

questions, some of which are only asked when the patient received services in a specific setting. The Hospice CAHPS Survey has fewer questions than NHPCO's well-known Family Evaluation of Hospice Care (FEHC) survey, which has 54 items. We offer a 36-page document on the CAHPS Survey Web site that contains survey materials (*www.hospicecahpssurvey.org*). The document packages three copies of the questionnaire, each set up for a different optical scanning program. This is offered for the convenience of the survey vendors. Vendors will use only one of these versions. In addition, the file includes some sample letters for vendors' use. We have implemented detailed specifications for the survey vendors to follow. This ensures standardization of survey administration procedures across vendors. Standardization is important for accurate data quality and to ensure that the data from different vendors is comparable for public reporting. While it is true that we have no way to monitor the way hospices are portraying the survey, we offer guidelines in the Quality Assurance Guidelines manual on the survey Web site (*www.hospicecahpssurvey.org*). We rely on the professionalism of the providers to cooperate with the survey's requirements.

The commenter also states that the survey is burdensome for bereaved families to complete. We thank the commenters for their comments; we have not received complaints from respondents regarding the survey being burdensome. Responses are voluntary and at the discretion of the person receiving the survey. If they find the survey too burdensome, they simply do not need to respond.

Comment: A few commenters stated that it is unclear whether public reporting will use only the eligible HIS quality measures or will also use the Hospice CAHPS results. Commenters claim that the inclusion of Hospice CAHPS results is essential if Hospice Compare is to provide a meaningful reflection of hospice care quality.

Response: We thank the commenters for their comments. We are currently building the infrastructure for the new Hospice Compare site and are evaluating the best method to include both the Hospice Item Set measures and the results of the Hospice CAHPS Survey.

Comment: One commenter made the point that, for smaller hospices, Hospice CAHPS data is likely to be more vulnerable to variations numerator size and variability than comparable data for larger hospices.

Response: We agree that smaller hospices may be subject to greater variability than large ones. We plan to report an eight-quarter rolling average for Hospice CAHPS public reporting. For the initial report, we may include fewer quarters, but we will build up to eight quarters and continue on an ongoing basis. These plans are intended to counterbalance concerns about variability of the data while at the same time including as many hospices as possible on the Compare site.

Comment: One commenter recommended that CMS conduct analysis to determine how CAHPS results are affected by survey eligibility requirements and response rates. Specifically, they express concern about the relationship between Hospice CAHPS data and the data that would be obtained if survey eligibility rules were modified.

Response: We thank the commenter for their comments. When a sample is taken, it is a random sample to represent the care of all eligible hospice patients. We do exclude patients who have been in hospice care for fewer than 48 hours since their caregivers do not have enough experience to evaluate the care provided by the hospice. We intend to conduct a variety of special and ongoing analyses of Hospice CAHPS data, as well as other related data available to the agency, including analyses of how non-responders differ from responders to determine if we need to control for non-response bias. Generally, the adjustment is already completed for differences in the mix of patients across providers also controls for any non-response bias. We will, however, continue to monitor how eligibility requirements and response rates impact the character of the data reported and whether changes in requirements need to be made.

Comment: A few commenters commented that hospices not included in public reporting might be disadvantaged.

Response: As mentioned previously, we are aware that hospices might want to be included in the Hospice Compare Web site. We are increasing the number of quarters included in the rolling average that will be reported on the public reporting site. The goal of this process is to make it possible for a larger proportion of hospices to be included on the site, while at the same time limiting the variability of the results for smaller hospices.

Comment: One commenter requested that CMS use two individual questions from the survey, the hospice rating item and the ''willingness to recommend'' item, on the Hospice Compare Web site.

Response: We plan to include both the hospice rating question and the willingness to recommend question as part of the Hospice CAHPS data reported on Hospice Compare.

Final Action: After consideration of comments, we are finalizing our proposals that hospices that receive their CCN after January 1, 2017 for the FY 2019 APU and January 1, 2018 for the FY 2020 APU are exempted from the Hospice CAHPS® requirements due to newness.

10. HQRP Reconsideration and Appeals Procedures for the FY 2017 Payment Determination and Subsequent Years

In the FY 2015 Hospice Wage Index final rule (79 FR 50496), we notified hospice providers on how to seek reconsideration if they received a noncompliance decision for the FY 2016 payment determination and subsequent years. A hospice may request reconsideration of a decision by CMS that the hospice has not met the requirements of the Hospice Quality Reporting Program for a particular period.

We clarified that any hospice that wishes to submit a reconsideration request must do so by submitting an email to CMS containing all of the requirements listed on the HQRP Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Reconsideration-Requests.html*. Electronic email sent to *HospiceQRPReconsiderations@cms.hhs.gov* is the only form of submission that will be accepted. Any reconsideration requests received through any other channel including the United States Postal Service or phone will not be considered as a valid reconsideration request. We codified this process at § 418.312(h). In addition, we codified at § 418.306(b)(2) that beginning with FY 2014 and each subsequent FY, the Secretary shall reduce the market basket update by 2 percentage points for any hospice that does not comply with the quality data submission requirements for that FY and solicited comments on all of the proposals and the associated regulations text at § 418.312 and in § 418.306 in section VI. Official instructions regarding the payment reduction reconsideration process can be located under the Regulations and Guidance, Transmittals, 2015 Transmittals Web site at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2015-Transmittals-Items/*

R52QRI.html?DLPage=1&DLEntries=10&DLSort=4&DLSortDir=descending.

In the past, only hospices found to be non-compliant with the reporting requirements set forth for a given payment determination received a notification from CMS of this finding along with instructions for requesting reconsideration in the form of a United States Postal Service (USPS) letter. In the FY 2016 Hospice Wage Index final rule (80 FR 47198), we stated that we would use the QIES CASPER reporting system as an additional mechanism to communicate to hospices regarding their compliance with the reporting requirements for the given reporting cycle. We will implement this additional communication mechanism via the QIES CASPER timeliness compliance reports referenced in section III.C.7e of this final rule. As stated in section III.C.7e of the rule, these QIES CASPER reports will be automated reports that hospices will be able to generate at any point in time to determine their preliminary compliance with HQRP requirements, specifically, the timeliness compliance threshold for the HIS. We believe the QIES CASPER timeliness compliance reports meet CMS's intent of developing a method to communicate as quickly, efficiently, and broadly as possible with hospices regarding their preliminary compliance with reporting requirements. We will continue to send notification of noncompliance via delivery of a letter via the United States Postal Service. Requesting access to the CMS systems is performed in 2 steps. Details are provided on the QIES Technical Support Office Web site at *https://www.qtso.com/hospice.html.* Providers may access the CMS QIES Hospice Users Guides and Training by going to the QIES Technical Support Office Web site and selecting Hospice and then selecting the CASPER Reporting Users Guide at *https://www.qtso.com/hospicetrain.html.* Additional information about how to access the QIES CASPER reports will be provided prior to the availability of these new reports.

We proposed to disseminate communications regarding the availability of hospice compliance reports in CASPER files through CMS HQRP communication channels, including postings and announcements on the CMS HQRP Web site, MLN eNews communications, national provider association calls, and announcements on Open Door Forums and Special Open Door Forums. We further proposed to publish a list of hospices who successfully meet the reporting requirements for the applicable payment determination on the CMS HQRP Web site *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/index.html.* We proposed updating the list after reconsideration requests are processed on an annual basis. We clarified that the published list of compliant hospices on the CMS HQRP Web site would include limited organizational data, such as the name and location of the hospice. Finalizing the list of compliant providers for any given year is most appropriately done after the final determination of compliance is made. It is our intent for the published list of compliant hospices to be as complete and accurate as possible, giving recognition to all providers who were compliant with HQRP requirements for that year. Finalizing the list after requests for reconsideration are reviewed and a final determination of compliance is made allows for a more complete and accurate listing of compliant providers than developing any such list prior to reconsideration. Developing the list after the final determination of compliance has been made allows providers whose initial determination of noncompliance was reversed to be included in the list of compliant hospices for that year. We believe that finalizing the list of compliant hospices annually after the reconsideration period will provide the most accurate listing of hospices compliant with HQRP requirements.

11. Public Display of Quality Measures and Other Hospice Data for the HQRP

Under section 1814(i)(5)(E) of the Act, the Secretary is required to establish procedures for making any quality data submitted by hospices available to the public. Such procedures shall ensure that a hospice program has the opportunity to review the data that is to be made public for the hospice program prior to such data being made public. The Secretary shall report quality measures that relate to hospice care provided by hospice programs on the CMS Web site.

We recognize that public reporting of quality data is a vital component of a robust quality reporting program and are fully committed to developing the necessary systems for transparent public reporting of hospice quality data. We also recognize that it is essential that the data made available to the public be meaningful and that comparing performance between hospices requires that measures be constructed from data collected in a standardized and uniform manner. Hospices have been required to use a standardized data collection approach (HIS) since July 1, 2014. Data from July 1, 2014 onward is currently being used to establish the scientific soundness of the quality measures prior to the onset of public reporting of the 7 quality measures implemented in the HQRP. We believe it is critical to establish the reliability and validity of the quality measures prior to public reporting to demonstrate the ability of the quality measures to distinguish the quality of services provided. To establish reliability and validity of the quality measures, at least four quarters of data will be analyzed. Typically, the first 1 or 2 quarters of data reflect the learning curve of the facilities as they adopt standardized data collection procedures; these data often are not used to establish reliability and validity. We began data collection in CY 2014; the data from CY 2014 for Quarter 3 (Q3) was not used for assessing validity and reliability of the quality measures. We analyzed data collected by hospices during Quarter 4 (Q4) CY 2014 and Q1 through Q3 CY 2015. Preliminary analyses of HIS data show that all 7 quality measures that can be calculated using HIS data are eligible for public reporting (NQF #1634, NQF #1637, NQF #1639, NQF #1638, NQF #1641, modified NQF #1647, NQF #1617). Based on analyses conducted to establish reportability of the measures, 71 percent through 90 percent of all hospices would be able to participate in public reporting, depending on the measure. For additional details regarding analysis, we refer readers to the Measure Testing Executive Summary document available on the ''Current Measures'' section of the CMS HQRP Web site: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Current-Measures.html.* Although analyses show that many hospices perform well on the 7 measures from the HIS measure set, the measures still show variation, especially among hospices with suboptimal performance, indicating that these measures are still meaningful for comparing quality of care across hospice providers. In addition to conducting quantitative analysis to establish scientific acceptability of the HIS measures, CMS's measure development contractor conducted interviews with family and caregivers of hospice patients. The purpose of these interviews was to determine what information patients and caregivers would find useful in selecting hospices, as well as gathering input about patient and caregiver experience with hospice

care. Results from these interviews indicate that all 7 HIS quality measures provide consumers with useful information. Interview participants stated that quality measure data would be especially helpful in identifying poor quality outliers that inform beneficiaries, families, caregivers, and other hospice stakeholders.

To inform which of the HIS measures are eligible for public reporting, CMS's measure development contractor, RTI International, examined the distribution of hospice-level denominator size for each quality measure to assess whether the denominator size is large enough to generate the statistically reliable scores necessary for public reporting. This goal of this analysis is to establish the minimum denominator size for public reporting, which is referred to as ''reportability'' analysis. Reportability analysis is necessary since small denominators may not yield statistically meaningful QM scores. Thus, for other quality reporting programs, such as Nursing Home Compare,[35] CMS sets a minimum denominator size for public reporting, as well as the data selection period necessary to generate the minimum denominator size. Reportability analysis showed that calculating and publicly displaying measures based on 12 months of data would allow for sufficient measure denominator size. Having ample denominator size ensures that quality measure scores that are publicly reported are reliable and stable; a minimum sample size of 20 stays is commonly applied to assessment-based quality measures in other reporting programs. The 12-month data selection period produced significantly larger mean and median sample sizes among hospices, which will generate more reliable quality measure scores. Additionally, our analysis revealed that when applying a minimum sample size of 20 stays, using rolling 12 months of data to create QMs would only exclude about 10 percent through 29 percent of hospices from public reporting, depending on the measure. For more information on analyses conducted to determine minimum denominator size and data selection period, we refer readers to the Reportability Analysis Section of the Measure Testing Executive Summary, available on the ''Current Measures'' portion of the CMS HQRP Web site: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Current-Measures.html*.

Based on reportability analysis and input from other stakeholders, we have determined that all 7 HIS measures are eligible for public reporting. Thus, we plan to publicly report all 7 HIS measures on a CMS Compare Web site for hospice agencies. For more details on each of the 7 measures, including information on measure background, justification, measure specifications, and measure calculation algorithms, we refer readers to the HQRP QM User's Manual, which is available on the downloads portion of the Current Measures CMS HQRP Web site: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Current-Measures.html*. Individual scores for each of the 7 HIS measure scores would be reported on a new publicly available CMS Hospice Compare Web site. Current reportability analysis indicates that a minimum denominator size of 20 based on 12 rolling months of data would be sufficient for public reporting of all HIS quality measures. Under this methodology, hospices with a quality measure denominator size of smaller than 20 patient stays would not have the quality measure score publicly displayed since a quality measure score on the basis of small denominator size may not be reliable. We will continue to monitor quality measure performance and reportability and will adjust public reporting methodology in the future if needed.

Reportability analysis is typically conducted on a measure-by-measure basis. We would like to clarify that any new measure adopted as part of the HQRP will undergo reportability analysis to determine: (1) If the measure is eligible for public reporting; and (2) the data selection period and minimum denominator size for the measure. Results of reportability analyses conducted for new measures will be communicated through future rulemaking.

In addition, the Affordable Care Act requires that reporting be made public on a CMS Web site and that providers have an opportunity to review their data prior to public reporting. We are currently developing the infrastructure for public reporting and will provide hospices an opportunity to review their quality measure data prior to publicly reporting information about the quality of care provided by Medicare-certified hospice agencies throughout the nation. These quality measure data reports or ''preview reports'' will be made available in the CASPER system prior to public reporting and will offer providers the opportunity to review their quality measure data prior to public reporting on the CMS Compare Web site for hospice agencies. Under this process, providers would have the opportunity to review and correct data they submit on all measures that are derived from the Hospice Item Set. Reports would contain the provider's performance on each measure calculated based on HIS submission to the QIES ASAP system. The data from the HIS submissions would be populated into reports with all data that have been submitted by the provider. CMS will post preview reports with sufficient time for providers to be able to submit, review data, make corrections to the data, and view their data. Providers are encouraged to regularly evaluate their performance in an effort to ensure the most accurate information regarding their agency is reflected.

We also plan to make available additional provider-level feedback reports, which are separate from public reporting and will be for provider viewing only, for the purposes of internal provider quality improvement. As is common in other quality reporting programs, quality reports would contain feedback on facility-level performance on quality metrics, as well as benchmarks and thresholds. For the CY 2015 Reporting Cycle, several new quality reporting provider participation reports were made available in CASPER. Providers can access a detailed list and description of each of the 12 reports currently available to hospices on the QIES Web site, under the Training & Education Selections, CASPER Reporting Users Guide at *https://www.qtso.com/hospicetrain.html.* We anticipate that providers would use the quality reports as part of their Quality Assessment and Performance Improvement (QAPI) efforts.

Furthermore, to meet the requirement for making such data public, we are developing a CMS Hospice Compare Web site, which will provide valuable information regarding the quality of care provided by Medicare-certified hospice agencies throughout the nation. Consumers would be able to search for all Medicare approved hospice providers that serve their city or zip code (which would include the quality measures and CAHPS® Hospice Survey results) and then find the agencies offering the types of services they need, along with provider quality information. Based on the efforts necessary to build the infrastructure for public reporting, we anticipate that public reporting of the eligible HIS quality measures on the CMS Compare Web site for hospice

[35] ''CMS Nursing Home Quality Initiative—Centers for Medicare . . .'' 2011. 25 Jan. 2016 *https://www.cms.gov/nursinghomequalityinits/45_nhqimds30trainingmaterials.asp*.

agencies will begin sometime in the spring/summer of CY 2017. To help providers prepare for public reporting, we will offer opportunities for stakeholder engagement and education prior to the rollout of a Hospice Compare site. We will offer outreach opportunities for providers through the MLN eNews, Open Door Forums and Special Open Door Forums; we will also post additional educational materials regarding public reporting on the CMS HQRP Web site. Finally, we will offer training to all hospice providers on the systems and processes for reviewing their data prior to public reporting; availability of trainings will be communicated through the regular CMS HQRP communication channels, including postings and announcements on the CMS HQRP Web site, MLN eNews communications, national provider association calls, and announcements on Open Door Forums and Special Open Door Forums.

Like other CMS Compare Web sites, the Hospice Compare Web site will, in time, feature a quality rating system that gives each hospice a rating of between 1 and 5 stars. Hospices will have prepublication access to their own agency's quality data, which enables each agency to know how it is performing before public posting of data on the Hospice Compare Web site. Public comments regarding how the rating system would determine a hospice's star rating and the methods used for calculations, as well as a proposed timeline for implementation will be announced via regular CMS HQRP communication channels, including postings and announcements on the CMS HQRP Web site, MLN eNews communications, provider association calls, and announcements on Open Door Forums and Special Open Door Forums. We will announce the timeline for development and implementation of the star rating system in future rulemaking.

Lastly, as part of our ongoing efforts to make healthcare more transparent, affordable, and accountable for all hospice stakeholders, the HQRP is prepared to post hospice data on a public data set, the Data.Medicare.gov Web site, and directory located at *https://data.medicare.gov.* This site includes the official datasets used on the Medicare.gov Compare Web sites provided by CMS. In addition, this data will serve as a helpful resource regarding information on Medicare-certified hospice agencies throughout the nation. In an effort to move toward public reporting of hospice data, we will initially post demographic data of hospice agencies that have been registered with Medicare. This list will include high-level demographic data for each agency including, provider name, address, phone numbers, ownership type, CMS Certification Number (CCN), profit status, and date of original CMS certification. The posting of this new hospice data directory occurred on June 14, 2016. Information can be located at *https://data.medicare.gov/data/hospice-directory*. Additional details regarding hospice datasets will be announced via regular CMS HQRP communication channels, including postings and announcements on the CMS HQRP Web site, MLN eNews communications, national provider association calls, and announcements on Open Door Forums and Special Open Door Forums. In addition, we have provided the list of CASPER/ASPEN and Regional Office coordinators in the event the Medicare-certified agency is either not listed in the database or the characteristics/administrative data (name, address, phone number, services, or type of ownership) are incorrect or have changed. To continue to meet Medicare enrollment requirements, all Medicare providers are required to report changes to their information in their enrollment application as outlined in the Provider-Supplier Enrollment Fact Sheet Series located at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/MedEnroll_InstProv_FactSheet_ICN903783.pdf.*

Comment: CMS received several comments that were supportive of public reporting of hospice quality measures. Commenters noted that they were in favor of CMS's efforts to publicly report hospice quality data to support the timely and transparent reporting of HQRP data. One commenter shared that public reporting of valid and reliable quality data demonstrates value, underpins compliance, and provides structure for hospice care. Several commenters did have suggestions, recommendations, and concerns about specific aspects of the public display of hospice quality measure data. These specific comments are summarized below.

Response: We appreciate the commenters' support of public reporting of hospice quality measures. We address commenters' specific concerns with respect to public reporting reports below.

Comment: CMS received a few comments expressing concerns that many hospice providers have high scores on the current HIS measures and some Hospice CAHPS measures. The potential lack of variation in scores for these measures may make differentiating between hospice providers' performance challenging for consumers. Given the limited range of scores, commenters thought that presenting data as rankings or percentiles may present results in a way that does not provide valuable information to consumers. One commenter suggested that CMS consider risk-adjusting quality measures reported on the Compare Web site.

Response: We agree that all publicly reported data should be presented in a manner that is meaningful and understandable to the general public. We will take steps and use recognized practices to ensure that any publicly reported data is displayed in an appropriate and meaningful manner. We are developing the format and content for public display of quality measure data on the Hospice Compare site. We appreciate the commenters input on how to most meaningfully display quality measure data and will take these suggestions into consideration as we finalize the format of public reporting (that is, whether to report scores or the percentiles for each quality measure (QM)).

Regarding commenters' concerns about the lack of variation in current HIS measure scores, the overall distribution and variability of the seven currently adopted HIS QMs is an indicator that most hospices are providing the required and recommended care to the majority of the patients around hospice admission, demonstrating overall high quality of care. However, the seven measures demonstrate room for improvement. Analysis conducted by our measure development contractor demonstrates that a low percentage of hospices have perfect scores for most measures and a small percentage of hospices have very low scores. We believe this is valuable and important information to communicate to consumers as well as to providers to motivate quality improvement. Additionally, we are working on the specific format for publicly reporting these 7 QMs and will take commenters' suggestions into consideration. We agree that given the skewed distribution, presenting hospice scores in formats like percentiles may provide misleading information. Presenting hospices' quality scores may provide information that is more straightforward for consumers and providers. Finally, input that we have received from hospice caregivers will also inform our strategy for public reporting of quality measure data. Our measure development contractor interviewed hospice caregivers about public display of quality data and what

types of data would be most meaningful to consumers. In these interviews, respondents supported the continued data collection and reporting of the individual HIS measures, noting that information on the individual measures is valuable to consumers. Respondents also noted that although overall performance on the 7 HIS measures is high, public display of these scores would still be meaningful as a way to identify low-performing hospices.

With respect to the commenter's suggestion to risk adjust quality measures reported on the Hospice Compare Web site, we would like to point out that both the current HIS measure set (NQF #1634, NQF #1637, NQF #1639, NQF #1638, NQF #1617, NQF #1641 and NQF #1647) and Hospice CAHPS quality measures are currently under review by the National Quality Forum (NQF) for maintenance endorsement and endorsement, respectively. NQF criteria for review and endorsement includes consideration of risk adjustment. As stated in section III.C.3 of this rule, it is CMS's intent to implement endorsed quality measures, using the specifications as endorsed by the NQF.

Comment: A few commenters suggested that CMS provide quarterly benchmark data to hospices for at least 1 year in advance of publicly reporting the data. Commenters believed the benchmark data would demonstrate to individual hospices how they perform compared to all hospices on the existing measures and allow opportunity for improvement prior to the onset of public reporting. One commenter shared that hospices have found stable benchmark scores for comparison to be far more useful for setting goals and tracking performance improvement.

Response: We appreciate the commenters' suggestion to provide quarterly benchmark data. As we previously stated, we plan to make available additional provider-level feedback reports prior to public reporting; these reports will help hospices with their quality assessment and performance improvement efforts. As is common in other quality reporting programs, these reports would provide feedback on facility-level performance on quality metrics, as well as national benchmarks. Additionally, national means of the HIS quality measures, based on Q4 2014 through Q3 2015 HIS data, are reported in the Hospice Quality Reporting Program: Executive Summary of Measure Testing and Validation, available on the ''Current Measures'' portion of the CMS HQRP Web site: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Current-Measures.html.*

Comment: One commenter urged CMS to not only showcase quality measures from HIS and Hospice CAHPS, but also demonstrate the scope and level of services provided by different hospice programs. The commenter stated that while hospices are required to be able to provide certain services, patient and family access to these services varies, especially for the non-clinical services. In addition, this commenter stated that there is variation in how well hospices meet the requirements. Moreover, the commenter stated that and a lack of enforcement allowed lower quality programs to minimally comply with requirements, if at all. For example, many hospice programs send mailings to families on bereavement; while this technically meets the bereavement requirements under the benefit; other hospices offer and provide robust, individualized bereavement support. The commenter thought that it would be important for consumers to have information about these services to help them select a hospice.

Response: We appreciate the commenter's recommendation to report quality metrics and hospice information beyond HIS and Hospice CAHPS measures. We recognize that information regarding the scope and level services provided would be valuable to consumers and hospice providers; however, we note that such information may not be readily available to us through billing records or other reporting mechanisms, and we are cognizant of the burden additional reporting could place on providers. We will take this recommendation into consideration as we move forward with the development for future HQRP measures.

Comment: The majority of commenters supported the minimum denominator size for public reporting. Although commenters were generally supportive of this requirement, some commenters had concerns about the possible negative impact on small hospices for which quality information is not included in public reporting due to not meeting the minimum denominator size. Commenters noted that hospices who do not meet the threshold of 20 stays for the HIS-based QMs or the size exemption for Hospice CAHPS® Survey, which is less than 50-survey eligible patients in the previous year, would not be included in all or part of public reporting. Commenters raised concerns that a lack of displayed data on Hospice Compare may disadvantage these smaller providers. Commenters believed that consumers using Hospice Compare to search for a provider might disregard hospices that do not have some or all of their data displayed due to size issues, and that, in turn, consumers may be more likely to seriously consider only those hospices for which quality information is presented. One commenter expressed concerns that there are some important statistical considerations, in addition to denominator size, that should be addressed in creating a means for public display of hospice quality data. Specifically, the commenter noted that a small denominator that meets the minimum denominator size is more sensitive to fluctuations in the numerator than a large denominator. Smaller hospices are likely to have smaller denominators and are more vulnerable to numerator size and variability than larger hospices. The commenters suggested that CMS create a means to counterbalance the potential negative consequences for those hospices for which quality information is not included in public reporting.

Response: We thank the commenters for their support of our recommendation to set a minimum denominator size for public reporting. We appreciate commenters sharing concerns regarding the possible negative impact on small hospices. To establish the minimum denominator size, we examined the national hospice-level denominator size for the HIS quality measures. The determination of the minimum denominator size balanced the necessity of yielding statistically meaningful QM scores and the goal of allowing as many hospices to have their quality measure scores publicly displayed as possible. To be consistent with other quality reporting programs' public reporting policies, we set a minimum denominator size for public reporting of quality measures, as well as the data selection period necessary to generate the minimum denominator size. The minimum denominator size is determined based on a hospice's patient stays over a 12-month period. Analysis conducted by RTI International shows that only about 10 percent of hospices would not have accumulated 20 patient stays to have any HIS quality measure publicly displayed. RTI's analysis also shows that quality measures calculated based on 12 months of data are stable and robust against fluctuation. These results were summarized in the Measure Testing Executive Summary document referenced in this section of the rule and posted on the ''Current Measures'' portion of the CMS HQRP Web site:

https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Current-Measures.html. On the Hospice Compare Web site, CMS plans to indicate in some manner (for example, through a footnote or some other statement) instances where data is not displayed due to denominator size issues. We believe this will minimize any potential negative impact on small providers and signal to consumers that in such instances, the lack of data is a result of the hospice having too few admissions to allow for reporting of a valid quality measure, and is not in and of itself an indicator of hospice quality. Finally, we will take the commenters suggestion regarding creating a means to counterbalance the potential negative consequences for small hospices as we move forward with the development and launch of Hospice Compare.

Comment: CMS received several comments regarding data sources that would be included in the launch of Hospice Compare. Overall, commenters offered two main considerations. First, commenters brought up concerns about the limitations of HIS data for consumer decision-making. Second, commenters requested clarification from and encouraged CMS to include Hospice CAHPS data in the launch of Hospice Compare. Regarding the first concern, commenters noted that HIS data alone might provide inadequate information to aid in consumer decision-making. Commenters noted that all HIS measures are process of care measures and, as such, do not address important issues such as whether the patient/family was treated with respect or felt supported by the hospice team. They strongly recommended that the Hospice CAHPS results be reported along with HIS measures to provide consumers with the most meaningful and comprehensive picture of quality of care. Finally, commenters encouraged CMS to provide appropriate disclaimers about the hospice quality data and information, outlining the limitations of the data and its utility.

Response: We appreciate the commenters' feedback on public reporting of HIS and Hospice CAHPS data. We agree with commenters that HIS and Hospice CAHPS data are complementary and, together, provide a more meaningful and comprehensive view of quality of care provided by hospices. As noted in section III.C.9 of this rule, we plan to include both HIS and Hospice CAHPS data in the launch of Hospice Compare. Reporting both data sources will address commenters' concerns and mirrors the approach for public reporting used in other CMS Compare sites. We will communicate additional plans for the public reporting of hospice quality data through the usual CMS HQRP communication channels, including postings and announcements on the CMS HQRP Web site, MLN eNews communications, national provider association calls, and announcements on Open Door Forums and Special Open Door Forums.

Comment: A few commenters expressed concerns that consumers will not understand the difference between a process measure and an outcome measure and be able to draw conclusions about the experience of hospice care from just the composite process measure. One commenter shared that CMS needs to provide education and resources to help the public understand what the measures mean.

Response: We agree that any publicly reported data should be presented in a manner that is meaningful and understandable by the public. We intend to take steps and use recognized practices to ensure that any publicly reported data is displayed in an appropriate and meaningful manner. We intend to work with our Web site development contractor to ensure that the Hospice Compare site has been tested for usability, readability, and navigation, and that consumers and stakeholders are continuously involved and have opportunities for input throughout the development process. We will write in plain language, with awareness of variations in health and general literacy, and solicit input from key stakeholders and technical experts in the development of the presentation of publicly available quality data.

Comment: CMS received a few comments regarding concerns about the publicly reported HIS measures because they are constructed using HIS data that is self-reported by hospice providers. Commenters had concerns about the validity of this data and encouraged CMS to determine methods to monitor the veracity of the data being submitted. Commenters noted that the launch of Hospice Compare might create perverse incentives for hospices to submit false data to avoid unfavorable scores being publicly reported on the Compare Web site.

Response: We acknowledge commenters' concerns regarding the validity of self-reported HIS measures. Publicly reported quality measure data relies on the submission of valid and reliable data at the patient level. Our measure development contractor conducts ongoing testing and validation of the quality measure data to identify data irregularities and trends. We will consider additional validation processes for future rulemaking cycles.

Comment: CMS received a few comments expressing providers' desire to review data prior to publication. One commenter inquired about the process for correcting data errors.

Response: We appreciate the commenters' interest in reviewing data prior to public reporting. We would like to take this opportunity to clarify the processes available to providers for reviewing and making changes to HIS data, and for previewing QM scores prior to public display. First, as outlined in the HIS Manual, providers have the opportunity to make corrections to HIS data through HIS record modification and inactivation processes. HIS record modifications and inactivations are available if a provider finds an error in HIS data that has been submitted and accepted by the QIES ASAP system. Further details on processes for modifications and inactivations are available in Chapter 3 of the HIS Manual, available on the HIS portion of the CMS HQRP Web site: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Hospice-Item-Set-HIS.html.* It is vital for providers to correct any errors in HIS data to ensure information in the QIES ASAP system accurately reflects the patient's hospice record and HIS-related care processes delivered to the patient; this initial corrections process for errors in HIS data helps ensure QM scores and any publicly displayed data are accurate.

In addition to modification and inactivation processes available in QIES ASAP, as we previously stated, we are currently developing the infrastructure to provide hospices with the opportunity to view their quality measure data via CASPER provider-level feedback reports. These internal provider-level feedback reports will provide hospices an initial opportunity to review QM *score* data in CASPER. Provider-level feedback reports are confidential and separate from the public reporting processes. The purpose of provider-level feedback reports is to provide hospices with QM score data that can be used at the individual facility level and for internal quality improvement. We are planning for release of the QM provider-level feedback reports sometime in December of 2016. Availability of the new CASPER QM reports will be communicated to providers through the usual CMS HQRP communication channels, including postings and announcements on the CMS HQRP Web site, MLN eNews communications,

national provider association calls, and announcements on Open Door Forums and Special Open Door Forums.

Finally, we will ensure providers have the opportunity to preview QM score data to be displayed on Hospice Compare, prior to public posting of the data. Prior to public reporting, quality measure data ''preview'' reports will be made available in CASPER system. Hospices will have a 30-day preview period prior to public display during which they can preview the performance information on their measures that will be made public. The ''preview'' reports will be made available using the Certification and Survey Provider Enhanced Reporting (CASPER) System because hospices are familiar with this system. In line with other PAC QRPs, hospices will have 30 days to review this information, beginning from the date on which they can access the preview report. Corrections to the underlying data would not be permitted during this time; however, hospices would be able to ask for a correction to their measure calculations during the 30-day preview period. If we determine that the measure, as it is displayed in the preview report, contains a calculation error, we would suppress the data on the public reporting Web site, recalculate the measure and publish the corrected rate at the time of the next scheduled public display date. This process is consistent with informal processes used in the Hospital IQR and other PAC programs. Technical details for how and when providers may contest their measure calculations, as well as the process for submitting a suppression request will be conveyed through the usual CMS HQRP communication channels.

Comment: CMS received a comment in support of the initiative to make available additional provider-level feedback reports in the CASPER reporting system. The commenter requested CMS consider additional reports to display quality metric scores that would be available 2 days after HIS records are submitted and accepted by the QIES ASAP system.

Response: We appreciate the commenter's support of the initiative to provide additional provider-level feedback reports in CASPER. We agree that providing timely feedback to hospice providers is a critical step in the process of quality improvement since providers need data about their performance to inform QAPI and other performance improvement efforts. We will continue to refine the provider-level feedback reports to make timely data available to providers within the CASPER system.

Comment: One commenter expressed concerns regarding consumers leaving anonymous negative comments or grievances on the Hospice Compare Web site. The commenter noted that there is no manner for the hospice to respond to or rebut negative comments or grievances.

Response: We would like to thank the commenters for taking the time to convey their concerns regarding consumers leaving anonymous negative comments or grievances on the Hospice Compare Web site. Consumers will only be able to search for hospice providers and review quality data; they will not be able to post comments or grievances on the CMS Hospice Compare Web site.

Comment: Though commenters were generally supportive of public reporting of quality data, several commenters expressed concerns over the methodology for the star rating system to be used in the future as part of the Hospice Compare Web site. One commenter urged CMS to be conservative and cautious about the use of star ratings when applied to Hospice CAHPS data because patient and family experience with care data is typically positively skewed. A few commenters cautioned CMS against evaluating hospice providers along a bell curve rather than on a grading scale when developing star ratings for hospice providers. They shared that the use of a bell curve creates confusion for consumers and may misrepresent the quality of the care provided by hospices. Commenters encouraged CMS to develop a star-rating methodology that incorporates both HIS and Hospice CAHPS data. A few commenters suggested that CMS provide sufficient time for stakeholders to review the star ratings model. One commenter voiced concerns about star-rating methodologies used in other care settings and recommended CMS take into consideration lessons learned about unintended consequences when developing the hospice star rating system. One commenter recommended that CMS take a criterion approach to constructing the CMS Hospice Compare Web site and determining the methodology to be used for calculating star ratings. Another commenter stated that any star rating system developed should reflect care provided by the entire interdisciplinary team and should be risk adjusted to account for individualized care, short lengths of stay and patient right to refuse care.

Response: We appreciate the thorough and detailed input on the development of a Hospice Compare Web site and the future development of a star rating system for hospices. We would like to assure commenters that it is of paramount concern to develop a star rating methodology that is valid, is reliable, and presents quality data that is meaningful to stakeholders. As with the development of star methodology in other care programs, we will allow continued opportunities for the provider community and other stakeholders to comment on and provide input to the proposed rating system. In addition to regular HQRP communication channels, we will solicit input from the public regarding star methodology through special listening sessions, invitation to submit comments via a Help Desk mailbox, Open Door Forums, a Technical Expert Panel, and other opportunities. Additionally, we will benefit from lessons learned from the development and implementation of star ratings in other QRPs to help guide the hospice star rating initiative.

D. The Medicare Care Choices Model

We want to remind the provider community that the Medicare Care Choices Model (MCCM) is testing a new option for Medicare beneficiaries with certain advanced diseases to receive hospice-like support services from MCCM hospices while receiving care from other Medicare providers for their terminal condition. This 5 year model is being tested to encourage greater and earlier use of the Medicare and Medicaid hospice benefit to determine whether it can improve the quality of life and care received by Medicare beneficiaries, increase beneficiary, family, and caregiver satisfaction, and reduce Medicare or Medicaid expenditures. Participation in the model is limited to Medicare and dual eligible beneficiaries with advanced cancers, chronic obstructive pulmonary disease, congestive heart failure, and Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome who qualify for the Medicare or Medicaid hospice benefit and meet the eligibility requirements of the model. The model includes more than 130 hospices from 39 states across the country and is projected to serve 100,000 beneficiaries by 2020. The first cohort of MCCM participating hospices began providing services under the model in January 2016, and the second cohort will begin to provide services under the model in January 2018. The last patient will be accepted into the model 6 months before the December 31, 2020 model end date.

For more information, see the MCCM Web site: *https://innovation.cms.gov/initiatives/Medicare-Care-Choices/.*

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. 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.

We solicited public comment on each of the following information collection requirements (ICRs).

A. Information Collection Requirements

Section 1814(i)(5)(C) of the Act requires that each hospice submit data to the Secretary on quality measures specified by the Secretary. Such data must be submitted in a form, manner, and at a time specified by the Secretary. In the FY 2014 Hospice Wage Index final rule (78 FR 48257), and in compliance with section 1814(i)(5)(C) of the Act, we finalized the specific collection of data items that support the following six NQF-endorsed measures and one modified measure for hospice:

- NQF #1617 Patients Treated with an Opioid who are Given a Bowel Regimen,
- NQF #1634 Pain Screening,
- NQF #1637 Pain Assessment,
- NQF #1638 Dyspnea Treatment,
- NQF #1639 Dyspnea Screening,
- NQF #1641 Treatment Preferences,
- NQF #1647 Beliefs/Values Addressed (if desired by the patient) (modified).

Data for the aforementioned 7 measures is collected via the HIS. Data collection for the 7 NQF-endorsed measures via the HIS V1.00.0 was approved by the Office of Management and Budget April 3, 2014 (OMB control number 0938–1153—Hospice Quality Reporting Program). As outlined in this final rule, we continue data collection for these 7 NQF-endorsed measures.

In this final rule, we finalized the implementation of two new measures. The first measure is the Hospice and Palliative Care Composite Process Measure—Comprehensive Assessment at Admission. Seven individual care processes will be captured in this composite measure, which includes the six NQF-endorsed quality measures and one modified NQF-endorsed quality measure currently implemented in the HQRP. Thus, the Hospice and Palliative Care Composite Process quality measure will use the current HQRP quality measures as its components. The data source for this measure will be currently implemented HIS items that are currently used in the calculation of the 7 component measures. Since the measure is a composite measure created from components, which are currently adopted HQRP measures, no new data collection will be required; data for the composite measure will come from existing items from the existing 7 HQRP component measures. CMS will begin calculating this measure using existing data items, beginning April 1, 2017; this means patient admissions occurring on or after April 1, 2017 will be included in the composite measure calculation.

The second measure is the Hospice Visits when Death is Imminent Measure Pair. Data for this measure will be collected via the existing data collection mechanism, the HIS. Four new items will be added to the HIS-Discharge record to collect the necessary data elements for this measure. CMS expects that data collection for this quality measure via the 4 new HIS items will begin no earlier than April 1, 2017. Thus, under current CMS timelines, hospice providers will begin data collection for this measure for patient admissions and discharges occurring on or after April 1, 2017.

The HIS V2.00.0 will fulfill the data collection requirements for the 7 currently adopted NQF measures and the 2 new measures. The HIS V2.00.0 contains:

- All items from the HIS V1.00.0, which are necessary to calculate the 7 adopted NQF measures (and thus the composite measure), plus the HIS V1.00.0 administrative items necessary for patient identification and record matching,
- One new item for measure refinement of the existing measure NQF #1637 Pain Assessment,
- New items to collect data for the Hospice Visits when Death is Imminent measure pair,
- New administrative items for patient record matching and future public reporting of hospice quality data.

Hospice providers will submit an HIS-Admission and an HIS-Discharge for each patient admission. Using HIS data for assessments submitted October 1, 2014 through September 30, 2015, we have estimated that there will be approximately 1,248,419 discharges across all hospices per year and, therefore, we would expect that there should be 1,248,419 Hospice Item Sets (consisting of one admission and one discharge assessment per patient) submitted across all hospices yearly. Over a three-year period, we expect 3,745,257 Hospice Item Sets across all hospices. There were 4,259 certified hospices in the U.S. as of January 2016; [36] we estimate that each individual hospice will submit on average 293 Hospice Item Sets annually, which is approximately 24 Hospice Items Sets per month or 879 Hospice Item Sets over 3 years.

The Hospice Item Set consists of an admission assessment and a discharge assessment. As noted above, we estimate that there will be 1,248,419 hospice admissions across all hospices per year. Therefore, we expect there to be 2,496,838 Hospice Item Set assessment submissions (admission and discharge assessments counted separately) submitted across all hospices annually, which is 208,070 across all hospices monthly, or 7,490,514 across all hospices over three years. We further estimate that there will be 586 Hospice Item Set submissions by each hospice annually, which is approximately 49 submissions monthly or 1,759 submissions over three years.

For the Admission Hospice Item Set, we estimate that it will take 14 minutes of time by a clinician, such as a Registered Nurse, at an hourly wage of $67.10 [37] to abstract data for Admission Hospice Item Set. This would cost the facility approximately $15.66 for each admission assessment. We further estimate that it will take 5 minutes of time by clerical or administrative staff person, such as a medical data entry clerk or medical secretary, at an hourly wage of $32.24 [38] to upload the Hospice Item Set data into the CMS system. This would cost each facility approximately $2.69 per assessment. For the Discharge Hospice Item Set, we estimate that it

[36] Quality Improvement and Evaluation System (QIES) List of Hospice Providers, January 2016.

[37] The adjusted hourly wage of $67.10 per hour for a Registered Nurse was obtained using the mean hourly wage from the U.S. Bureau of Labor Statistics, $33.55. This mean hourly wage is adjusted by a factor of 100 percent to include fringe benefits. See *http://www.bls.gov/oes/current/oes291141.htm.*

[38] The adjusted hourly wage of $32.24 per hour for a Medical Secretary was obtained using the mean hourly wage from the U.S. Bureau of Labor Statistics, $16.12. This mean hourly wage is adjusted by a factor of 100 percent to include fringe benefits. See *http://www.bls.gov/oes/current/oes436013.htm.*

will take 9 minutes of time by a clinician, such as a nurse, at an hourly wage of $67.10 to abstract data for Discharge Hospice Item Set. This would cost the facility approximately $10.07. We further estimate that it will take 5 minutes of time by clerical or administrative staff, such as a medical data entry clerk or medical secretary, at an hourly wage of $32.24 to upload data into the CMS system. This would cost each facility approximately $2.69. The estimated cost for each full Hospice Item Set submission (admission assessment and discharge assessment) is $31.10.

We estimate that the total nursing time required for completion of both the admission and discharge assessments is 23 minutes at a rate of $67.10 per hour. The cost across all hospices for the nursing/clinical time required to complete both the admission and discharge Hospice Item Sets is estimated to be $32,111,417 annually, or $96,334,252 over 3 years, and the cost to each individual hospice is estimated to be $7,539.66 annually, or $22,618.98 over 3 years. The estimated time burden to hospices for a medical data entry clerk to complete the admission and discharge Hospice Item Set assessments is 10 minutes at a rate of $32.24 per hour. The cost for completion of the both the admission and discharge Hospice Item Sets by a medical data entry clerk is estimated to be $6,708,171 across all hospices annually, or $20,124,514 across all hospices over 3 years, and $1,575.06 to each hospice annually, or $4,725.17 to each hospice over 3 years.

The total combined time burden for completion of the Admission and Discharge Hospice Item Sets is estimated to be 33 minutes. The total cost across all hospices is estimated to be $38,819,589 annually or $116,458,766 over 3 years. For each individual hospice, this cost is estimated to be $9,114.72 annually or $27,344.16 over 3 years. See Table 18 for breakdown of burden and cost by assessment form.

TABLE 18—SUMMARY OF BURDEN HOURS AND COSTS

Regulation section(s)	OMB Control No.	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total cost ($)
Hospice Item Set Admission Assessment.	0938–1153	4,259	1,248,419 per year.	0.233 clinician hours; 0.083 clerical hours.	395,333 hours ...	Clinician at $67.10 per hour; Clerical staff at $32.24 per hour.	$22,900,166
Hospice Item Set Discharge Assessment.	0938–1153	4,259	1,248,419 per year.	0.150 clinician hours; 0.083 clerical hours.	291,298 hours ...	Clinician at $67.10 per hour; Clerical staff at $32.24 per hour.	15,919,423
3-year Total	0938–1153	4,259	7,490,514	0.55 hours	2,059,891 hours	Clinician at $67.10 per hour; Clerical staff at $32.24 per hour.	116,458,766

C. Submission of PRA-Related Comments

We have submitted a copy of this final rule to OMB for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by the OMB.

To obtain copies of the supporting statement and any related forms for the collections discussed above, please visit CMS's Web site at *https://www.cms.gov/RegulationsandGuidance/Legislation/PaperworkReductionActof1995/PRAListing.html*, or call the Reports Clearance Office at 410–786–1326.

We invited public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **ADDRESSES** section of this final rule and identify the rule (CMS–1652–F) the ICR's CFR citation, CMS ID number, and OMB control number.

Public Comments Received for PRA Package (CMS Form Number—CMS–R–245)

Comment: CMS received one supportive comment indicating that the additional data sought by CMS for the calculation of the Hospice Visits when Death is Imminent Measure Pair does not represent a significant burden on providers and may result in useful information. Other commenters stated that CMS's burden estimates underestimate the costs of completing the HIS. One commenter stated that the typical admission assessment time is 45 minutes to 1 hour, and that staff travel can significantly increase costs. Another commenter stated that the costs of training and operational processes to support valid data abstraction should be included in the burden estimate.

Response: We thank the commenters for their feedback regarding the burden of the HIS V2.00.0, and the support of the new items used to collect data for the Hospice Visits when Death is Imminent Measure Pair. Regarding the cost estimates for the HIS Admission form, the HIS is a set of data elements that can be used to calculate 7 NQF endorsed quality measures and 2 new measures adopted in this rule. The HIS is not a patient assessment that would be directly administered to the patient and/or family or caregivers during the initial assessment or comprehensive assessment visit. Since the HIS is not intended to replace the initial/comprehensive assessment, the PRA burden estimates, by definition, do not include the time spent assessing the patient. HIS PRA burden estimates are intended to reflect only the time needed to complete HIS items, independent of clinical time spent assessing the patient. Similarly, PRA burden estimates include the Annualized Cost to the Federal Government related to the HIS V2.00.0 for provider training, preparation of HIS V2.00.0 manuals and materials, receipt and storage of data, data analysis, and upkeep of data submission software. In order to mitigate costs of operational processes, providers may use the Hospice Abstraction Reporting Tool (HART) software, which is free to download and use, to collect and maintain facility, patient, and HIS Record information for subsequent submission to the QIES

ASAP system. Burden estimates for completing the HIS data items were based on the HIS V1.00.0 and HIS V2.00.0 pilot tests. We recognize additional activities and efforts will be required to implement and use the HIS V2.00.0 as part of the quality reporting program. We agree that it is important for hospices to learn about and understand the new HIS, and we plan to provide hospices with training resources to facilitate implementation of the HIS.

Comment: One commenter stated that the addition of new items to the HIS Discharge record will require vendor software development and testing, hospice implementation, education and training, and internal validation. The commenter stated that the target implementation date of April 1, 2017 may not provide adequate time for implementation.

Response: We appreciate the commenter's feedback regarding the timeline for implementation and of the HIS V2.00.0. The HIS V2.00.0 is undergoing review as part of a PRA package under OMB number 0938–1153 and will be implemented April 1, 2017. We believe the April 1, 2017 implementation date will allow sufficient time for providers to update their clinical documentation systems and train staff on new HIS items. The timeline for implementation of the HIS V2.00.0 is consistent with the timeline from prior years when the HIS V1.00.0 was implemented. We expect training and implementation activities to take considerably less time for the HIS V2.00.0 compared to the HIS V1.00.0 since the HIS V2.00.0 can capitalize on existing infrastructures used by stakeholders for the HIS V1.00.0 and contains only 17 new item components (compared to the 60 item components that were implemented in the HIS V1.00.0). Moreover, we encourage providers to begin preparations for HIS V2.00.0 implementation as soon as possible. The HIS V2.00.0 is currently available for review by software vendors and hospice providers. Some of the activities that are necessary prior to implementation can be done concurrently. For example, hospice education and training on the new items and data abstraction can be conducted at the same time as vendor development of software.

We are aware of the effort hospices and vendors will have to make to prepare for implementation of the HIS. The HIS pilot showed that implementing the HIS is feasible and that hospices are most likely already collecting the information needed to complete the HIS data items. A draft version of the HIS technical data specifications was posted on the CMS Web site on May 19, 2016. Thus, vendors have been provided with more than adequate time to develop products for their clients. We expect vendors to begin reviewing the draft technical data specifications as soon as they are posted. We encourage vendors to submit questions and comments to the HIS technical email box: *HospiceTechnicalIssues@cms.hhs.gov.* Software vendors should not be waiting for final technical data specifications to be posted to begin development of their own products. Therefore, we believe that vendors have been provided with adequate time and resources to meet the April 1, 2017 implementation date of the HIS. For providers that currently use a vendor-designed software to complete HIS records, if a provider has concerns about the timeliness of release of HIS V2.00.0 items in vendor-designed software, CMS reminds providers that alternative means of completing HIS records (HART software) are available to all providers free of charge. Although electronic submission of HIS records is required, hospices do not need to have an electronic medical record to complete or submit HIS data. In the FY 2014 Hospice Wage Index, final rule (78 FR 48258) we finalized that to complete HIS records providers can use either the HART software, which is free to download and use, or vendor-designed software. HART provides an alternative option for hospice providers to collect and maintain facility, patient, and HIS Record information for subsequent submission to the QIES ASAP system. Once HIS records are complete, electronic HIS files must be submitted to CMS via the QIES ASAP system. Electronic data submission via the QIES ASAP system is required for all HIS submissions; there are no other data submission methods available. Hospices have 30 days from a patient admission or discharge to submit the appropriate HIS record for that patient through the QIES ASAP system. We will continue to make HIS completion and submission software available to hospices at no cost. We provided details on data collection and submission timing under the downloads section of the HIS Web page on the CMS.gov Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-AssessmentInstruments/Hospice-Quality-Reporting/Hospice-Item-Set-HIS.html.*

Comment: One commenter stated that although the burden associated with the HIS assessment may not be unduly burdensome, the collective burden of various reporting requirements makes a large fiscal impact on hospices.

Response: We thank the commenters for taking the time to convey their concerns about the burden and cost of data collection for the HQRP and other regulatory requirements. We attempted to reduce the regulatory burden of our quality reporting programs to the greatest extent possible. The estimated burden for completing the HIS V2.00.0 can be viewed here: (*https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html*). Specifically, CMS estimates 19 minutes per response for the Admission HIS and 14 minutes per response for the Discharge HIS. Details regarding the estimate can be found at *http://cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.* Comments concerning the accuracy of the time estimate(s) or suggestions for improving the HIS can be directed to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4–26–05, Baltimore, Maryland 21244–1850. With respect to the commenter's concern about additional expenses incurred as part of quality reporting, any additional costs incurred as part of quality reporting programs should be reported on the cost reports. Cost report data may be considered in future payment reform.

Comment: One commenter stated that the addition of the J0905 Pain Active Problem item to the HIS V2.00.0 would be burdensome to hospice providers since it requires an update to the Admission HIS documentation and the item will not be used in calculation of the Pain Assessment measure. The commenter suggested adding the item when a Patient Reported Outcome Pain Measure is implemented or when a Hospice Patient Assessment Instrument is developed.

Response: We thank the commenter for their comments regarding the new item J0905, Pain Active problem. CMS would like to clarify our reasoning and intent behind the addition of the J0905 Pain Active Problem item. Since the HIS V1.00.0 was implemented on July 1, 2014, CMS has received an overwhelming amount of feedback from the provider community regarding the items in Section J: Pain of the HIS V1.00.0 (J0900. Pain Screening and J0910. Comprehensive Pain Assessment). These items correspond to the National Quality Forum (NQF) #1634 Pain Screening quality measure and the NQF #1637 Pain Assessment quality measure, respectively. NQF #1634 calculates the percentage of

patients who were screened for pain within two days of admission. Patients who screen positive for pain are included in the denominator for NQF #1637, which measures the percentage of patients who screened positive for pain who received a comprehensive pain assessment within 1 day.

Under current specifications for NQF #1634 and NQF #1637, if a patient is *not* in pain at the time of the first screening, that patient is not included in the denominator for NQF #1637—even if pain is an active problem for the patient. As such, if a patient is not in current pain at the time of the first pain screening, HIS V1.00.0 skip patterns direct providers to skip Item J0910, the comprehensive pain assessment item. RTI received feedback from the provider community that the measure specifications and associated skip pattern between J0900 and J0910 do not align with clinical practice, as clinicians will often complete a comprehensive pain assessment for patients when pain is an active problem but the patient is not in pain at the time of the screening. Providers further noted that some vendor-designed software built HIS skip patterns into clinical documentation systems and the skip pattern between J0900 and J0910 was thus restricting the ability of clinicians to document comprehensive assessments that were conducted per clinical best practice but not required for the purposes of the HIS pain quality measures. Due to these factors, CMS has received feedback from the provider community to consider changing items in the pain section to align HIS pain items with current clinical practice.

Thus, directly in response to feedback from providers, CMS added the J0905 Pain Active Problem item to the HIS V2.00.0. We believe this addition will actually reduce burden on providers since it is better aligned with current clinical practice. The addition of J0905 also better aligns items in the pain section with items in Section J: Respiratory Status. CMS plans to analyze data from J0905 to inform future potential refinements to the NQF-endorsed pain quality measures.

ICR-related comments are due October 4, 2016.

V. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA, March 22, 1995; Pub. L. 104–4), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This final rule has been designated as economically significant under section 3(f)(1) of Executive Order 12866 and thus a major rule under the Congressional Review Act. Accordingly, we have prepared a regulatory impact analysis (RIA) that, to the best of our ability, presents the costs and benefits of the rulemaking. This final rule was also reviewed by OMB.

2. Statement of Need

This final rule meets the requirements of our regulations at § 418.306(c), which requires annual issuance, in the **Federal Register**, of the hospice wage index based on the most current available CMS hospital wage data, including any changes to the definitions of Core-Based Statistical Areas (CBSAs), or previously used Metropolitan Statistical Areas (MSAs). This final rule will also update payment rates for each of the categories of hospice care described in § 418.302(b) for FY 2017 as required under section 1814(i)(1)(C)(ii)(VII) of the Act. The payment rate updates are subject to changes in economy-wide productivity as specified in section 1886(b)(3)(B)(xi)(II) of the Act. In addition, the payment rate updates may be reduced by an additional 0.3 percentage point (although for FY 2014 to FY 2019, the potential 0.3 percentage point reduction is subject to suspension under conditions specified in section 1814(i)(1)(C)(v) of the Act). In 2010, the Congress amended section 1814(i)(6) of the Act with section 3132(a) of the Affordable Care Act. The amendment authorized the Secretary to revise the methodology for determining the payment rates for routine home care and other services included in hospice care, no earlier than October 1, 2013. In the FY 2016 Hospice Wage Index and Rate Update final rule (80 FR 47164), we finalized the creation of two different payment rates for RHC that resulted in a higher base payment rate for the first 60 days of hospice care and a reduced base payment rate for days 61 and over of hospice and created a SIA payment, in addition to the per diem rate for the RHC level of care, equal to the CHC hourly payment rate multiplied by the amount of direct patient care provided by an RN or social worker that occurs during the last 7 days of a beneficiary's life, if certain criteria are met. Finally, section 3004 of the Affordable Care Act amended the Act to authorize a quality reporting program for hospices, and this rule discusses changes in the requirements for the hospice quality reporting program in accordance with section 1814(i)(5) of the Act.

3. Overall Impacts

We estimate that the aggregate impact of this final rule will be an increase of $350 million in payments to hospices, resulting from the hospice payment update percentage of 2.1 percent. The impact analysis of this final rule represents the projected effects of the changes in hospice payments from FY 2016 to FY 2017. Using the most recent data available at the time of rulemaking, in this case FY 2015 hospice claims data, we apply the current FY 2016 wage index and labor-related share values to the level of care per diem payments and SIA payments for each day of hospice care to simulate FY 2016 payments. Then, using the same FY 2015 data, we apply the FY 2017 wage index and labor-related share values to simulate FY 2017 payments. Certain events may limit the scope or accuracy of our impact analysis, because such an analysis is susceptible to forecasting errors due to other changes in the forecasted impact time period. The nature of the Medicare program is such that the changes may interact, and the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon hospices.

4. Detailed Economic Analysis

The FY 2017 hospice payment impacts appear in Table 19. We tabulate the resulting payments according to the classifications in Table 19 (for example, facility type, geographic region, facility ownership), and compare the difference between current and proposed payments to determine the overall impact.

The first column shows the breakdown of all hospices by urban or rural status, census region, hospital-based or freestanding status, size, and type of ownership, and hospice base. The second column shows the number of hospices in each of the categories in the first column.

The third column shows the effect of the annual update to the wage index. This represents the effect of using the FY 2017 hospice wage index. The aggregate impact of this change is zero percent, due to the hospice wage index standardization factor. However, there are distributional effects of the FY 2017 hospice wage index.

The fourth column shows the effect of the hospice payment update percentage for FY 2017. The 2.1 percent hospice payment update percentage for FY 2017 is based on an estimated 2.7 percent inpatient hospital market basket update, reduced by a 0.3 percentage point productivity adjustment and by a 0.3 percentage point adjustment mandated by the Affordable Care Act, and is constant for all providers.

The fifth column shows the effect of all the changes on FY 2017 hospice payments. It is projected that aggregate payments will increase by 2.1 percent, assuming hospices do not change their service and billing practices in response.

As illustrated in Table 19, the combined effects of all the proposals vary by specific types of providers and by location. For example, due to the changes in this rule, the estimated impacts on FY 2017 payments range from a 1.1 percent increase for hospices providing care in the rural West North Central region to a 2.8 percent increase for hospices providing care in the rural Pacific region.

TABLE 19—PROJECTED IMPACT TO HOSPICES FOR FY 2017

(1)	Number of providers (2)	Updated wage data (%) (3)	Proposed hospice payment update (%) (4)	FY 2017 total change (%) (5)
All Hospices	4,177	0.0	2.1	2.1
Urban Hospices	3,179	0.0	2.1	2.1
Rural Hospices	998	−0.1	2.1	2.0
Urban Hospices—New England	138	0.4	2.1	2.5
Urban Hospices—Middle Atlantic	252	0.2	2.1	2.3
Urban Hospices—South Atlantic	422	−0.1	2.1	2.0
Urban Hospices—East North Central	399	−0.1	2.1	2.0
Urban Hospices—East South Central	162	−0.1	2.1	2.0
Urban Hospices—West North Central	220	−0.5	2.1	1.6
Urban Hospices—West South Central	616	−0.2	2.1	1.9
Urban Hospices—Mountain	313	−0.3	2.1	1.8
Urban Hospices—Pacific	618	0.6	2.1	2.7
Urban Hospices—Outlying	39	−0.7	2.1	1.4
Rural Hospices—New England	23	−0.4	2.1	1.7
Rural Hospices—Middle Atlantic	42	−0.2	2.1	1.9
Rural Hospices—South Atlantic	136	0.2	2.1	2.3
Rural Hospices—East North Central	141	0.1	2.1	2.2
Rural Hospices—East South Central	129	−0.1	2.1	2.0
Rural Hospices—West North Central	186	−1.0	2.1	1.1
Rural Hospices—West South Central	184	−0.1	2.1	2.0
Rural Hospices—Mountain	107	−0.2	2.1	1.9
Rural Hospices—Pacific	47	0.7	2.1	2.8
Rural Hospices—Outlying	3	−0.2	2.1	1.9
0–3,499 RHC Days (Small)	912	0.0	2.1	2.1
3,500–19,999 RHC Days (Medium)	2,004	0.0	2.1	2.1
20,000+ RHC Days (Large)	1,261	0.0	2.1	2.1
Non-Profit Ownership	1,071	0.1	2.1	2.2
For Profit Ownership	2,553	−0.1	2.1	2.0
Govt Ownership	160	0.5	2.1	2.6
Other Ownership	393	−0.1	2.1	2.0
Freestanding Facility Type	3,184	0.0	2.1	2.1
HHA/Facility-Based Facility Type	993	0.2	2.1	2.3

Source: FY 2015 hospice claims data from the Standard Analytic Files for CY 2014 (as of June 30, 2015) and CY 2015 (as of March 31, 2016).

Region Key:

New England=Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont; Middle Atlantic=Pennsylvania, New Jersey, New York; South Atlantic=Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia; East North Central=Illinois, Indiana, Michigan, Ohio, Wisconsin; East South Central=Alabama, Kentucky, Mississippi, Tennessee; West North Central=Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota; West South Central=Arkansas, Louisiana, Oklahoma, Texas; Mountain=Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming; Pacific=Alaska, California, Hawaii, Oregon, Washington; Outlying=Guam, Puerto Rico, Virgin Islands.

5. Alternatives Considered

Since the hospice payment update percentage is determined based on statutory requirements, we did not consider not updating hospice payment rates by the payment update percentage. The 2.1 percent hospice payment update percentage for FY 2017 is based on a 2.7 percent inpatient hospital market basket update for FY 2017, reduced by a 0.3 percentage point productivity adjustment and by an

additional 0.3 percentage point. Payment rates since FY 2002 have been updated according to section 1814(i)(1)(C)(ii)(VII) of the Act, which states that the update to the payment rates for subsequent years must be the market basket percentage for that FY. Section 3401(g) of the Affordable Care Act also mandates that, starting with FY 2013 (and in subsequent years), the hospice payment update percentage will be annually reduced by changes in economy-wide productivity as specified in section 1886(b)(3)(B)(xi)(II) of the Act. In addition, section 3401(g) of the Affordable Care Act mandates that in FY 2013 through FY 2019, the hospice payment update percentage will be reduced by an additional 0.3 percentage point (although for FY 2014 to FY 2019, the potential 0.3 percentage point reduction is subject to suspension under conditions specified in section 1814(i)(1)(C)(v) of the Act).

We considered not adopting a hospice wage index standardization factor. However, as discussed in section III.C.1 of this final rule, we believe that adopting a hospice wage index standardization factor would provide a safeguard to the Medicare program, as well as to hospices, because it will mitigate changes in overall hospice expenditures due to annual fluctuations in the hospital wage data from year-to-year by ensuring that hospice wage index updates and revisions are implemented in a budget neutral manner. We estimate that if the hospice wage index standardization factor is not finalized, total payments in a given year would increase or decrease by as much as 0.3 percent or $50 million.

6. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table 20, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule. Table 20 provides our best estimate of the possible changes in Medicare payments under the hospice benefit as a result of the policies in this final rule. This estimate is based on the data for 4,177 hospices in our impact analysis file, which was constructed using FY 2015 claims available as of March 31, 2016. All expenditures are classified as transfers to hospices.

TABLE 20—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS, FROM FY 2016 TO FY 2017

[in $Millions]

Category	Transfers
FY 2017 Hospice Wage Index and Payment Rate Update	
Annualized Monetized Transfers.	$350 *
From Whom to Whom?	Federal Government to Medicare Hospices.

* The net increase of $350 million in transfer payments is a result of the 2.1 percent hospice payment update percentage compared to payments in FY 2016.

7. Conclusion

We estimate that aggregate payments to hospices in FY 2017 would increase by $350 million, or 2.1 percent, compared to payments in FY 2016. We estimate that in FY 2017, hospices in urban and rural areas would experience, on average, a 2.1 percent and a 2.0 percent increase, respectively, in estimated payments compared to FY 2016. Hospices providing services in the urban Pacific and rural Pacific regions would experience the largest estimated increases in payments of 2.7 percent and 2.8 percent, respectively. Hospices serving patients in rural areas in the West North Central region would experience the lowest estimated increase of 1.1 percent in FY 2017 payments.

B. Regulatory Flexibility Act Analysis

The RFA requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. The great majority of hospitals and most other health care providers and suppliers are small entities by meeting the Small Business Administration (SBA) definition of a small business (in the service sector, having revenues of less than $7.5 million to $38.5 million in any 1 year), or being nonprofit organizations. For purposes of the RFA, we consider all hospices as small entities as that term is used in the RFA. HHS's practice in interpreting the RFA is to consider effects economically ''significant'' only if they reach a threshold of 3 to 5 percent or more of total revenue or total costs. The effect of the final FY 2017 hospice payment update percentage results in an overall increase in estimated hospice payments of 2.1 percent, or $350 million. Therefore, the Secretary has determined that this final rule will not create a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This final rule only affects hospices. Therefore, the Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

C. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 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 2016, that threshold is approximately $146 million. This final rule is not anticipated to have an effect on State, local, or tribal governments, in the aggregate, or on the private sector of $146 million or more.

VI. Federalism Analysis

Executive Order 13132, Federalism (August 4, 1999) requires an agency to provide federalism summary impact statement when it promulgates a proposed rule (and subsequent final rule) that has federalism implications and which imposes substantial direct requirement costs on State and local governments which are not required by statute. 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.

Dated: July 18, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: July 25, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2016–18221 Filed 7–29–16; 4:15 pm]

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Part V

Department of Energy

10 CFR Part 430
Energy Conservation Program: Energy Conservation Standards for Uninterruptible Power Supplies; Proposed Rule

DEPARTMENT OF ENERGY

10 CFR Part 430

[Docket Number EERE–2016–BT–STD–0022]

RIN 1904–AD69

Energy Conservation Program: Energy Conservation Standards for Uninterruptible Power Supplies

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of proposed rulemaking (NOPR) and announcement of public meeting.

SUMMARY: The Energy Policy and Conservation Act of 1975 (EPCA), as amended, prescribes energy conservation standards for various consumer products and certain commercial and industrial equipment, including battery chargers. In this notice, the U.S. Department of Energy (DOE) proposes new energy conservation standards for uninterruptible power supplies, a class of battery chargers, and also announces a public meeting to receive comment on these proposed standards and associated analyses and results.

DATES: *Comments:* DOE will accept comments, data, and information regarding this notice of proposed rulemaking (NOPR) before and after the public meeting, but no later than October 4, 2016. See section VII, ''Public Participation,'' for details.

Comments regarding the likely competitive impact of the proposed standard should be sent to the Department of Justice contact listed in the **ADDRESSES** section before September 6, 2016.

Meeting: DOE will hold a public meeting on Friday, September 9, 2016, from 9:30 a.m. to 2:00 p.m., in Washington, DC. The meeting will also be broadcast as a webinar. See section VII, ''Public Participation,'' for webinar registration information, participant instructions, and information about the capabilities available to webinar participants.

ADDRESSES: The public meeting will be held at the U.S. Department of Energy, Forrestal Building, Room 6E–069, 1000 Independence Avenue SW., Washington, DC 20585.

Instructions: Any comments submitted must identify the NOPR on Energy Conservation Standards for Battery Chargers, and provide docket number EERE–2016–BT–STD–0022 and/or regulatory information number (RIN) 1904–AD69. Comments may be submitted using any of the following methods:

(1) *Federal eRulemaking Portal: www.regulations.gov*. Follow the instructions for submitting comments.

(2) *Email: BatteryChargersUPS2016STD0022@ee.doe.gov*. Include the docket number and/or RIN in the subject line of the message. Submit electronic comments in WordPerfect, Microsoft Word, PDF, or ASCII file format, and avoid the use of special characters or any form of encryption.

(3) *Postal Mail:* Mr. Jeremy Dommu, U.S. Department of Energy, Building Technologies Office, Mailstop EE–5B, 1000 Independence Avenue SW., Washington, DC 20585–0121. If possible, please submit all items on a compact disc (CD), in which case it is not necessary to include printed copies.

(4) *Hand Delivery/Courier:* Mr. Jeremy Dommu, U.S. Department of Energy, Building Technologies Office, 950 L'Enfant Plaza SW., Washington, DC 20024. Telephone: (202) 586–2945. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

No telefacsimilies (faxes) will be accepted. For detailed instructions on submitting comments and additional information on the rulemaking process, see section VII of this document (''Public Participation'').

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this proposed rule may be submitted to Office of Energy Efficiency and Renewable Energy through the methods listed above and by email to *Chad_S_Whiteman@omb.eop.gov*.

EPCA requires the Attorney General to provide DOE a written determination of whether the proposed standard is likely to lessen competition. The U.S. Department of Justice Antitrust Division invites input from market participants and other interested persons with views on the likely competitive impact of the proposed standard. Interested persons may contact the Division at *energy.standards@usdoj.gov* before September 6, 2016. Please indicate in the ''Subject'' line of your email the title and Docket Number of this proposed rulemaking.

Docket: The docket, which includes **Federal Register** notices, public meeting attendee lists and transcripts, comments, and other supporting documents/materials, is available for review at *www.regulations.gov*. All documents in the docket are listed in the *www.regulations.gov* index. However, some documents listed in the index may not be publicly available, such as those containing information that is exempt from public disclosure.

The docket Web page can be found at: *http://www.regulations.gov/#!docketDetail;D=EERE-2016-BT-STD-0022*. This Web page contains a link to the docket for this notice on the *www.regulations.gov* site. The *www.regulations.gov* Web page contains simple instructions on how to access all documents, including public comments, in the docket. See section VII, ''Public Participation,'' for further information on how to submit comments through *www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT:
Jeremy Dommu, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–5B, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 586–9870. Email: *battery_chargers_and_external_power_supplies@ee.doe.gov*.

Celia Sher, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 287–6122. Email: *Celia.Sher@hq.doe.gov*.

For further information on how to submit a comment, review other public comments and the docket, or participate in the public meeting, contact Appliance and Equipment Standards Program staff at (202) 586–6636 or by email: *battery_chargers_and_external_power_supplies@ee.doe.gov*.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Synopsis of the Proposed Rule

Title III, Part B [1] of the Energy Policy and Conservation Act of 1975 (EPCA or the Act), Public Law 94–163 (42 U.S.C. 6291–6309, as codified), established the Energy Conservation Program for Consumer Products Other Than Automobiles.[2] These products include battery chargers, the subject of this rulemaking.

Pursuant to EPCA, any new or amended energy conservation standard must be designed to achieve the maximum improvement in energy efficiency that is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A)) Furthermore, the new or amended standard must result in a significant conservation of energy. (42 U.S.C. 6295(o)(3)(B)) EPCA also provides that not later than 6 years after issuance of any final rule establishing or amending a standard, DOE must publish either a notice of determination that standards for the product do not need to be amended, or a notice of proposed rulemaking including new proposed energy conservation standards (proceeding to a final rule, as appropriate). (42 U.S.C. 6295(m)(1))

In accordance with these and other statutory provisions discussed in this document, DOE proposes new energy conservation standards for uninterruptible power supplies (hereafter referred to as ''UPSs''), a class of battery chargers. The proposed standards, which are expressed in average load adjusted efficiency, are shown in Table I.1.

These proposed standards, if adopted, would apply to all UPSs listed in Table I.1 and manufactured in, or imported into, the United States starting on and after the date two years after the publication of the final rule for this rulemaking.

[1] For editorial reasons, upon codification in the U.S. Code, Part B was redesignated Part A.

[2] All references to EPCA in this document refer to the statute as amended through the Energy Efficiency Improvement Act of 2015, Public Law 114–11 (Apr. 30, 2015).

Table I.1 Proposed Energy Conservation Standards for Uninterruptible Power Systems

UPS Product Class	Rated Output Power	Minimum Efficiency
Voltage and Frequency Dependent	$0\ W < P_{rated} \leq 300\ W$	-1.09E-06 * P_{rated}^2 + 6.50E-04 * P_{rated} + 0.876
	$300\ W < P_{rated} \leq 700\ W$	-5.63E-08 * P_{rated}^2 + 7.61E-05 * P_{rated} + 0.955
	$P_{rated} > 700\ W$	-6.22E-09 * P_{rated}^2 + 3.91E-06 * P_{rated} + 0.981
Voltage Independent	$0\ W < P_{rated} \leq 300\ W$	-6.45E-07 * P_{rated}^2 + 3.80E-04 * P_{rated} + 0.929
	$300\ W < P_{rated} \leq 700\ W$	-3.94E-08 * P_{rated}^2 + 4.87E-05 * P_{rated} + 0.974
	$P_{rated} > 700\ W$	-2.28E-09 * P_{rated}^2 – 7.40E-07 * P_{rated} + 0.990
Voltage and Frequency Independent	$0\ W < P_{rated} \leq 300\ W$	-3.13E-06 * P_{rated}^2 + 1.96E-03 * P_{rated} + 0.544
	$300\ W < P_{rated} \leq 700\ W$	-2.60E-07 * P_{rated}^2 + 3.65E-04 * P_{rated} + 0.765
	$P_{rated} > 700\ W$	-1.70E-08 * P_{rated}^2 + 3.85E-05 * P_{rated} + 0.877

A. Benefits and Costs to Consumers

Table I.2 presents DOE's evaluation of the economic impacts of the proposed standards on consumers of UPSs, as measured by the average life-cycle cost (LCC) savings and the simple payback period (PBP).[3] The average LCC savings are positive for all product classes, and the PBP is less than the average lifetime of UPSs, which is estimated to be between 5 and 10 years, depending on product class (see section IV.F.6).

TABLE I.2—IMPACTS OF PROPOSED ENERGY CONSERVATION STANDARDS ON CONSUMERS OF UPSS

Product class	Description	Average LCC savings [*2015$*]	Simple payback period *years*
10a	VFD UPS	$33.1	0.0
10b	VI UPS	6.09	4.6
10c	VFI UPS	34.7	4.7

DOE's analysis of the impacts of the proposed standards on consumers is described in section IV.F of this document.

B. Impact on Manufacturers

The industry net present value (INPV) is the sum of the discounted cash flows to the industry from the reference year through the end of the analysis period (2016 to 2048). Using a real discount rate of 6.1 percent, DOE estimates that the INPV for manufacturers of UPSs in the case without standards is $2,555 million in 2015$. Under the proposed standards, DOE expects that manufacturers may lose up to 23.4 percent of this INPV, which is approximately $598 million. Additionally, based on DOE's interviews with the manufacturers of UPSs, DOE does not expect significant impacts on manufacturing capacity or loss of employment for the industry as a whole to result from the proposed standards for UPSs.

DOE's analysis of the impacts of the proposed standards on manufacturers is described in section IV.J of this document.

C. National Benefits and Costs[4]

DOE's analyses indicate that the proposed energy conservation standards for UPSs would save a significant amount of energy. Relative to the case without new standards, the lifetime energy savings for UPSs purchased in the 30-year period that begins in the anticipated year of compliance with the new standards (2019–2048) amount to 1.18 quadrillion British thermal units (Btu), or quads.[5] This represents a savings of 22.6 percent relative to the energy use of these products in the case without new standards (referred to as the ''no-standards case'').

The cumulative net present value (NPV) of total consumer costs and savings of the proposed standards for UPSs ranges from $1.87 billion (at a 7-percent discount rate) to $4.40 billion (at a 3-percent discount rate). This NPV expresses the estimated total value of future operating-cost savings minus the estimated increased product costs for UPSs purchased in 2019–2048.

In addition, the proposed standards for UPSs are projected to yield significant environmental benefits. DOE estimates that the proposed standards would result in cumulative emission reductions (over the same period as for energy savings) of 72.0 million metric tons (Mt)[6] of carbon dioxide (CO_2), 40.9 thousand tons of sulfur dioxide (SO_2), 130 thousand tons of nitrogen oxides (NO_X), 306 thousand tons of methane

[3] The average LCC savings are measured relative to the efficiency distribution in the no-standards case, which depicts the market in the compliance year in the absence of standards (see section IV.F.8). The simple PBP, which is designed to compare specific efficiency levels, is measured relative to the baseline model (see section IV.F.9).

[4] All monetary values in this document are expressed in 2015 dollars and, where appropriate, are discounted to 2016 unless explicitly stated otherwise.

[5] The quantity refers to full-fuel-cycle (FFC) energy savings. FFC energy savings includes the energy consumed in extracting, processing, and transporting primary fuels (*i.e.,* coal, natural gas, petroleum fuels), and, thus, presents a more complete picture of the impacts of energy efficiency standards. For more information on the FFC metric, see section IV.H.2.

[6] A metric ton is equivalent to 1.1 short tons. Results for emissions other than CO_2 are presented in short tons.

(CH_4), 0.850 thousand tons of nitrous oxide (N_2O), and 0.151 tons of mercury (Hg).[7] The cumulative reduction in CO_2 emissions through 2030 amounts to 19.1 Mt, which is equivalent to the emissions resulting from the annual electricity use of 2.63 million homes.

The value of the CO_2 reductions is calculated using a range of values per metric ton (t) of CO_2 (otherwise known as the ''Social Cost of Carbon'', or SCC) developed by a Federal interagency working group.[8] The derivation of the SCC values is discussed in section IV.L. Using discount rates appropriate for each set of SCC values (see Table I.3), DOE estimates the present monetary value of the CO_2 emissions reduction (not including CO_2 equivalent emissions of other gases with global warming potential) is between $0.559 billion and $7.49 billion, with a value of $2.46 billion using the central SCC case represented by $40.6/t in 2015. DOE also estimates the present monetary value of the NO_X emissions reduction to be $126 million at a 7-percent discount rate and $274 million at a 3-percent discount rate.[9] DOE is investigating appropriate valuation of the reduction in methane and other emissions, and did not include any values in this rulemaking.

Table I.3 summarizes the national economic benefits and costs expected to result from the proposed standards for UPSs.

TABLE I.3—SUMMARY OF NATIONAL ECONOMIC BENEFITS AND COSTS OF PROPOSED ENERGY CONSERVATION STANDARDS FOR UPSS

[TSL 2]*

Category	Present value billion 2015$	Discount rate (percent)
Benefits		
Consumer Operating Cost Savings	4.40	7
	9.02	3
CO_2 Reduction Monetized Value ($12.4/t case)**	0.559	5
CO_2 Reduction Monetized Value ($40.6/t case)**	2.46	3
CO_2 Reduction Monetized Value ($63.2/t case)**	3.87	2.5
CO_2 Reduction Monetized Value ($118/t case)**	7.49	3
NO_X Reduction Monetized Value†	0.126	7
	0.274	3
Total Benefits‡	6.99	7
	11.8	3
Costs		
Consumer Incremental Installed Costs	2.53	7
	4.62	3
Total Net Benefits		
Including CO_2 and NO_X Reduction Monetized Value†	4.46	7
	7.14	3

* This table presents the costs and benefits associated with UPSs shipped in 2019–2048. These results include benefits to consumers which accrue after 2048 from the products purchased in 2019–2048. The costs account for the incremental variable and fixed costs incurred by manufacturers due to the standard, some of which may be incurred in preparation for the rule. Note that the Benefits and Costs may not sum to the Net Benefits due to rounding.

** The CO_2 values represent global monetized values of the SCC, in 2015$ per metric ton (t), in 2015 under several scenarios of the updated SCC values. The first three cases use the averages of SCC distributions calculated using 5-percent, 3-percent, and 2.5-percent discount rates, respectively. The fourth case represents the 95th percentile of the SCC distribution calculated using a 3% discount rate. The SCC time series incorporate an escalation factor.

† DOE estimated the monetized value of NO_X emissions reductions associated with electricity savings using benefit per ton estimates from the ''Regulatory Impact Analysis for the Clean Power Plan Final Rule,'' published in August 2015 by EPA's Office of Air Quality Planning and Standards. (Available at *www.epa.gov/cleanpowerplan/clean-power-plan-final-rule-regulatory-impact-analysis.*) See section IV.L for further discussion. DOE is primarily using a national benefit-per-ton estimate for NO_X emitted from the Electricity Generating Unit sector based on an estimate of premature mortality derived from the ACS study (Krewski et al. 2009). If the benefit-per-ton estimates were based on the Six Cities study (Lepuele et al. 2011), the values would be nearly two-and-a-half times larger.

‡ Total Benefits for both the 3% and 7% cases are derived using the series corresponding to average SCC with 3-percent discount rate ($40.6/t case).

[7] DOE calculated emissions reductions relative to the no-standards case, which reflects key assumptions in the *Annual Energy Outlook 2015* (*AEO 2015*) Reference case, which generally represents current legislation and environmental regulations for which implementing regulations were available as of October 31, 2014.

[8] United States Government—Interagency Working Group on Social Cost of Carbon. Technical Support Document: Technical Update of the Social Cost of Carbon for Regulatory Impact Analysis Under Executive Order 12866, May 2013). Revised July 2015. Available at *https://www.whitehouse.gov/sites/default/files/omb/inforeg/scc-tsd-final-july-2015.pdf.*

[9] DOE estimated the monetized value of NO_X emissions reductions associated with electricity savings using benefit per ton estimates from the *Regulatory Impact Analysis for the Clean Power Plan Final Rule,* published in August 2015 by EPA's Office of Air Quality Planning and Standards. Available at *www.epa.gov/cleanpowerplan/clean-power-plan-final-rule-regulatory-impact-analysis.* See section IV.L for further discussion. The U.S. Supreme Court has stayed the rule implementing the Clean Power Plan until the current litigation against it concludes. Chamber of Commerce, et al. v. EPA, et al., Order in Pending Case, 577 U.S. __ __ (2016). However, the benefit-per-ton estimates established in the Regulatory Impact Analysis for the Clean Power Plan are based on scientific studies that remain valid irrespective of the legal status of the Clean Power Plan. DOE is primarily using a national benefit-per-ton estimate for NO_X emitted from the Electricity Generating Unit sector based on an estimate of premature mortality derived from the ACS study (Krewski et al. 2009). If the benefit-per-ton estimates were based on the Six Cities study (Lepuele et al. 2011), the values would be nearly two-and-a-half times larger.

The benefits and costs of the proposed standards, for UPSs sold in 2019–2048, can also be expressed in terms of annualized values. The monetary values for the total annualized net benefits are the sum of (1) the national economic value of the benefits in reduced consumer operating costs, minus (2) the increase in product purchase prices and installation costs, plus (3) the value of the benefits of CO_2 and NO_X emission reductions, all annualized.[10]

Although the values of operating cost savings and CO_2 emission reductions are both important, two issues are relevant. First, the national operating savings are domestic U.S. consumer monetary savings that occur as a result of market transactions, whereas the value of CO_2 reductions is based on a global value. Second, the assessments of operating cost savings and CO_2 savings are performed with different methods that use different time frames for analysis. The national operating cost savings is measured for the lifetime of UPSs shipped in 2019–2048. Because CO_2 emissions have a very long residence time in the atmosphere,[11] the SCC values in future years reflect future CO_2-emissions impacts that continue beyond 2100.

Estimates of annualized benefits and costs of the proposed standards are shown in Table I.4. The results under the primary estimate are as follows. Using a 7-percent discount rate for benefits and costs other than CO_2 reduction (for which DOE used a 3-percent discount rate along with the average SCC series that has a value of $40.6/t in 2015),[12] the estimated cost of the standards proposed in this rule is $234 million per year in increased equipment costs, while the estimated annual benefits are $406 million in reduced equipment operating costs, $133 million in CO_2 reductions, and $11.6 million in reduced NO_X emissions. In this case, the net benefit amounts to $317 million per year. Using a 3-percent discount rate for all benefits and costs and the average SCC series that has a value of $40.6/t in 2015, the estimated cost of the proposed standards is $250 million per year in increased equipment costs, while the estimated annual benefits are $488 million in reduced operating costs, $133 million in CO_2 reductions, and $14.8 million in reduced NO_X emissions. In this case, the net benefit amounts to $386 million per year.

TABLE I.4—ANNUALIZED BENEFITS AND COSTS OF PROPOSED ENERGY CONSERVATION STANDARDS FOR UPSS

[TSL 2]

	Discount rate	Million 2015$/year		
		Primary estimate *	Low net benefits estimate *	High net benefits estimate *
Benefits				
Consumer Operating Cost Savings	7%	406	348	462.
	3%	488	413	565.
CO_2 Reduction Monetized Value ($12.4/t case) **	5%	40.1	35.5	44.4.
CO_2 Reduction Monetized Value ($40.6/t case) **	3%	133	117	148.
CO_2 Reduction Monetized Value ($63.2/t case) **	2.5%	194	171	216.
CO_2 Reduction Monetized Value ($118/t case) **	3%	405	357	451.
NO_X Reduction Monetized Value †	7%	11.6	10.4	28.6.
	3%	14.8	13.1	37.5.
Total Benefits ‡	7% plus CO_2 range	458 to 823	394 to 716	535 to 941.
	7%	551	476	638.
	3% plus CO_2 range	543 to 908	462 to 783	647 to 1,050.
	3%	636	544	751.
Costs				
Consumer Incremental Product Costs	7%	234	209	256.
	3%	250	221	277.
Net Benefits				
Total ‡	7% plus CO_2 range	224 to 589	185 to 507	278 to 685.
	7%	317	267	382.
	3% plus CO_2 range	293 to 658	241 to 563	369 to 776.
	3%	386	323	473.

* This table presents the annualized costs and benefits associated with UPSs shipped in 2019 − 2048. These results include benefits to consumers which accrue after 2048 from the products purchased in 2019 − 2048. The results account for the incremental variable and fixed costs incurred by manufacturers due to the standard, some of which may be incurred in preparation for the rule. The Primary, Low Net Benefits, and High Net Benefits Estimates utilize projections of energy prices from the *AEO 2015* Reference case, Low Economic Growth case, and High Economic Growth case, respectively. .Note that the Benefits and Costs may not sum to the Net Benefits due to rounding.

[10] To convert the time-series of costs and benefits into annualized values, DOE calculated a present value in 2016, the year used for discounting the NPV of total consumer costs and savings. For the benefits, DOE calculated a present value associated with each year's shipments in the year in which the shipments occur (*e.g.,* 2020 or 2030), and then discounted the present value from each year to 2016. The calculation uses discount rates of 3 and 7 percent for all costs and benefits except for the value of CO_2 reductions, for which DOE used case-specific discount rates, as shown in Table I.3. Using the present value, DOE then calculated the fixed annual payment over a 30-year period, starting in the compliance year, that yields the same present value.

[11] The atmospheric lifetime of CO_2 is estimated on the order of 30–95 years. Jacobson, M. Z. Correction to ''Control of fossil-fuel particulate black carbon and organic matter, possibly the most effective method of slowing global warming.'' *J. Geophys. Res.* 2005. 110: D14105. doi:10.1029/2005JD005888

[12] DOE used a 3-percent discount rate because the SCC values for the series used in the calculation were derived using a 3-percent discount rate (section IV.L).

** The CO_2 values represent global monetized values of the SCC, in 2015$ per metric ton (t), in 2015 under several scenarios of the updated SCC values. The first three cases use the averages of SCC distributions calculated using 5-percent, 3-percent, and 2.5-percent discount rates, respectively. The fourth case represents the 95th percentile of the SCC distribution calculated using a 3-percent discount rate. The SCC time series incorporate an escalation factor.

† DOE estimated the monetized value of NO_X emissions reductions associated with electricity savings using benefit per ton estimates from the ''Regulatory Impact Analysis for the Clean Power Plan Final Rule,'' published in August 2015 by EPA's Office of Air Quality Planning and Standards. (Available at *www.epa.gov/cleanpowerplan/clean-power-plan-final-rule-regulatory-impact-analysis*.) See section IV.L for further discussion. For the Primary Estimate and Low Net Benefits Estimate, DOE used a national benefit-per-ton estimate for NO_X emitted from the Electric Generating Unit sector based on an estimate of premature mortality derived from the ACS study (Krewski et al. 2009). For DOE's High Net Benefits Estimate, the benefit-per-ton estimates were based on the Six Cities study (Lepuele et al. 2011), which are nearly two-and-a-half times larger than those from the ACS study.

‡ Total Benefits for both the 3% and 7% cases are derived using the series corresponding to the average SCC with a 3-percent discount rate ($40.6/t case). In the rows labeled ''7% plus CO_2 range'' and ''3% plus CO_2 range,'' the operating cost and NO_X benefits are calculated using the labeled discount rate, and those values are added to the full range of CO_2 values.

DOE's analysis of the national impacts of the proposed standards is described in sections IV.H, IV.K, and IV.L of this document.

D. Conclusion

DOE has tentatively concluded that the proposed standards represent the maximum improvement in energy efficiency that is technologically feasible and economically justified, and would result in the significant conservation of energy. DOE further notes that UPSs achieving these standard levels are already commercially available for all product classes covered by this proposal. Based on the analyses described above, DOE has tentatively concluded that the benefits of the proposed standards to the Nation (energy savings, positive NPV of consumer benefits, consumer LCC savings, and emission reductions) would outweigh the burdens (loss of INPV for manufacturers and LCC increases for some consumers).

DOE also considered more-stringent energy efficiency levels as potential standards, and is still considering them in this rulemaking. However, DOE has tentatively concluded that the potential burdens of the more-stringent energy efficiency levels would outweigh the projected benefits. Based on consideration of the public comments DOE receives in response to this notice and related information collected and analyzed during the course of this rulemaking effort, DOE may adopt energy efficiency levels presented in this notice that are either higher or lower than the proposed standards, or some combination of level(s) that incorporate the proposed standards in part.

II. Introduction

The following section briefly discusses the statutory authority underlying this proposed rule, as well as some of the relevant historical background related to the establishment of standards for battery chargers. DOE's regulations define ''battery charger'' as a device that charges batteries for consumer products, including battery chargers embedded in other consumer products. 10 CFR 430.2.

A. Authority

Title III, Part B of the Energy Policy and Conservation Act of 1975 (EPCA or the Act), Public Law 94–163 (codified as 42 U.S.C. 6291–6309) established the Energy Conservation Program for Consumer Products Other Than Automobiles, a program covering most major household appliances (collectively referred to as ''covered products''), which includes battery chargers.

Section 309 of the Energy Independence and Security Act of 2007 (''EISA 2007'') amended EPCA by directing DOE to prescribe, by rule, definitions and test procedure for the power use of battery chargers (42 U.S.C. 6295(u)(1)), and to issue a final rule that prescribes energy conservation standards for battery chargers or classes of battery chargers or determine that no energy conservation standard is technologically feasible and economically justified. (42 U.S.C. 6295(u)(1)(E)).

Pursuant to EPCA, DOE's energy conservation program for covered products consists essentially of four parts: (1) Testing, (2) labeling, (3) the establishment of Federal energy conservation standards, and (4) certification and enforcement procedures. The Federal Trade Commission (FTC) is primarily responsible for labeling, and DOE implements the remainder of the program. Subject to certain criteria and conditions, DOE is required to develop test procedures to measure the energy efficiency, energy use, or estimated annual operating cost of each covered product. (42 U.S.C. 6295(o)(3)(A) and (r)) Manufacturers of covered products must use the prescribed DOE test procedure as the basis for certifying to DOE that their products comply with the applicable energy conservation standards adopted under EPCA and when making representations to the public regarding the energy use or efficiency of those products. (42 U.S.C. 6293(c) and 6295(s)) Similarly, DOE must use these test procedures to determine whether the products comply with standards adopted pursuant to EPCA. (42 U.S.C. 6295(s)) The DOE test procedure for battery chargers appears at title 10 of the Code of Federal Regulations (CFR) part 430, subpart B, appendix Y.

DOE must follow specific statutory criteria for prescribing new or amended standards for covered products, including battery chargers. Any new or amended standard for a covered product must be designed to achieve the maximum improvement in energy efficiency that is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A) and (3)(B)) Furthermore, DOE may not adopt any standard that would not result in the significant conservation of energy. (42 U.S.C. 6295(o)(3)) Moreover, DOE may not prescribe a standard: (1) For certain products, including battery chargers, if no test procedure has been established for the product, or (2) if DOE determines by rule that the standard is not technologically feasible or economically justified. (42 U.S.C. 6295(o)(3)(A)and (B)) In deciding whether a proposed standard is economically justified, DOE must determine whether the benefits of the standard exceed its burdens. (42 U.S.C. 6295(o)(2)(B)(i)) DOE must make this determination after receiving comments on the proposed standard, and by considering, to the greatest extent practicable, the following seven statutory factors:

(1) The economic impact of the standard on manufacturers and consumers of the products subject to the standard;

(2) The savings in operating costs throughout the estimated average life of the covered products in the type (or class) compared to any increase in the price, initial charges, or maintenance expenses for the covered products that are likely to result from the standard;

(3) The total projected amount of energy (or as applicable, water) savings likely to result directly from the standard;

(4) Any lessening of the utility or the performance of the covered products likely to result from the standard;

(5) The impact of any lessening of competition, as determined in writing by the Attorney General, that is likely to result from the standard;

(6) The need for national energy and water conservation; and

(7) Other factors the Secretary of Energy (Secretary) considers relevant. (42 U.S.C. 6295(o)(2)(B)(i)(I)–(VII))

Further, EPCA, as codified, establishes a rebuttable presumption that a standard is economically justified if the Secretary finds that the additional cost to the consumer of purchasing a product complying with an energy conservation standard level will be less than three times the value of the energy savings during the first year that the consumer will receive as a result of the standard, as calculated under the applicable test procedure. (42 U.S.C. 6295(o)(2)(B)(iii))

EPCA, as codified, also contains what is known as an ''anti-backsliding'' provision, which prevents the Secretary from prescribing any amended standard that either increases the maximum allowable energy use or decreases the minimum required energy efficiency of a covered product. (42 U.S.C. 6295(o)(1)) Also, the Secretary may not prescribe an amended or new standard if interested persons have established by a preponderance of the evidence that the standard is likely to result in the unavailability in the United States in any covered product type (or class) of performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as those generally available in the United States. (42 U.S.C. 6295(o)(4))

Additionally, EPCA specifies requirements when promulgating an energy conservation standard for a covered product that has two or more subcategories. DOE must specify a different standard level for a type or class of product that has the same function or intended use, if DOE determines that products within such group: (A) Consume a different kind of energy from that consumed by other covered products within such type (or class); or (B) have a capacity or other performance-related feature which other products within such type (or class) do not have and such feature justifies a higher or lower standard. (42 U.S.C. 6295(q)(1)) In determining whether a performance-related feature justifies a different standard for a group of products, DOE must consider such factors as the utility to the consumer of the feature and other factors DOE deems appropriate. *Id.* Any rule prescribing such a standard must include an explanation of the basis on which such higher or lower level was established. (42 U.S.C. 6295(q)(2))

Federal energy conservation requirements generally supersede State laws or regulations concerning energy conservation testing, labeling, and standards. (42 U.S.C. 6297(a) through (c)) DOE may, however, grant waivers of Federal preemption for particular State laws or regulations, in accordance with the procedures and other provisions set forth under 42 U.S.C. 6297(d)).

Finally, pursuant to the amendments contained in EISA 2007, any final rule for new or amended energy conservation standards promulgated after July 1, 2010, is required to address standby mode and off mode energy use. (42 U.S.C. 6295(gg)(3)) Specifically, when DOE adopts a standard for a covered product after that date, it must, if justified by the criteria for adoption of standards under EPCA (42 U.S.C. 6295(o)), incorporate standby mode and off mode energy use into a single standard, or, if that is not feasible, adopt a separate standard for such energy use for that product. (42 U.S.C. 6295(gg)(3)(A)and (B))

B. Background

1. Current Standards

In a final rule published on June 13, 2016, DOE prescribed the current energy conservation standards for battery chargers manufactured on and after June 13, 2018. 81 FR 38266. These standards, which do not cover UPSs, are set forth in DOE's regulations at 10 CFR 430.32 and are repeated in Table II.1.

Table II.1 Federal Energy Conservation Standards for Battery Chargers

Product Class	Product Class Description	Battery Energy Watt-hours (Wh)	Special Characteristic or Battery Voltage	Adopted Standard as a Function of Battery Energy (kWh/yr)
1	Low-Energy	≤ 5 Wh	Inductive Connection in Wet Environments	3.04
2	Low-Energy, Low-Voltage	< 100 Wh	< 4 V	0.1440 * E_{batt} + 2.95
3	Low-Energy, Medium-Voltage		4 – 10 V	For E_{batt} < 10Wh, 1.42 kWh/y E_{batt} ≥ 10 Wh, 0.0255 * E_{batt} + 1.16
4	Low-Energy, High-Voltage		> 10 V	0.11 * E_{batt} + 3.18
5	Medium-Energy, Low-Voltage	100 – 3000 Wh	< 20 V	0.0257 * E_{batt} + .815
6	Medium-Energy, High-Voltage		≥ 20 V	0.0778 * E_{batt} + 2.4
7	High-Energy	> 3000 Wh	-	0.0502 * E_{batt} + 4.53

2. History of Standards Rulemaking for UPSs

DOE originally proposed energy conservation standards for battery chargers including UPSs in the battery charger energy conservation standards NOPR published on March 27, 2012 (March 2012 NOPR). In this NOPR, DOE proposed to test all covered battery chargers, including UPSs, using the battery charger test procedure finalized on June 1, 2011 and to regulate them using a unit energy consumption (''UEC'') metric. See 77 FR 18478.

DOE issued a battery charger energy conservation standards supplemental notice of proposed rulemaking (''SNOPR'') to propose revised energy standards for battery chargers on September 1, 2015. See 80 FR 52850. This notice did not propose standards for UPSs because of DOE's intention to regulate UPS as part of the separate rulemaking for computer and battery backup systems. DOE also issued a battery charger test procedure NOPR on August 6, 2015, which proposed to exclude backup battery chargers, including UPSs, from the scope of the battery charger test procedure. See 80 FR 46855. DOE held a public meeting on September 15, 2015 to discuss both of these notices.

During 2014, DOE explored whether to regulate UPSs as ''computer systems.'' See, *e.g.,* 79 FR 11345 (Feb. 28, 2014) (proposed coverage determination); 79 FR 41656 (July 17, 2014) (computer systems framework document). DOE received a number of comments in response to those documents (and the related public meetings) regarding testing of UPSs and the appropriate venue to address these devices.

Additionally, DOE received a number of stakeholder comments on the August 2015 battery charger test procedure NOPR and the September 2015 battery charger energy conservation standard SNOPR regarding regulation of UPSs. After considering these comments, DOE reconsidered its position and found that since a UPS meets the definition of a battery charger, it is more appropriate to regulate UPSs as part of the battery charger rulemaking, rather than the computers rulemaking. While the changes proposed in the August 2015 battery charger test procedure NOPR and the September 2015 energy conservation standard SNOPR were finalized on May 20, 2016 (81 FR 31827) and June 13, 2016 (81 FR 38266), respectively, DOE continues to conduct rulemaking activities to consider test procedures and energy conservations standards for UPSs as part of ongoing and future battery charger rulemaking proceedings. To that end, DOE published a notice of proposed rulemaking on May 19, 2016 to amend the battery charger test procedure to include specific testing requirements for UPSs (''UPS test procedure NOPR''). See 81 FR 31542. DOE is now proposing energy conservation standards for UPSs as part of the battery charger regulations in this NOPR.

III. General Discussion

DOE developed this proposal after considering verbal and written comments, data, and information from interested parties that represent a variety of interests. The following discussion addresses issues raised by these commenters.

A. Test Procedure

DOE recently published the UPS test procedure NOPR on May 19, 2016. See 81 FR 31542. DOE advises all stakeholders to review that proposal.

B. Technological Feasibility

1. General

In each energy conservation standards rulemaking, DOE conducts a screening analysis based on information gathered on all current technology options and prototype designs that could improve the efficiency of the products or equipment that are the subject of the rulemaking. As the first step in such an analysis, DOE develops a list of technology options for consideration in consultation with manufacturers, design engineers, and other interested parties. DOE then determines which of those means for improving efficiency are technologically feasible. DOE considers technologies incorporated in commercially-available products or in working prototypes to be technologically feasible. 10 CFR part 430, subpart C, appendix A, section 4(a)(4)(i)

After DOE has determined that particular technology options are technologically feasible, it further evaluates each technology option in light of the following additional screening criteria: (1) Practicability to manufacture, install, and service; (2) adverse impacts on product utility or availability; and (3) adverse impacts on health or safety. 10 CFR part 430, subpart C, appendix A, section 4(a)(4)(ii)–(iv). Additionally, it is DOE policy not to include in its analysis any proprietary technology that is a unique pathway to achieving a certain efficiency level. Section IV.B of this notice discusses the results of the screening analysis for UPSs, particularly the designs DOE considered, those it screened out, and those that are the basis for the standards considered in this rulemaking. For further details on the screening analysis for this rulemaking, see chapter 4 of the NOPR technical support document (''TSD'').

2. Maximum Technologically Feasible Levels

When DOE proposes to adopt an amended standard for a type or class of covered product, it must determine the maximum improvement in energy efficiency or maximum reduction in energy use that is technologically feasible for such product. (42 U.S.C. 6295(p)(1)) Accordingly, in the engineering analysis, DOE determined the maximum technologically feasible (''max-tech'') improvements in energy efficiency for UPSs, using the design parameters for the most efficient products available on the market or in working prototypes. The max-tech levels that DOE determined for this rulemaking are described in section IV.C of this proposed rule and in chapter 5 of the NOPR TSD.

C. Energy Savings

1. Determination of Savings

For each trial standard level (TSL), DOE projected energy savings from application of the TSL to UPSs purchased in the 30-year period that begins in the year of compliance with the proposed standards (2019–2048).[13] The savings are measured over the entire lifetime of UPSs purchased in the above 30-year period. DOE quantified the energy savings attributable to each TSL as the difference in energy consumption between each standards case and the no-standards case. The no-standards case represents a projection of energy consumption that reflects how the market for a product would likely evolve in the absence of new energy conservation standards.

DOE used its national impact analysis (NIA) spreadsheet model to estimate national energy savings (NES) from potential amended or new standards for UPSs. The NIA spreadsheet model (described in section IV.H of this notice) calculates energy savings in terms of site energy, which is the energy directly consumed by products at the locations where they are used. Based on the site energy, DOE calculates NES in terms of primary energy savings at the site or at power plants, and also in terms of full-

[13] Each TSL is composed of specific efficiency levels for each product class. The TSLs considered for this NOPR are described in section V.A. DOE conducted a sensitivity analysis that considers impacts for products shipped in a 9-year period.

fuel-cycle (FFC) energy savings. The FFC metric includes the energy consumed in extracting, processing, and transporting primary fuels (*i.e.,* coal, natural gas, petroleum fuels), and thus presents a more complete picture of the impacts of energy conservation standards.[14] DOE's approach is based on the calculation of an FFC multiplier for each of the energy types used by covered products or equipment. For more information on FFC energy savings, see section IV.H.2 of this NOPR.

2. Significance of Savings

To adopt any new or amended standards for a covered product, DOE must determine that such action would result in significant energy savings. (42 U.S.C. 6295(o)(3)(B)) Although the term ''significant'' is not defined in the Act, the U.S. Court of Appeals for the District of Columbia Circuit, in *Natural Resources Defense Council* v. *Herrington,* 768 F.2d 1355, 1373 (D.C. Cir. 1985), opined that Congress intended ''significant'' energy savings in the context of EPCA to be savings that are not ''genuinely trivial.'' The energy savings for all of the TSLs considered in this rulemaking, including the proposed standards (presented in section V.B.3.a), are nontrivial, and, therefore, DOE considers them ''significant'' within the meaning of section 325 of EPCA.

D. Economic Justification

1. Specific Criteria

As noted above, EPCA provides seven factors to be evaluated in determining whether a potential energy conservation standard is economically justified. (42 U.S.C. 6295(o)(2)(B)(i)(I) through (VII)) The following sections discuss how DOE has addressed each of those seven factors in this rulemaking.

a. Economic Impact on Manufacturers and Consumers

In determining the impacts of a potential amended standard on manufacturers, DOE conducts a manufacturer impact analysis (MIA), as discussed in section IV.J. DOE first uses an annual cash-flow approach to determine the quantitative impacts. This step includes both a short-term assessment—based on the cost and capital requirements during the period between when a regulation is issued and when entities must comply with the regulation—and a long-term assessment over a 30-year period. The industry-wide impacts analyzed include (1) industry net present value (INPV), which values the industry on the basis of expected future cash flows, (2) cash flows by year, (3) changes in revenue and income, and (4) other measures of impact, as appropriate. Second, DOE analyzes and reports the impacts on different types of manufacturers, including impacts on small manufacturers. Third, DOE considers the impact of standards on domestic manufacturer employment and manufacturing capacity, as well as the potential for standards to result in plant closures and loss of capital investment. Finally, DOE takes into account cumulative impacts of various DOE regulations and other regulatory requirements on manufacturers.

For individual consumers, measures of economic impact include the changes in LCC and payback period (PBP) associated with new standards. These measures are discussed further in the following section. For consumers in the aggregate, DOE also calculates the national net present value of the consumer costs and benefits expected to result from particular standards. DOE also evaluates the impacts of potential standards on identifiable subgroups of consumers that may be disproportionately affected by a standard.

b. Savings in Operating Costs Compared to Increase in Price

EPCA requires DOE to consider the savings in operating costs throughout the estimated average life of the covered product in the type (or class) compared to any increase in the price of, or in the initial charges for, or maintenance expenses of, the covered product that are likely to result from a standard. (42 U.S.C. 6295(o)(2)(B)(i)(II)) DOE conducts this comparison in its LCC and PBP analysis.

The LCC is the sum of the purchase price of a product (including its installation) and the operating expense (including energy, maintenance, and repair expenditures) discounted over the lifetime of the product. The LCC analysis requires a variety of inputs, such as product prices, product energy consumption, energy prices, maintenance and repair costs, product lifetime, and discount rates appropriate for consumers. To account for uncertainty and variability in specific inputs, such as product lifetime and discount rate, DOE uses a distribution of values, with probabilities attached to each value.

The PBP is the estimated amount of time (in years) it takes consumers to recover the increased purchase cost (including installation) of a more-efficient product through lower operating costs. DOE calculates the PBP by dividing the change in purchase cost due to a more-stringent standard by the change in annual operating cost for the year that standards are assumed to take effect.

For its LCC and PBP analysis, DOE assumes that consumers will purchase the covered products in the first year of compliance with new standards. The LCC savings for the considered efficiency levels are calculated relative to the case that reflects projected market trends in the absence of new standards. DOE's LCC and PBP analysis is discussed in further detail in section IV.F.

c. Energy Savings

Although significant conservation of energy is a separate statutory requirement for adopting an energy conservation standard, EPCA requires DOE, in determining the economic justification of a standard, to consider the total projected energy savings that are expected to result directly from the standard. (42 U.S.C. 6295(o)(2)(B)(i)(III)) As discussed in section III.C, DOE uses the NIA spreadsheet models to project national energy savings.

d. Lessening of Utility or Performance of Products

In establishing product classes and in evaluating design options and the impact of potential standard levels, DOE evaluates potential standards that would not lessen the utility or performance of the considered products. (42 U.S.C. 6295(o)(2)(B)(i)(IV)) Based on data available to DOE, the standards proposed in this NOPR would not reduce the utility or performance of the products under consideration in this rulemaking.

e. Impact of Any Lessening of Competition

EPCA directs DOE to consider the impact of any lessening of competition, as determined in writing by the Attorney General, that is likely to result from a proposed standard. (42 U.S.C. 6295(o)(2)(B)(i)(V)) It also directs the Attorney General to determine the impact, if any, of any lessening of competition likely to result from a proposed standard and to transmit such determination to the Secretary within 60 days of the publication of a proposed rule, together with an analysis of the nature and extent of the impact. (42 U.S.C. 6295(o)(2)(B)(ii)) DOE will transmit a copy of this proposed rule to the Attorney General with a request that the Department of Justice (DOJ) provide

[14] The FFC metric is discussed in DOE's statement of policy and notice of policy amendment. 76 FR 51282 (Aug. 18, 2011), as amended at 77 FR 49701 (Aug. 17, 2012).

its determination on this issue. DOE will publish and respond to the Attorney General's determination in the final rule. DOE invites comment from the public regarding the competitive impacts that are likely to result from this proposed rule. In addition, stakeholders may also provide comments separately to DOJ regarding these potential impacts. See the **ADDRESSES** section for information to send comments to DOJ.

f. Need for National Energy Conservation

DOE also considers the need for national energy conservation in determining whether a new or amended standard is economically justified. (42 U.S.C. 6295(o)(2)(B)(i)(VI)) The energy savings from the proposed standards are likely to provide improvements to the security and reliability of the Nation's energy system. Reductions in the demand for electricity also may result in reduced costs for maintaining the reliability of the Nation's electricity system. DOE conducts a utility impact analysis to estimate how standards may affect the nation's needed power generation capacity, as discussed in section IV.M.

The proposed standards also are likely to result in environmental benefits in the form of reduced emissions of air pollutants and greenhouse gases (GHGs) associated with energy production and use. DOE conducts an emissions analysis to estimate how potential standards may affect these emissions, as discussed in section IV.K; the emissions impacts are reported in section V.B.6 of this NOPR. DOE also estimates the economic value of emissions reductions resulting from the considered TSLs, as discussed in section IV.L.

g. Other Factors

In determining whether an energy conservation standard is economically justified, DOE may consider any other factors that the Secretary deems to be relevant. (42 U.S.C. 6295(o)(2)(B)(i)(VII)) To the extent interested parties submit any relevant information regarding economic justification that does not fit into the other categories described above, DOE could consider such information under ''other factors.''

2. Rebuttable Presumption

As set forth in 42 U.S.C. 6295(o)(2)(B)(iii), EPCA creates a rebuttable presumption that an energy conservation standard is economically justified if the additional cost to the consumer of a product that meets the standard is less than three times the value of the first year's energy savings resulting from the standard, as calculated under the applicable DOE test procedure. DOE's LCC and PBP analyses generate values used to calculate the effects that proposed energy conservation standards would have on the payback period for consumers. These analyses include, but are not limited to, the 3-year payback period contemplated under the rebuttable-presumption test. In addition, DOE routinely conducts an economic analysis that considers the full range of impacts to consumers, manufacturers, the Nation, and the environment, as required under 42 U.S.C. 6295(o)(2)(B)(i). The results of this analysis serve as the basis for DOE's evaluation of the economic justification for a potential standard level (thereby supporting or rebutting the results of any preliminary determination of economic justification). The rebuttable presumption payback calculation is discussed in section IV.F.9 of this proposed rule.

IV. Methodology and Discussion of Related Comments

This section addresses the analyses DOE has performed for this rulemaking with regard to UPSs. Separate subsections address each component of DOE's analyses.

DOE used several analytical tools to estimate the impact of the standards proposed in this document. The first tool is a spreadsheet that calculates the LCC savings and PBP of potential amended or new energy conservation standards. The national impacts analysis uses a second spreadsheet set that provides shipments forecasts and calculates national energy savings and net present value of total consumer costs and savings expected to result from potential energy conservation standards. DOE uses the third spreadsheet tool, the Government Regulatory Impact Model (GRIM), to assess manufacturer impacts of potential standards. These three spreadsheet tools are available on the DOE Web site for this rulemaking: *https://www1.eere.energy.gov/buildings/appliance_standards/standards.aspx?productid=26*. Additionally, DOE used output from the latest version of EIA's *Annual Energy Outlook* (*AEO),* a widely known energy forecast for the United States, for the emissions and utility impact analyses.

A. Market and Technology Assessment

DOE develops information in the market and technology assessment that provides an overall picture of the market for the products concerned, including the purpose of the products, the industry structure, manufacturers, market characteristics, and technologies used in the products. This activity includes both quantitative and qualitative assessments, based primarily on publicly-available information. The subjects addressed in the market and technology assessment for this rulemaking include: (1) A determination of the scope of the rulemaking and product classes, (2) manufacturers and industry structure, (3) existing efficiency programs, (4) shipments information, (5) market and industry trends, and (6) technologies or design options that could improve the energy efficiency of UPSs. The key findings of DOE's market assessment are summarized below. See chapter 3 of the NOPR TSD for further discussion of the market and technology assessment.

1. Scope of Coverage and Product Classes

In the May 2016 UPS test procedure NOPR, DOE proposed the definition of UPS from section 3.1.1 of IEC 62040–3 Edition. 2.0, ''Uninterruptible power systems (UPS)—Method of specifying the performance and test requirements'', March 2011 (IEC 62040–3 Ed. 2.0). See 81 FR 31542.

DOE also proposed to include definitions for voltage and frequency dependent (VFD), voltage independent (VI), and voltage and frequency independent (VFI) UPS architectures based on the definitions from section 1.0 of ENERGY STAR UPS Version 1.0, ''ENERGY STAR Program Requirements for Uninterruptible Power Supplies,'' Rev. July 2012 (ENERGY STAR UPS V. 1.0) to differentiate between different UPS load ratings. The proposed definitions are as follows:

''Uninterruptible power supply or UPS means a combination of convertors, switches and energy storage devices (such as batteries), constituting a power system for maintaining continuity of load power in case of input power failure.''

''Voltage and frequency dependent UPS or VFD UPS means a UPS that produces an AC output where the output voltage and frequency are dependent on the input voltage and frequency. This UPS architecture does not provide corrective functions like those in voltage independent and voltage and frequency independent systems.''

''Voltage independent UPS or VI UPS means a UPS that produces an AC output within a specific tolerance band that is independent of under-voltage or over-voltage variations in the input voltage. The output frequency of a VI

UPS is dependent on the input frequency, similar to a voltage and frequency dependent system.''

''Voltage and frequency independent UPS or VFI UPS means a UPS that produces an AC output voltage and frequency that is independent of input voltage and frequency variations and protects the load against adverse effects from such variations without depleting the stored energy source. The input voltage and frequency variations through which the UPS must remain in Normal Mode are as follows:

i. ±10% of the rated input voltage or the tolerance range specified by the manufacturer, whichever is greater
ii. ±2% of the rated input frequency or the tolerance range specified by the manufacturer, whichever is greater.''

DOE also specified in the May 2016 UPS test procedure NOPR that only the devices that meet the definition of a UPS as outlined above and have an AC output will be subject to the testing requirements proposed in the battery charger test procedure NOPR. See 81 FR 31542. For this rulemaking, DOE proposes to maintain the scope of coverage as defined by its current proposal for the battery charger test procedure.

When evaluating and establishing energy conservation standards, DOE often divides covered products into classes by the type of energy used, the capacity of the product, or any other performance-related feature that justifies different standard levels, such as features affecting consumer utility. (42 U.S.C. 6295(q)) DOE then conducts its analysis and considers establishing or amending standards to provide separate standard levels for each product class. DOE has created three product classes to analyze UPSs as follows: Product Class 10a (VFD UPSs), Product Class 10b (VI UPSs), and Product Class 10c (VFI UPSs). UPSs are tested at different load ratings and a normal mode average efficiency rating is calculated. This is based on ENERGY STAR UPSs. Within UPSs, VFD, VI, and VFI UPSs are different product classes based on the UPS's ability to filter and correct the incoming power against faults such as over and under-voltage conditions, noise, harmonic distortions and instability in the mains frequency. These product classes are VFD for units that do not provide any corrective functions, VI for units capable of correcting only the voltage and VFI for units that can correct the voltage as well as the frequency when they are outside specifications. In addition to providing such corrective functions, devices in these three product classes offer greater utility to sensitive loads by reducing the transfer time from utility power to the internal battery in the event of a power disruption. DOE recognizes that these additional utilities as well as increasing device capacity come at the cost of efficiency. DOE therefore proposes individual standards for each product class that scale with rated output power. This is consistent with ENERGY STAR Version 1.0, ''ENERGY STAR Program Requirements for Uninterruptible Power Supplies,'' Rev. July 2012 (ENERGY STAR UPS V. 1.0) and IEC 62040–3 Edition 2.0. Additional details on DOE's assessment of UPS technologies can be found in chapter 3 of the NOPR TSD.

2. Technology Options

In the July 2014 computer and battery backup systems (computer systems) framework document, DOE identified three technology options for UPSs that would be expected to improve the efficiency of UPSs. These technology options are: Semiconductor improvements, digital signal processing and space vector modulation, and transformer-less UPS topologies.[15] Since the July 2014 framework document for computer systems, DOE has identified the following additional technology options from stakeholder comments and manufacturer interviews for UPSs: Use of core materials with high magnetic permeability such as Sendust and Litz wiring in inductor design, wide band gap semiconductors such as silicon carbide and gallium arsenide, capacitors with low equivalent series resistance (ESR), printed circuit boards (PCBs) with higher copper content, and variable speed fan control.

DOE's further research into space vector modulation technology for UPSs has shown that it may have limited advantage in the scope of this rule and is intended primarily for higher power applications. Therefore, DOE did not consider this technology.

DOE requests comment on the potential technology options identified for improving the efficiency of UPSs (see section VII.E).

After identifying all potential technology options for improving the efficiency of UPSs, DOE performed the screening analysis (see section IV.B of this document and chapter 4 of the NOPR TSD) on these technologies to determine which to consider further in the analysis and which to eliminate.

B. Screening Analysis

DOE uses the following four screening criteria to determine which technology options are suitable for further consideration in an energy conservation standards rulemaking:

(1) *Technological feasibility.* Technologies that are not incorporated in commercial products or in working prototypes will not be considered further.

(2) *Practicability to manufacture, install, and service.* If it is determined that mass production and reliable installation and servicing of a technology in commercial products could not be achieved on the scale necessary to serve the relevant market at the time of the projected compliance date of the standard, then that technology will not be considered further.

(3) *Impacts on product utility or product availability.* If it is determined that a technology would have significant adverse impact on the utility of the product to significant subgroups of consumers or would result in the unavailability of any covered product type with performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as products generally available in the United States at the time, it will not be considered further.

(4) *Adverse impacts on health or safety.* If it is determined that a technology would have significant adverse impacts on health or safety, it will not be considered further.

10 CFR part 430, subpart C, appendix A, 4(a)(4) and 5(b)

If DOE determines that a technology, or a combination of technologies, fails to meet one or more of the above four criteria, it will be excluded from further consideration in the engineering analysis. The reasons for eliminating any technology in this rulemaking are discussed below.

1. Screened-Out Technologies

Transformer-Less UPS Designs

Transformer-less UPS designs offer some of the highest efficiencies in the industry with lowered weight, wider input voltage tolerance, near unity input power factor, reduced harmonic distortion and need for components that mitigate electromagnetic interference (EMI) generated by the device. However, interviews with manufacturers have shown this to be a limited access technology with select manufacturers holding the intellectual property required for effective implementation. DOE therefore does not intend to consider this technology for this rule.

[15] *See* July 2014 computer and battery backup systems framework document, pp. 48–49.

2. Remaining Technologies

Through a review of each technology, DOE tentatively concludes that all of the other identified technologies listed in section IV.A.2 met all four screening criteria to be examined further as design options in DOE's NOPR analysis. In summary, DOE did not screen out the following technology options: Use of materials with high magnetic permeability such as Sendust for the inductor core and Litz wiring in inductor coils, silicon carbide, gallium arsenide and other wide band gap semiconductors, capacitors with low ESR, PCBs with higher copper content and variable speed fan control.

DOE determined that these technology options are technologically feasible because they are being used or have previously been used in commercially-available products or working prototypes. DOE also finds that all of the remaining technology options meet the other screening criteria. For additional details, see chapter 4 of the NOPR TSD.

DOE requests comment on its screening analysis used to select the most viable options for consideration in setting this proposed standards (see section VII.E).

C. Engineering Analysis

In the engineering analysis, DOE establishes the relationship between the manufacturer production cost (MPC) and improved UPS efficiency. This relationship serves as the basis for cost-benefit calculations for individual consumers, manufacturers, and the Nation. DOE typically structures the engineering analysis using one of three approaches: (1) Design option, (2) efficiency level, or (3) reverse engineering (cost assessment). The design-option approach involves adding the estimated cost and associated efficiency of various efficiency-improving design changes to the baseline product to model different levels of efficiency. The efficiency-level approach uses estimates of costs and efficiencies of products available on the market at distinct efficiency levels to develop the cost-efficiency relationship. The reverse-engineering approach involves testing products for efficiency and determining cost from a detailed bill of materials (BOM) derived from reverse engineering representative products. The efficiency ranges from that of the least-efficient UPS sold today (*i.e.,* the baseline) to the maximum technologically feasible efficiency level. At each efficiency level examined, DOE determines the MPC; this relationship is referred to as a cost-efficiency curve.

DOE used a combination of the design-option and efficiency-level approach when determining the efficiency curves for UPSs. UPSs are composed of a single highly integrated PCB consisting of control and power conversion circuitry without any interchangeable components. The efficiency-level approach therefore is more suited to creating the cost-efficiency relationship since components cannot be removed to understand their impact on overall power consumption. However, DOE did use the design-option approach to determine the maximum technologically feasible EL because these products are not available on the market currently.

DOE began its analysis by completing a comprehensive study of the market for units that are in scope. A review of retail sales data, the ENERGY STAR qualified product list of compliant devices and manufacturer interviews aided DOE in identifying the most prevalent units in the market as well as those that are the least and most expensive and efficient. DOE then purchased units for in-house efficiency testing according to the May 2016 UPS test procedure NOPR. This testing allowed DOE to choose representative units and create multiple ELs for each product class.

1. Testing

In taking the hybrid efficiency-level and design option approach, DOE tested multiple units of the same product class striving to ensure variations between successive units (*e.g.* LCDs, communication ports, etc.) were removed. The resultant efficiency values and data obtained from manufacturers were then curve-fitted and extrapolated to the entire power range (defined by the scope) to create multiple ELs. For example, DOE tested several VFD representative units in the 300–500 W range to create four ELs for VFD UPSs, which when compared against the device's MPC demonstrated a direct positive correlation.

2. Representative Units and Efficiency Levels

Individual ELs for a UPS product class were created by curve-fitting and extrapolating the efficiency values of a single test unit known as the representative unit for that particular EL. Each of the ELs are labeled EL 0 through EL 3 and reflect increasing efficiency due to technological advances. EL 0 represents baseline performance, EL 1 is the minimum required efficiency to be ENERGY STAR compliant, EL 2 is the best technology currently available in the market and EL 3 is the maximum efficiency theoretically achievable. As such, the representative unit for EL 0 was the least efficient unit tested by DOE with EL 1 and EL 2 being represented by the least and most efficient ENERGY STAR unit respectively. While DOE derived EL 0 through EL 2 via testing, DOE created EL 3 from data obtained during manufacturer interviews.

The proposed standard for UPSs varies based on its maximum output power rating. The standard is a set of curve-fit equations. Figure IV.1 through Figure IV.3 are graphical representations of the ELs for VFD UPS, VI UPS and VFI UPS types respectively. Each EL is subdivided into power ranges for simplicity and is a piecewise approximation of the units overall efficiency across the entire power range as shown in the figures. Chapter 5 of the NOPR TSD has additional detail on the curve-fit equations for each EL and UPS product class.

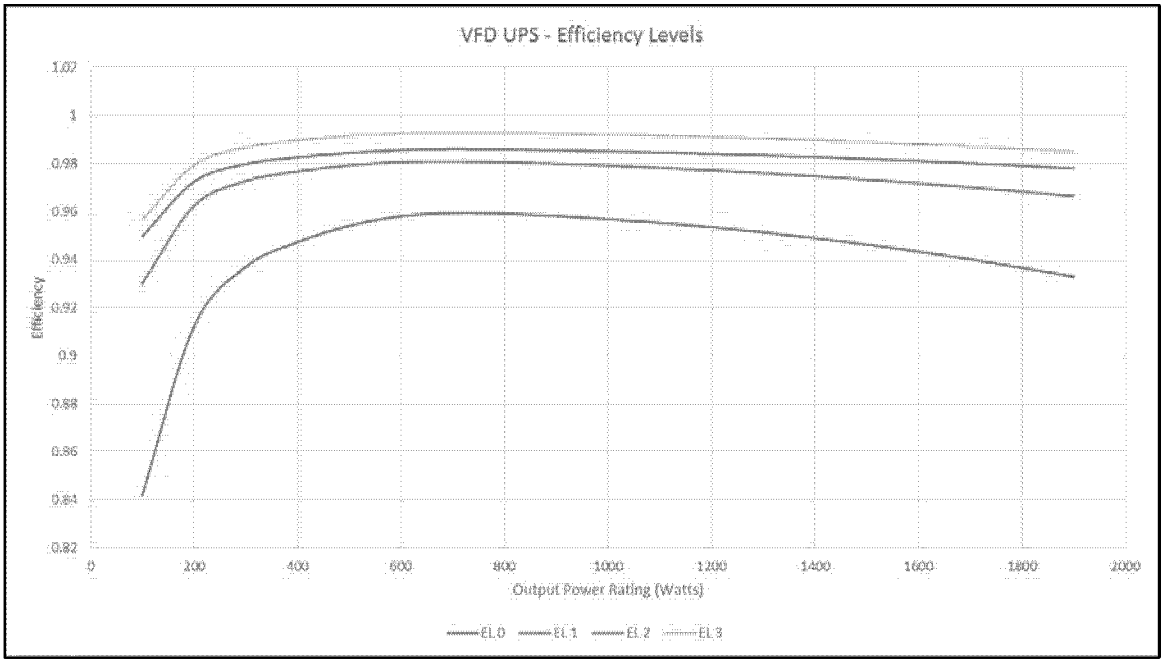

Figure IV.1 Graphical Representation of VFD UPS Efficiency Levels

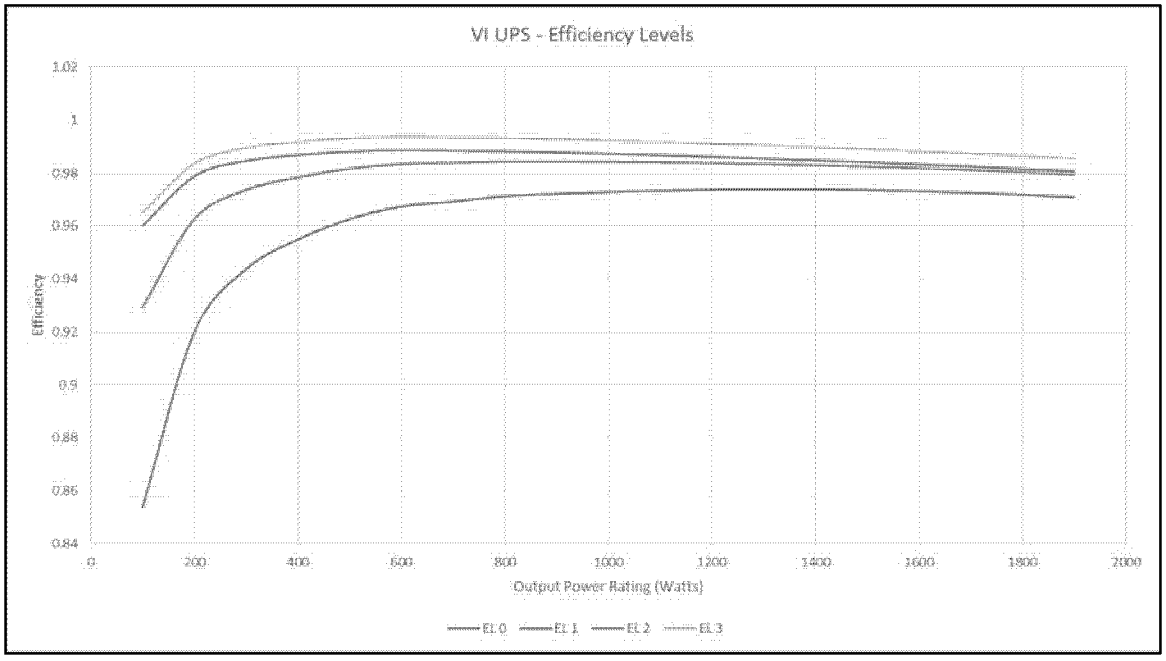

Figure IV.2 Graphical Representation of VI UPS Efficiency Levels

DOE requests comment on the ELs selected for each product class for its analysis (see section VII.E).

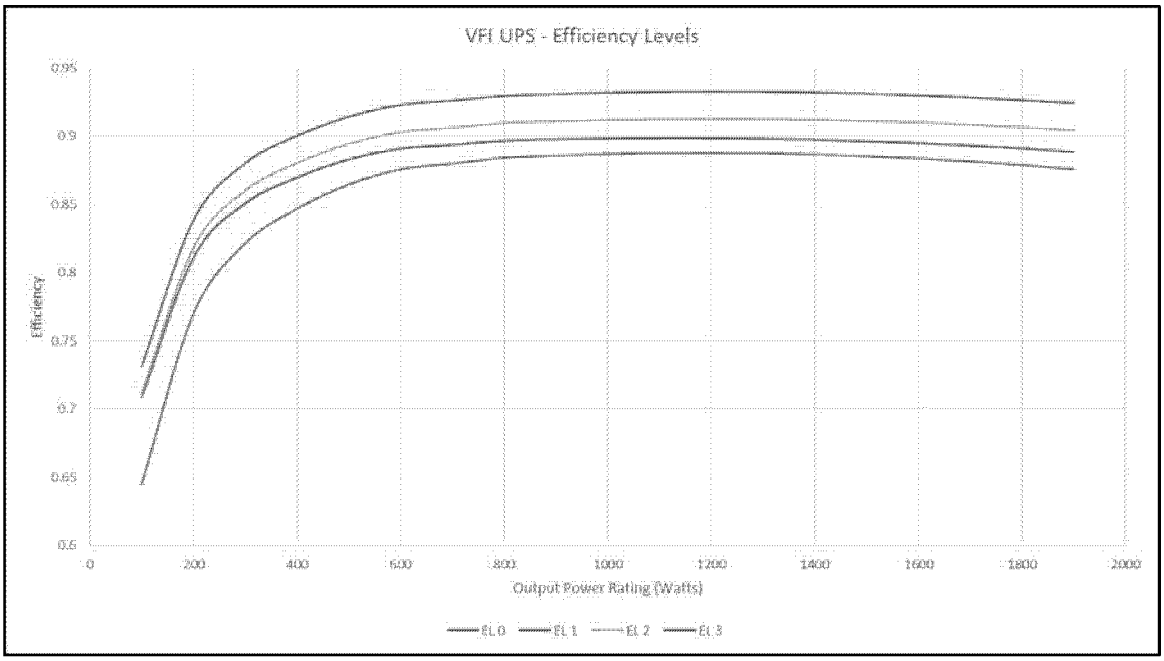

Figure IV.3 Graphical Representation of VFI UPS Efficiency Levels

3. Cost Analysis

For UPSs, DOE developed an average manufacturer and distribution markups for ELs by examining the annual Securities and Exchange Commission (SEC) 10–K reports filed by publicly-traded UPS manufacturers and distribution chains and further verified during stakeholder interviews. DOE used these validated markups to convert consumer prices into manufacturer selling prices (MSPs) and then into MPCs.

Table I.3 summarizes national economic costs expected to result from the proposed standards.

In general, DOE's cost analysis of representative units demonstrated a direct correlation between MPC and average load adjusted efficiency (see Figure 5.5.1 through 5.5.3 in chapter 5 of the Technical Support Document). However, the one exception to this correlation was the EL 1 representative unit for VFD UPSs. This representative unit has a higher output power rating and average load adjusted efficiency, but a lower MPC compared to the EL 0 representative unit of the same product class, resulting in a negative total incremental installed cost of $139 million and $253 million at seven and three percent discount rates, respectively.

In addition to the two representative units discussed here, DOE has found other VFD UPSs that demonstrate this negative correlation between MPC and average load adjusted efficiency between EL 0 and EL 1.

DOE believes that this exception to the otherwise direct correlation between MPC and average load adjusted efficiency of UPSs has several possible explanations. For the VFD UPSs in scope of this rulemaking, DOE believes consumers may typically be more concerned with the reliability of the protection the product provides, than its energy efficiency. Despite the presence of less expensive and more efficient units, DOE believes less efficient legacy units continue to be sold in the marketplace because consumers are familiar with these models and trust the level of protection and safety they offer even if more energy efficient UPS models with similar functionality and dependability are available at lower prices. Additionally, an unproven model that is more efficient yet less expensive may be perceived by consumers as less reliable. Therefore, UPS manufacturers may not have an incentive to improve the design of UPS models that have established a reputation of being reliable. It is also worth noting that the difference in MSP between the VFD UPS EL 0 and EL 1 representative units is $5.10 and while this can be significant on its own, it may only be a small fraction of the cost of the connected equipment that it is protecting or the potential loss in productivity if said connected equipment were to lose power. DOE believes this is one of the reasons why devices at EL 0 continue to exist in the market place at a price higher than more efficient EL 1 models.

However, negative compliance costs are unexpected in an economic theory that assumes a perfect capital market with perfect rationality of agents having complete information. In such a market, because more efficient UPSs save consumers money on operating costs compared to the baseline product, consumers would have an incentive to purchase them even in the absence of standards. For these reasons, DOE requests comment on its understanding of why less efficient UPSs continue to exist in the market place at a price higher than more efficient units and the impact that energy conservation standards for UPSs will have on the costs and efficiencies of existing UPS models, including various aspects of the inputs to the installed cost analysis, such as assumptions about consumers' response to first cost versus long-term operating cost, assumptions for manufacturer capital and product conversion costs, and other factors.

D. Markups Analysis

The markups analysis develops appropriate markups (*e.g.,* retailer markups, distributor markups, contractor markups) in the distribution chain and sales taxes to convert the consumer prices, derived in the engineering analysis, into the MSPs for each product class and EL. The MSPs calculated in the markups analysis are then used as inputs to the MIA. The prices derived in the engineering analysis are marked up to reflect the distribution chain of UPSs. At each step

in the distribution channel, companies mark up the price of the product to cover business costs and profit margin. For UPSs, the main parties in the distribution chain are retailers. The final prices, which also include sales taxes, are then used in the LCC and PBP analyses.

For retailers, DOE developed separate markups for baseline products (baseline markups) and for the incremental cost of more-efficient products (incremental markups). Incremental markups are coefficients that relate the change in the MSP of higher-efficiency models to the change in the retailer sales price. DOE relied on economic data from the U.S. Census Bureau [16] to estimate average baseline and incremental markups.

The manufacturer markups, which convert MSPs to MPCs are calculated as part of the MIA and are not presented in the markups analysis. DOE developed average manufacturer markups by examining the annual SEC 10–K reports filed by publicly traded UPS manufacturers then refining these estimates based on manufacturer feedback.

Chapter 6 of the NOPR TSD provides details on DOE's development of markups for UPSs.

E. Energy Use Analysis

The purpose of the energy use analysis is to determine the annual energy consumption of UPSs at different efficiencies in representative U.S. single-family homes, multi-family residences, and commercial buildings, and to assess the energy savings potential of increased UPS efficiency. The energy use analysis estimates the range of energy use of UPSs in the field (*i.e.,* as they are actually used by consumers). The energy use analysis provides the basis for other analyses DOE performed, particularly assessments of the energy savings and the savings in consumer operating costs that could result from adoption of amended or new standards.

To develop energy use estimates, DOE multiplied UPS power loss as a function of rated output power, as derived in the engineering analysis, by annual operating hours. DOE assumed that UPSs are operated for 24 hours per day, 365 days per year, at a typical load specific to each product class. In early 2015, UPS manufacturers indicated that a majority of in-scope products were used to back up and condition power to servers and desktop computers, with most VFD and low-end VI products attached to desktop computers and workstations. The average loading assumptions from ENERGY STAR UPS V. 1.0 with input power less than or equal to 1500 W are 67.5 percent for VFD and 75 percent for VI and VFI UPSs.[17] However, the devices to which UPSs provide power may not always be on, especially in the case of desktop computers. Thus there is some uncertainty about how many hours per year UPSs are typically operated at various load points.

The responses to manufacturer interviews conducted in early 2015 suggest that most VFD products are used with personal computers, around three quarters of low-end VI products are used with computers and workstations, and around three quarters of higher-end VI and VFI products are used with servers. To account for the typical power draw of desktop computers, and because such computers spend some time in off or standby modes, DOE assumed average loading for VFD UPSs to be 25 percent. DOE further assumed average loading for VI products, which are operated in conjunction with both computers and servers, to be 50 percent, and average loading for VFI products to be 75 percent, in line with ENERGY STAR UPS V. 1.0. DOE requests further comment on the average loading conditions for these product classes (see section VII.E).

To capture the diversity of products available to consumers, DOE collected data on the distribution of UPS output power rating from product specifications listed on online retail Web sites. DOE then developed product samples for each UPS product class based on a market-weighted distribution of product features found to impact efficiency as determined by the engineering analysis.

Chapter 7 of the NOPR TSD provides details on DOE's energy use analysis for UPSs.

F. Life-Cycle Cost and Payback Period Analysis

DOE conducted LCC and PBP analyses to evaluate the economic impacts on individual consumers of potential energy conservation standards for UPSs. The effect of new or amended energy conservation standards on individual consumers usually involves a reduction in operating cost and an increase in purchase cost. DOE used the following two metrics to measure consumer impacts:

The LCC (life-cycle cost) is the total consumer expense of an appliance or product over the life of that product, consisting of total installed cost (manufacturer selling price, distribution chain markups, sales tax, and installation costs) plus operating costs (expenses for energy use, maintenance, and repair). To compute the operating costs, DOE discounts future operating costs to the time of purchase and sums them over the lifetime of the product.

The PBP (payback period) is the estimated amount of time (in years) it takes consumers to recover the increased purchase cost (including installation) of a more-efficient product through lower operating costs. DOE calculates the PBP by dividing the change in purchase cost at higher efficiency levels by the change in annual operating cost for the year that amended or new standards are assumed to take effect.

For any given efficiency level, DOE measures the change in LCC relative to the LCC in the no-standards case, which reflects the estimated efficiency distribution of UPSs in the absence of new or amended energy conservation standards. In contrast, the PBP for a given efficiency level is measured relative to the baseline product.

For each considered efficiency level in each product class, DOE calculated the LCC and PBP for a nationally representative set of housing units, as well as one for commercial buildings. For each sample household and commercial building, DOE determined the energy consumption for the UPS and the appropriate electricity price. By developing a representative sample of households and commercial buildings, the analysis captured the variability in energy consumption and energy prices associated with the use of UPSs.

DOE was unable to locate a survey sample specific to UPS users for either the residential or commercial sector. However, as mentioned in the previous section, manufacturer interviews indicate that most VFD products are used with personal computers, around three quarters of low-end VI products are used with computers and workstations, and around three quarters of higher-end VI and VFI products are used with servers. DOE thus created residential and commercial samples for desktop computers as a proxy for the sample of VFD and VI UPS owners, and a sample for servers as a proxy for the sample of VFI UPS owners.

DOE developed its residential sample from the set of individual responses to

[16] U.S. Census Bureau. Annual Retail Trade Survey, Electronics and Appliance Stores. 2012. *www.census.gov/retail/arts/historic_releases.html.*

[17] These were calculated by multiplying the proportion of time spent at each specified proportion of the reference test load in Table 1 of the following reference. ENERGY STAR. *ENERGY STAR Program Requirements: Product Specification for Uninterruptible Power Supplies (UPSs), Version 1.0.* 2012.

the Consumer Electronics Association's (CEA's) *16th Annual CE Ownership and Market Potential Study*.[18] CEA administered the survey to a random, nationally representative sample of more than 2,000 U.S. adults in January and February 2014. The individual-level survey data that CEA provided to DOE were weighted to reflect the known demographics of the sample population; weighting by geographic region, gender, age, and race were used to make the data generalizable to the entire U.S. adult population. From this dataset, DOE constructed its household sample for UPSs by considering the number of desktop computers per household in conjunction with 2013 household income and state of residence.

To create a commercial building sample, DOE relied on EIA's Commercial Buildings Energy Consumption Survey (CBECS), a nationally representative survey with a rich dataset of energy-related characteristics of the nation's stock of commercial buildings.[19] Individual survey responses from the most recent survey in 2012 allowed DOE to consider how the commercial penetration of servers and desktop computers varies by principal building activity and by Census Division. DOE used these microdata to construct the commercial sample of UPSs, which are assumed to back up and condition power for servers and desktop computers.

Inputs to the calculation of total installed cost include the cost of the product—which includes MPCs, manufacturer markups, retailer and distributor markups, and sales taxes—and installation costs. Inputs to the calculation of operating expenses include annual energy consumption, energy prices and price projections, repair and maintenance costs, product lifetimes, and discount rates. DOE created distributions of values for product lifetime, discount rates, and sales taxes, with probabilities attached to each value, to account for their uncertainty and variability.

The computer model DOE uses to calculate the LCC and PBP relies on a Monte Carlo simulation to incorporate uncertainty and variability into the analysis. The Monte Carlo simulations randomly sample input values from the probability distributions and UPS user samples. The model calculated the LCC and PBP for products at each efficiency level for 10,000 housing units and 10,000 commercial buildings per simulation run.

DOE calculated the LCC and PBP for all consumers of UPSs as if each were to purchase a new product in the expected year of required compliance with new standards. Any new standards would apply to UPSs manufactured two years after the date on which any new standard is published. At this time, DOE estimates publication of a final rule in 2017. Therefore, for purposes of its analysis, DOE used 2019 as the first year of compliance with any new standards for UPSs.

Table IV.1 summarizes the approach and data DOE used to derive inputs to the LCC and PBP calculations. The subsections that follow provide further discussion. Details of the spreadsheet model, and of all the inputs to the LCC and PBP analyses, are contained in chapter 8 of the NOPR TSD and its appendices.

TABLE IV.1—SUMMARY OF INPUTS AND METHODS FOR THE LCC AND PBP ANALYSIS *

Inputs	Source/method
Product Cost	Derived by multiplying MPCs by manufacturer and retailer markups and sales tax, as appropriate. Used historical data to derive a price scaling index to forecast product costs.
Installation Costs	Assumed no change with efficiency level.
Annual Energy Use	Power loss (a function of rated output power) multiplied by annual operating hours. Average number of hours at a typical load based on manufacturer input. Variability: Distribution of rated power from online retail websites.
Energy Prices	Electricity: Based on 2014 marginal electricity price data from the Edison Electric Institute. Variability: Electricity prices vary by season, U.S. region, and baseline electricity consumption level.
Energy Price Trends	Based on *AEO 2015* price forecasts.
Repair and Maintenance Costs	Assumed no change with efficiency level.
Product Lifetime	Based on literature review and manufacturer interviews. Variability: Based on a Weibull distribution.
Discount Rates	Approach involves identifying all possible debt or asset classes that might be used to purchase the considered appliances, or might be affected indirectly. Primary data source was the Federal Reserve Board's Survey of Consumer Finances.
Compliance Date	2019.

* References for the data sources mentioned in this table are provided in the sections following the table or in chapter 8 of the NOPR TSD.

1. Product Cost

To calculate consumer product costs, DOE multiplied the MPCs developed in the engineering analysis by the markups described above (along with sales taxes). DOE used different markups for baseline products and higher-efficiency products, because DOE applies an incremental markup to the increase in MSP associated with higher-efficiency products. The prices used in the LCC and PBP analysis are MPC in the compliance year, as described in chapter 5 of the TSD.

Examination of historical price trends for a number of appliances that have been subject to energy conservation standards indicates that an assumption of constant real prices and costs may overestimate long-term trends in appliance prices. Economic literature and historical data suggest that the real costs of these products may in fact trend downward over time according to ''learning'' or ''experience'' curves. On February 22, 2011, DOE published a notice of data availability (NODA) stating that DOE may consider refining its analysis by addressing equipment price trends. 76 FR 9696. It also raised the possibility that once sufficient long-term data are available on the cost or price trends for a given product subject to energy conservation standards, DOE would consider these data to forecast future trends. However, DOE found no data or manufacturer input to suggest

[18] Available for purchase at *http://store.ce.org/Default.aspx?TabID=251&productId=782583*.

[19] U.S. Department of Energy—U.S. Energy Information Administration. Commercial Buildings Energy Consumption Survey (CBECS). 2012 Public Use Microdata File. 2015. Washington, DC. *http://www.eia.gov/consumption/commercial/data/2012/index.cfm?view=microdata*.

appreciable price trends for UPSs, and thus assumed no price trend for UPSs.

2. Installation Cost

Installation cost includes labor, overhead, and any miscellaneous materials and parts needed to install the product. DOE found no evidence that installation costs would be impacted with increased efficiency levels for UPSs.

3. Annual Energy Consumption

For each sampled household and commercial building, DOE determined the energy consumption for a UPS at different efficiency levels using the approach described in section IV.E of this document.

4. Energy Prices

DOE used marginal electricity prices to characterize the incremental savings associated with ELs above the baseline. The marginal electricity prices vary by season, region, and baseline household electricity consumption level for the LCC. DOE estimated these prices using data published with the Edison Electric Institute (EEI) Typical Bills and Average Rates reports for summer and winter 2014.[20] DOE assigned seasonal marginal prices to each household or commercial building in the LCC sample based on its location and its baseline monthly electricity consumption for an average summer or winter month. For a detailed discussion of the development of electricity prices, see appendix 8B of the NOPR TSD.

The Information Technology Industry Council (ITI) suggested that EIA's *Annual Energy Outlook (AEO)* be used for estimating current and forecasted energy prices. (ITI, No. 0010 at p. 18) Available information suggests that marginal electricity prices more accurately represent savings associated with a new standard, and therefore DOE relied on EEI data instead of *AEO* data for current prices. However, to estimate energy prices in future years, DOE multiplied the average regional energy prices by the forecast of annual change in national-average residential energy price in the Reference case from *AEO 2015,* which has an end year of 2040.[21] To estimate price trends after 2040, DOE used the average annual rate of change in prices from 2020 to 2040.

5. Maintenance and Repair Costs

Repair costs are associated with repairing or replacing product components that have failed in an appliance; maintenance costs are associated with maintaining the operation of the product. For UPSs, DOE assumed that small incremental increases in product efficiency produce no changes in repair and maintenance costs compared to baseline efficiency products. This assumption is supported by the National Electrical Manufacturers Association (NEMA's) comment that no increased maintenance, repair, or installation costs are associated with more efficient UPS designs. (NEMA, No. 0015 at p. 7)

6. Product Lifetime

For UPSs, DOE performed a search of the published literature to identify minimum and maximum average lifetimes from a variety of sources. DOE also considered input from manufacturer interviews conducted in early 2015. ITI commented that UPS products have lifetimes of up to 20 years. (ITI, No. 0010 at p. 19) Table IV.2 summarizes the UPS lifetimes that DOE compiled from the literature and manufacture interviews. Where a range for lifetime was given, DOE noted the minimum and maximum values; where there was only one figure, DOE recorded this figure as both the minimum and maximum value. DOE computed mean lifetime by averaging these values across the product class.

TABLE IV.2—UPS PRODUCT LIFETIMES FROM LITERATURE AND MANUFACTURER INPUT

Product class	Description	Lifetimes (years)			
		Minimum	Mean	Median	Maximum
10a	VFD UPS	3	5	5	7
10b	VI UPS	5	6.3	6	8
10c	VFI UPS	8	10	10	12

Using these minimum, maximum, and mean lifetimes, DOE constructed survival functions for the various UPS product classes. No more than 10 percent of units were assumed to fail before the minimum lifetime, and no more than 90 percent of units were assumed to fail before the maximum lifetime. DOE assumed these survival functions have the form of a cumulative Weibull distribution, a probability distribution commonly used to model appliance lifetimes. Its form is similar to that of an exponential distribution, which models a fixed failure rate, except a Weibull distribution allows for a failure rate that can increase over time as appliances age. For additional discussion of UPS lifetimes, refer to chapter 8 of the NOPR TSD.

7. Discount Rates

In the calculation of LCC, DOE applies discount rates appropriate to households to estimate the present value of future operating costs. DOE estimated a distribution of residential discount rates for UPSs based on consumer financing costs and opportunity cost of funds related to appliance energy cost savings and maintenance costs.

To establish residential discount rates for the LCC analysis, DOE identified all relevant household debt or asset classes in order to approximate a consumer's opportunity cost of funds related to appliance energy cost savings. It estimated the average percentage shares of the various types of debt and equity by household income group using data from the Federal Reserve Board's Survey of Consumer Finances[22] (SCF) for 1995, 1998, 2001, 2004, 2007, and 2010. Using the SCF and other sources, DOE developed a distribution of rates for each type of debt and asset by income group to represent the rates that may apply in the year in which amended standards would take effect. DOE assigned each sample household a specific discount rate drawn from one of the distributions. The average rate across all types of household debt and

[20] Edison Electric Institute. *Typical Bills and Average Rates Report.* Winter 2014 published April 2014, Summer 2014 published October 2014. *http://www.eei.org/resourcesandmedia/products/Pages/Products.aspx.*

[21] U.S. Department of Energy—Energy Information Administration. *Annual Energy Outlook 2015 with Projections to 2040.* 2015. *http://www.eia.gov/forecasts/aeo/.*

[22] Board of Governors of the Federal Reserve System. *Survey of Consumer Finances.* Various dates. Washington, DC. *http://www.federalreserve.gov/pubs/oss/oss2/scfindex.html.*

equity and income groups, weighted by the shares of each type, is 4.4 percent. See chapter 8 of the NOPR TSD for further details on the development of consumer discount rates.

To establish commercial discount rates for the LCC analysis, DOE estimated the cost of capital for companies that purchase a UPS. The weighted average cost of capital is commonly used to estimate the present value of cash flows to be derived from a typical company project or investment. Most companies use both debt and equity capital to fund investments, so their cost of capital is the weighted average of the cost to the firm of equity and debt financing, as estimated from financial data for publicly traded firms in the sectors that purchase UPSs. For this analysis, DOE used Damodaran online [23] as the source of information about company debt and equity financing. The average rate across all types of companies, weighted by the shares of each type, is 5.2 percent. See chapter 8 of the NOPR TSD for further details on the development of commercial discount rates.

8. Efficiency Distribution in the No-Standards Case

To accurately estimate the share of consumers that would be affected by a potential energy conservation standard at a particular efficiency level, DOE's LCC analysis considered the projected distribution (market shares) of product efficiencies under the no-standards case (*i.e.,* the case without amended or new energy conservation standards). To estimate the efficiency distribution of UPSs for 2019, DOE examined a recent ENERGY STAR qualified product list. Although these model lists are not sales-weighted, DOE assumed they were a reasonable representation of the market.

The estimated market penetration of ENERGY STAR-qualified UPSs was 78 percent in 2013, the most recent year for which data were available.[24] DOE assumed market penetration to be 78 percent for all three UPS product classes, as the 2013 Unit Shipment Data report does not distinguish between UPS architectures. In order to assess how qualified products fit into proposed efficiency levels, DOE analyzed a qualified product list downloaded on February 16, 2016, after cross-checking inconsistencies in reported UPS product type with product specifications on retail Web sites. For the 266 qualified in-scope models, DOE compared average efficiency to the efficiency required for each EL, as determined in the engineering analysis. Finally, DOE assumed that the market share represented by non-ENERGY STAR-qualified products would belong to the least-efficient efficiency level analyzed. The estimated market shares for the no-standards case for UPSs are shown in Table IV.3. See chapter 8 of the NOPR TSD for further information on the derivation of the efficiency distributions.

TABLE IV.3—ESTIMATED MARKET SHARES (%) IN EACH EFFICIENCY LEVEL FOR NO-STANDARDS CASE

Product class	Description	Efficiency level			
		EL 0 (baseline)	EL 1	EL 2	EL 3
10a	VFD UPS	47	31	21	1.5
10b	VI UPS	72	25	3.9	0
10c	VFI UPS	77	17	5.8	0

9. Payback Period Analysis

The payback period is the amount of time it takes the consumer to recover the additional installed cost of more-efficient products, compared to baseline products, through energy cost savings. Payback periods are expressed in years. Payback periods that exceed the life of the product mean that the increased total installed cost is not recovered in reduced operating expenses.

The inputs to the PBP calculation for each efficiency level are the change in total installed cost of the product and the change in the first-year annual operating expenditures relative to the baseline. The PBP calculation uses the same inputs as the LCC analysis, except that discount rates are not needed.

As noted in this preamble, EPCA, as amended, establishes a rebuttable presumption that a standard is economically justified if the Secretary finds that the additional cost to the consumer of purchasing a product complying with an energy conservation standard level will be less than three times the value of the first year's energy savings resulting from the standard, as calculated under the applicable test procedure. (42 U.S.C. 6295(o)(2)(B)(iii)) For each considered efficiency level, DOE determined the value of the first year's energy savings by calculating the energy savings in accordance with the applicable DOE test procedure, and multiplying those savings by the average energy price forecast for the year in which compliance with the new standards would be required.

G. Shipments Analysis

DOE uses forecasts of annual product shipments to calculate the national impacts of potential amended energy conservation standards on energy use, NPV, and future manufacturer cash flows.[25] Because UPSs back up and condition power for electronics, whose technology evolves more rapidly than many other appliances, DOE did not rely on a stock accounting approach common to other appliances. Instead, DOE largely elected to extrapolate forecasted trends from market research data. Data from Frost & Sullivan [26] and ENERGY STAR unit shipments [27] provided the foundation for DOE's shipments analysis for UPSs. DOE calculated shipment values for 30 years, from 2019, the first year of compliance, through 2048, the last year of the analysis period.

[23] Damodaran, A. *Cost of Capital by Sector.* January 2014. (Last accessed September 25, 2014.) New York, NY. *http://people.stern.nyu.edu/adamodar/New_Home_Page/datafile/wacc.htm.*

[24] Environmental Protection Agency—ENERGY STAR Program. *Certification Year 2013 Unit Shipment Data.* 2014. Washington, DC. *https://www.energystar.gov/index.cfm?c=partners.unit_shipment_data.*

[25] DOE uses data on manufacturer shipments as a proxy for national sales, as aggregate data on sales are lacking. In general one would expect a close correspondence between shipments and sales.

[26] Cherian, A. *Analysis of the Global Uninterruptible Power Supplies Market: Need for Greater Power Reliability Driving Growth.* Frost & Sullivan. 2013. San Antonio, TX. *http://www.frost.com/c/10077/sublib/display-report.do?id=NC62-01-00-00-00.*

[27] Environmental Protection Agency—ENERGY STAR Program. *Certification Year 2013 UPS Unit Shipment Data.* 2013. Washington, DC. *https://www.energystar.gov/index.cfm?c=partners.unit_shipment_data.*

1. Shipment Projections in the No-Standards Case

DOE relied on data from Frost & Sullivan and ENERGY STAR to develop the shipments in the no-standards case for UPSs.[28] Frost & Sullivan provide global UPS unit shipments from 2009 to 2019 for the relevant output range <1000 W. Because the next power range for which shipments are provided is 1–5 kilo-watts (kW), and only UPSs with rated output power ≤1500 W are in scope, DOE excluded this power range from the shipments analysis. For <1000 W, Frost & Sullivan supply North American revenue as a percent of global revenue 2009 to 2019, so DOE assumed that percent of revenue is a reasonable proxy for percent of shipments. Multiplying global shipments by the North American percentage of revenue, and then by 0.9 under the assumption that the United States makes up 90 percent of the North American market, yielded U.S. UPS shipments.

Frost & Sullivan provided no classification by type of UPS within the relevant power range. However, the 2013 ENERGY STAR unit shipment data collection process [29] provides such a breakdown; in that year, market penetration of UPSs was 78 percent,[30] so DOE assumed these data are representative of the market. DOE used these data to determine how <1000 W UPSs are apportioned among different topologies for 2013 to 2019, assuming this allocation stays constant: 50 percent VFD, 39 percent VI, and 12 percent VFI. The Frost & Sullivan data indicate that the commercial sector dominates UPS revenue in the <1000 W market segment; therefore, DOE assumed a split of 90 percent commercial and 10 percent residential shipments.

To project UPS shipments from 2020–2048, DOE extrapolated the linear trends forecasted by Frost & Sullivan from 2014 to 2019. In conjunction with the 2013 fixed split between topologies and a fixed portion of 0.9 for the United States relative to North American shipments, DOE projected the increasing linear trend in global UPS shipments <1 kW and the decreasing linear share of North American revenue to forecast shipments from 2019 to 2048. DOE requests additional information on UPS shipments and projections (see section VII.E).

2. Shipment Projections in the Standards Case

Increases in product prices resulting from standards may affect shipment volumes. To DOE's knowledge, price elasticity estimates are not readily available in existing literature for UPSs, and hence DOE assumed a price elasticity of demand of zero. DOE requests comment on commercial and residential price elasticity data for UPS product classes (see section VII.E).

ITI commented that voluntary programs such as ENERGY STAR are what drive manufacturers to design products to be as efficient as possible and NEMA commented that because of the significant influence of ENERGY STAR on UPSs, little potential remains in product efficiency. (ITI, No. 0010 at p. 19) (NEMA, No. 0015 at p. 3)

DOE disagrees with the claim that little potential remains in product efficiency for UPSs. DOE's engineering analysis indicates that UPSs with higher efficiency than that required for ENERGY STAR designation are now or could be available, and the economic analysis indicates that some of these higher levels are economically justified. In the absence of standards, it is unlikely that the entire market would move to these levels. At present, approximately 20 percent of UPSs sold have efficiency below the ENERGY STAR level.

See chapter 9 of the NOPR TSD for further details on the development of shipments projections.

H. National Impact Analysis

The NIA assesses the national energy savings (NES) and the national net present value (NPV) from a national perspective of total consumer costs and savings that would be expected to result from new or amended standards at specific efficiency levels.[31] (''Consumer'' in this context refers to consumers of the product being regulated.) DOE calculates the NES and NPV for the potential standard levels considered based on projections of annual product shipments, along with the annual energy consumption and total installed cost data from the energy use and LCC analyses.[32] For the present analysis, DOE forecasted the energy savings, operating cost savings, product costs, and NPV of consumer benefits over the lifetime of UPSs sold from 2019 through 2048.

DOE evaluates the impacts of new and amended standards by comparing a case without such standards with standards-case projections. The no-standards case characterizes energy use and consumer costs for each product class in the absence of new energy conservation standards. For this projection, DOE considers historical trends in efficiency and various forces that are likely to affect the mix of efficiencies over time. DOE compares the no-standards case with projections characterizing the market for each product class if DOE adopted new standards at specific energy efficiency levels (*i.e.,* the TSLs or standards cases) for that class. For the standards cases, DOE considers how a given standard would likely affect the market shares of products with efficiencies greater than the standard.

DOE uses a spreadsheet model to calculate the energy savings and the national consumer costs and savings from each TSL. Interested parties can review DOE's analyses by changing various input quantities within the spreadsheet. The NIA spreadsheet model uses typical values (as opposed to probability distributions) as inputs.

Table IV.4 summarizes the inputs and methods DOE used for the NIA analysis for the NOPR. Discussion of these inputs and methods follows the table. See chapter 10 of the NOPR TSD for further details.

TABLE IV.4—SUMMARY OF INPUTS AND METHODS FOR THE NATIONAL IMPACT ANALYSIS

Inputs	Method
Shipments	Annual shipments from shipments model.
Compliance Date of Standard	2019.
Efficiency Trends	No-standards case: No efficiency trend. Standards cases: ''roll-up'' scenario.

[28] Cherian, A. *Analysis of the Global Uninterruptible Power Supplies Market: Need for Greater Power Reliability Driving Growth.* Frost & Sullivan. 2013. San Antonio, TX. *http://www.frost.com/c/10077/sublib/display-report.do?id=NC62-01-00-00-00.*

[29] Environmental Protection Agency—ENERGY STAR Program. *Certification Year 2013 UPS Unit Shipment Data.* 2013. Washington, DC. *https://www.energystar.gov/index.cfm?c=partners.unit_shipment_data.*

[30] Ibid.

[31] The NIA accounts for impacts in the 50 states and U.S. territories.

[32] For the NIA, DOE adjusts the installed cost data from the LCC analysis to exclude sales tax, which is a transfer.

TABLE IV.4—SUMMARY OF INPUTS AND METHODS FOR THE NATIONAL IMPACT ANALYSIS—Continued

Inputs	Method
Annual Energy Consumption per Unit.	Annual weighted-average values are a function of energy use at each TSL.
Total Installed Cost per Unit	Annual weighted-average values are a function of cost at each TSL. Incorporates projection of future product prices based on historical data.
Annual Energy Cost per Unit	Annual weighted-average values as a function of the annual energy consumption per unit and energy prices.
Repair and Maintenance Cost per Unit.	Annual values do not change with efficiency level.
Energy Prices	*AEO 2015* forecasts (to 2040) and extrapolation through 2048.
Energy Site-to-Primary and FFC Conversion.	A time-series conversion factor based on *AEO 2015.*
Discount Rate	3 percent and 7 percent.
Present Year	2016.

1. Product Efficiency Trends

A key component of the NIA is the trend in energy efficiency projected for the no-standards case and each of the standards cases. Section IV.F.8 of this NOPR describes how DOE developed an energy efficiency distribution for the no-standards case (which yields a shipment-weighted average efficiency) for each of the considered product classes for the year of anticipated compliance with a new standard. To project the trend in efficiency for UPSs over the entire shipments projection period, DOE examined past improvements in efficiency over time. Little data exists to suggest that UPS efficiencies would improve in the 30 years following 2019 in the no-standards case. The approach is further described in chapter 10 of the NOPR TSD. DOE requests further comment on relevant efficiency trends for UPSs (see section VII.E).

For the standards cases, DOE used a ''roll-up'' scenario to establish the shipment-weighted efficiency for the year that standards are assumed to become effective (2019). In this scenario, the market shares of products in the no-standards case that do not meet the standard under consideration would ''roll up'' to meet the new standard level, and the market share of products above the standard would remain unchanged. To develop standards case efficiency trends after 2019, DOE implemented the same trend as in the no-standards case: Zero percent for UPSs.

2. National Energy Savings

The national energy savings analysis involves a comparison of national energy consumption of the considered products between each potential standards case (TSL) and in the case with no energy conservation standards. DOE calculated the national energy consumption by multiplying the number of units (stock) of each product (by vintage or age) by the unit energy consumption (also by vintage). DOE calculated annual NES based on the difference in national energy consumption for the no-standards case and for each higher efficiency standard case. DOE estimated energy consumption and savings based on site energy and converted the electricity consumption and savings to primary energy (*i.e.,* the energy consumed by power plants to generate site electricity) using annual conversion factors derived from *AEO 2015.* Cumulative energy savings are the sum of the NES for each year over the timeframe of the analysis.

In 2011, in response to the recommendations of a committee on ''Point-of-Use and Full-Fuel-Cycle Measurement Approaches to Energy Efficiency Standards'' appointed by the National Academy of Sciences, DOE announced its intention to use full-fuel-cycle (FFC) measures of energy use and greenhouse gas and other emissions in the national impact analyses and emissions analyses included in future energy conservation standards rulemakings. 76 FR 51281 (Aug. 18, 2011). After evaluating the approaches discussed in the August 18, 2011 notice, DOE published a statement of amended policy in which DOE explained its determination that EIA's National Energy Modeling System (NEMS) is the most appropriate tool for its FFC analysis and its intention to use NEMS for that purpose. 77 FR 49701 (Aug. 17, 2012). NEMS is a public domain, multi-sector, partial equilibrium model of the U.S. energy sector [33] that EIA uses to prepare its *Annual Energy Outlook.* The approach used for deriving FFC measures of energy use and emissions is described in appendix 10A of the NOPR TSD.

3. Net Present Value Analysis

The inputs for determining the NPV of the total costs and benefits experienced by consumers are (1) total annual installed cost, (2) total annual savings in operating costs, and (3) a discount factor to calculate the present value of costs and savings. DOE calculates net savings each year as the difference between the no-standards case and each standards case in terms of total savings in operating costs versus total increases in installed costs. DOE calculates operating cost savings over the lifetime of each product shipped during the forecast period.

The operating cost savings are energy cost savings, which are calculated using the estimated energy savings in each year and the projected price of the appropriate form of energy. To estimate energy prices in future years, DOE multiplied the average regional energy prices by the forecast of annual national-average residential energy price changes in the Reference case from *AEO 2015,* which has an end year of 2040. To estimate price trends after 2040, DOE used the average annual rate of change in prices from 2020 through 2040. As part of the NIA, DOE also analyzed scenarios that used inputs from the *AEO 2015* Low Economic Growth and High Economic Growth cases. Those cases have higher and lower energy price trends compared to the Reference case. NIA results based on these cases are presented in appendix 10B of the NOPR TSD.

In calculating the NPV, DOE multiplies the net savings in future years by a discount factor to determine their present value. For this NOPR, DOE estimated the NPV of consumer benefits using both a 3-percent and a 7-percent real discount rate. DOE uses these discount rates in accordance with guidance provided by the Office of

[33] For more information on NEMS, refer to *The National Energy Modeling System: An Overview,* DOE/EIA–0581(98), February 1998. Available at *www.eia.gov/forecasts/aeo/index.cfm.*

Management and Budget (OMB) to Federal agencies on the development of regulatory analysis.[34] The discount rates for the determination of NPV are in contrast to the discount rates used in the LCC analysis, which are designed to reflect a consumer's perspective. The 7-percent real value is an estimate of the average before-tax rate of return to private capital in the U.S. economy. The 3-percent real value represents the ''social rate of time preference,'' which is the rate at which society discounts future consumption flows to their present value.

CEA commented that DOE should not use a 30-year projection to calculate national energy savings given the short product lifecycle of consumer electronics. (CEA, No. 0012 at p. 6) NEMA also disagreed with the 30-year projection and suggested a 6-year projection. (NEMA, No. 0015 at p. 2)

In performing the NIA for its energy conservation standards rulemakings, DOE has used a 30-year analysis period, beginning on the effective date of the standard, because it matches the lifetime of the longest-lived products among the products being considered for standards. Matching the lifetime of the longest-lived products allows for a full turnover of the stock. Because products have varying lifetimes, DOE uses a 30-year analysis period to maintain a consistent time frame to compare the energy savings and economic impacts from all the standards rulemakings. DOE acknowledges that using a 30-year period for shorter-lived products such as UPSs presents challenges with respect to projecting future trends. However, DOE also provides a 9-year sensitivity analysis that considers impacts for products shipped in a 9-year period. Further, with respect to the economic analysis, projected impacts for products shipped in the later part of the 30-year period play a relatively small role due to the effects of discounting.

I. Consumer Subgroup Analysis

In analyzing the potential impact of new or amended energy conservation standards on consumers, DOE evaluates the impact on identifiable subgroups of consumers that may be disproportionately affected by a new or amended national standard. The purpose of a subgroup analysis is to determine the extent of any such disproportional impacts. DOE evaluates impacts on particular subgroups of consumers by analyzing the LCC impacts and PBP for those particular consumers from alternative standard levels. For this NOPR, DOE analyzed the impacts of the considered standard levels on two subgroups: (1) Low-income households and (2) small businesses. DOE used the LCC and PBP spreadsheet model to estimate the impacts of the considered efficiency levels on these subgroups. Chapter 11 in the NOPR TSD describes the consumer subgroup analysis.

J. Manufacturer Impact Analysis

1. Overview

DOE performed an MIA to estimate the financial impacts of new energy conservation standards on manufacturers of UPSs and to estimate the potential impacts of such standards on domestic employment, manufacturing capacity, and cumulative regulatory burden for those manufacturers. The MIA has both quantitative and qualitative aspects. The quantitative part of the MIA includes analyses of forecasted industry cash flows to create the INPV, as well as an analysis of the additional investments in research and development (R&D) and manufacturing capital necessary to comply with new standards, and the potential impact on domestic manufacturing employment. Additionally, the MIA seeks to qualitatively determine how new energy conservation standards might affect manufacturers' capacity and competition, as well as how standards contribute to manufacturers' overall regulatory burden. Finally, the MIA serves to identify any disproportionate impacts on manufacturer subgroups, including small business manufacturers.

The quantitative part of the MIA primarily relies on the GRIM, an industry cash flow model with inputs specific to this rulemaking. The key GRIM inputs include data on the industry cost structure, unit production costs, product shipments, manufacturer markups, and investments in R&D and manufacturing capital required to produce compliant products. The key GRIM outputs are INPV, which is the sum of industry annual cash flows over the analysis period, discounted using the industry-weighted average cost of capital, and the impact on domestic manufacturing employment. The model uses standard accounting principles to estimate the impacts of new energy conservation standards on the UPS manufacturing industry by comparing changes in INPV and domestic manufacturing employment between the no-standards case and each of the standards levels. To capture the uncertainty relating to manufacturer pricing strategies following potential new standards, the GRIM estimates a range of possible impacts under different markup scenarios.

The qualitative part of the MIA addresses manufacturer characteristics and market trends. Specifically, the MIA considers such factors as a potential standard's impact on manufacturing capacity, competition within the industry, the cumulative impact of other DOE and non-DOE regulations, and impacts on manufacturer subgroups. The complete MIA is outlined in chapter 12 of the NOPR TSD.

DOE conducted the MIA for this rulemaking in three phases. In the first phase of the MIA, DOE prepared a profile of the UPS manufacturing industry based on the market and technology assessment, preliminary manufacturer interviews, and publicly-available information. This included a top-down analysis of UPS manufacturers that DOE used to derive preliminary financial inputs for the GRIM (*e.g.,* revenues; materials, labor, overhead, and depreciation expenses; selling, general, and administrative expenses (SG&A); and R&D expenses). DOE also used public sources of information to further calibrate its initial characterization of the UPS manufacturing industry, including company filings of 10–K from the SEC,[35] corporate annual reports, and the U.S. Census Bureau's Economic Census.[36]

In the second phase of the MIA, DOE prepared a framework industry cash-flow analysis to quantify the potential impacts of new energy conservation standards. The GRIM uses several factors to determine a series of annual cash flows starting with the announcement of the standards and extending over a 30-year period following the compliance date of the standards. These factors include annual expected revenues, costs of sales, SG&A and R&D expenses, taxes, and capital expenditures. In general, energy conservation standards can affect manufacturer cash flow in three distinct ways: (1) Creating a need for increased investment, (2) raising production costs per unit, and (3) altering revenue due to higher per-unit prices and changes in sales volumes.

In addition, during the second phase, DOE developed an interview guide to distribute to UPS manufacturers in order to develop other key GRIM inputs, including product and capital

[34] United States Office of Management and Budget. Circular A–4: Regulatory Analysis. September 17, 2003. Section E. Available at *www.whitehouse.gov/omb/memoranda/m03-21.html.*

[35] *http://www.sec.gov/edgar.shtml.*

[36] *http://factfinder.census.gov/faces/nav/jsf/pages/searchresults.xhtml.*

conversion costs, and to gather additional information on the anticipated effects of new energy conservation standards on revenue, direct employment, capital assets, industry competition, and manufacturer subgroup impacts.

In the third phase of the MIA, DOE conducted structured, detailed interviews with representative UPS manufacturers. During these interviews, DOE discussed engineering, manufacturing, procurement, and financial topics to validate assumptions used in the GRIM and to identify key issues or concerns. See section IV.J.4 for a description of the key issues raised by manufacturers during the interviews. As part of the third phase, DOE also evaluated manufacturer subgroups that may be disproportionately impacted by new standards or that may not be accurately represented by the average cost assumptions used to develop the industry cash flow analysis. Such manufacturer subgroups may include small business manufacturers, low-volume manufacturers, niche players, and/or manufacturers exhibiting a cost structure that largely differs from the industry average.

DOE identified one manufacturer subgroup for a separate impact analysis—small business manufacturers—using the small business employee threshold of 500 total employees published by the Small Business Administration (SBA). This threshold includes all employees in a business' parent company and any other subsidiaries. The complete MIA is presented in chapter 12 and in sections V.B.2.d and VII.B, and the analysis required by the Regulatory Flexibility Act, 5 U.S.C. 601, *et. seq.*, is presented in section VI.B of this NOPR.

2. GRIM Analysis and Key Inputs

DOE uses the GRIM to quantify the changes in cash flows over time due to new energy conservation standards. These changes in cash flows result in either a higher or lower INPV for the standards cases compared to the no-standards case. The GRIM analysis uses a standard annual cash flow analysis that incorporates manufacturer costs, manufacturer markups, shipments, and industry financial information as inputs. It then models changes in costs, investments, and manufacturer margins that result from new energy conservation standards. The GRIM uses these inputs to calculate a series of annual cash flows beginning with the reference year of the analysis, 2016, and continuing to 2048. DOE computes INPV by summing the stream of annual discounted cash flows during the analysis period.

DOE used a real discount rate of 6.1 percent for UPS manufacturers. The discount rate estimate was derived from industry corporate annual reports to the Securities and Exchange Commission (SEC 10–Ks). During manufacturer interviews, UPS manufacturers were asked to provide feedback on this specific discount rate. Based on this feedback, DOE determined that a discount rate of 6.1 percent was appropriate to use for the UPS industry. Many of the GRIM inputs came from the engineering analysis, the NIA, manufacturer interviews, and other research conducted during the MIA. The major GRIM inputs are described in detail in the following sections.

DOE seeks comment on its use of 6.1 percent as a discount rate for UPS manufacturers (see section VII.E).

a. Capital and Product Conversion Costs

DOE expects new energy conservation standards for UPSs to cause manufacturers to incur conversion costs to bring their production facilities and product designs into compliance with new standards. For the MIA, DOE classified these conversion costs into two major groups: (1) Capital conversion costs and (2) product conversion costs. Capital conversion costs are investments in property, plant, and equipment necessary to adapt or change existing production facilities such that new product designs can be fabricated and assembled. Product conversion costs are investments in research, development, testing, marketing, certification, and other non-capitalized costs necessary to make product designs comply with new standards.

Using feedback from manufacturer interviews, DOE conducted a bottom-up analysis of the conversion costs necessary to comply with new standards for all product classes at each analyzed EL. DOE used manufacturer input from manufacturer interviews regarding the types and dollar amounts of discrete capital and product expenditures that would be necessary to convert specific production lines for each product class at each EL.

DOE determined that UPS manufacturers would not incur any additional capital conversion costs in the standards cases that would not be incurred in the no-standards case. Manufacturers stated that any product redesigns required to meet the proposed ELs would represent changes in component configuration as opposed to changes in the tooling and equipment used to manufacture more efficient UPSs (DOE does capture the additional costs of the more efficient components in the MPCs). Additionally, manufacturers stated that product design cycles for the majority of covered UPSs would be three years or less. The potential standards proposed in this NOPR would have a three-year compliance timeframe between the announcement of the potential standards and the compliance year of those standards. Therefore, the majority of these product design cycles would coincide with or take place before the compliance year of any potential standards. For manufacturers that have product design cycles that do not coincide with or take place before the compliance year and would have to redesign their UPSs to comply with the proposed standards, DOE included the cost of product redesign in the product conversion costs.

DOE seeks comment on its determination that product redesigns necessary to meet the ELs required by the proposed standard would not require investments in equipment and tooling and on its determination that the majority of product design cycles would either take place before or coincide with the compliance period of the potential standards for UPSs (see section VII.E).

DOE also assumes that there would be no stranded capital assets for UPS manufacturers. Again, DOE made this determination based on manufacturer feedback stating that no investments in equipment and tooling are necessary to comply with proposed standards.

The two main types of product conversion costs for UPSs that manufacturers shared with DOE during manufacturer interviews were the engineering time and effort necessary to redesign their products to meet higher efficiency standards and the testing and certification costs necessary to comply with efficiency standards. Once DOE had compiled these product conversion costs, DOE then took average values for a UPS platform (*i.e.,* average number of hours or average dollar amounts) based on the range of responses given by manufacturers for the product conversion cost of each product class at each EL. Finally, DOE scaled the per platform costs by the estimated number of platforms that would need to be redesigned at each EL to calculate the total industry product conversion cost at each EL that was used in the MIA.

DOE seeks comment on its methodology used to calculate product conversion costs, including the assumption of no capital conversion costs or stranded assets for UPS manufacturers at analyzed ELs (see section VII.E).

See chapter 12 of the NOPR TSD for a complete description of DOE's assumptions for the product conversion costs.

b. Manufacturer Production Costs

Manufacturing more efficient UPSs is more expensive than manufacturing baseline products due to the need for more costly materials and components. The higher MPCs for these more efficient products can affect the revenue and gross margin, which will then affect total volume of future shipments, and the cash flows of UPS manufacturers. DOE developed MPCs for UPSs by using efficiency testing and market data to determine the cost-efficiency relationship for UPSs currently on the market that met each efficiency level in each product class. For more information about MPCs, see section IV.C of this NOPR.

For a complete description of the MPCs, see chapter 5 of this NOPR TSD.

c. Shipment Scenarios

INPV, the key GRIM output, depends on industry revenue, which depends on the quantity and prices of UPSs shipped in each year of the analysis period. Industry revenue calculations require forecasts of: (1) Total annual shipment volume of UPSs; (2) the distribution of shipments across product classes (because prices vary by product class); and, (3) the distribution of shipments across ELs (because prices vary by efficiency).

In the no-standards case shipment analysis, shipments of UPSs were based on market forecast data. Since UPS technology evolves more rapidly than other appliance technologies, DOE extrapolated forecasted trends from market research data instead of relying on a stock accounting approach. Market forecasts from Frost and Sullivan as well as ENERGY STAR were used as the basis for standards case UPS shipments.

In the standards cases, DOE modeled a roll-up shipment scenario for UPSs. In the roll-up shipment scenario, consumers who would have purchased UPSs that fail to meet the new standards in the no-standards case, purchase UPSs that just meet the new standards, but are not more efficient than those standards, in the standards cases. Those consumers that would have purchased compliant UPSs in the no-standards case continue to purchase the exact same UPSs in the standards cases.

DOE believes that consumers purchasing UPSs covered by this rulemaking are primarily driven by the first cost of the UPSs and, therefore, most consumers will continue to purchase the lowest-cost UPSs available. This behavior is best modeled by the roll-up shipment scenario.

For a complete description of the shipments see the shipments analysis discussion in section IV.G of this NOPR.

d. Markup Scenarios

As discussed in section IV.J.2.b, the MPCs for each of the UPS product classes are the UPS manufacturers' costs for those products. These costs include materials, direct labor, depreciation, and overhead, which are collectively referred to as the cost of goods sold (COGS). The MSP is the price received by UPS manufacturers from their customers, typically a distributor but could be the direct users, regardless of the downstream distribution channel through which the UPSs are ultimately sold. The MSP is not necessarily the cost the end-user pays for the UPS since there are typically multiple sales along the distribution chain and various markups applied to each sale. The MSP equals the MPC multiplied by the manufacturer markup. The manufacturer markup covers all the UPS manufacturer's non-production costs (*i.e.,* SG&A, R&D, and interest, etc.) as well as profit. Total industry revenue for UPS manufacturers equals the MSPs at each EL for each product class multiplied by the number of shipments at that EL.

Modifying these manufacturer markups in the standards cases yields a different set of impacts on UPS manufacturers than in the no-standards case. For the MIA, DOE modeled two standards case markup scenarios to represent the uncertainty regarding the potential impacts on prices and profitability for UPS manufacturers following the implementation of new energy conservation standards. The two markup scenarios are; (1) a preservation of gross margin, or flat, markup scenario and (2) a pass through markup scenario. Each scenario leads to different manufacturer markup values, which, when applied to the inputted MPCs, result in varying revenue and cash flow impacts on UPS manufacturers.

The preservation of gross margin markup scenario assumes that the MPC for each product is marked up by a flat percentage to cover SG&A expenses, R&D expenses, interest expenses, and profit. This allows manufacturers to preserve the same gross margin percentage in the standards cases as in the no-standards case. This markup scenario represents the upper bound of the UPS industry's profitability in the standards cases because UPS manufacturers are able to fully pass on additional costs due to standards to their consumers.

To derive the preservation of gross margin markup percentages for UPSs, DOE examined the SEC 10–Ks of all publicly traded UPS manufacturers to estimate the average UPS manufacturer markup. DOE analyzed manufacturer markups for each product class separately since, based on manufacturer interviews, manufacturers frequently apply different markups to different product classes. The manufacturer markup represents the markup manufacturers apply to their MPCs to arrive at their MSPs. Based on SEC 10–Ks, DOE found the typical manufacturer markup for manufacturers that produce UPSs was 1.57.

During manufacturer interviews, DOE asked UPS manufacturers if 1.57 was an appropriate manufacturer markup to use for all UPSs. While most manufacturers agreed that 1.57 was an appropriate average manufacturer markup for all VFI, VI and VFD UPSs, these manufacturers stated that their manufacturer markup tends to vary by product class. Therefore, based on manufacturer feedback, DOE increased the manufacturer markup for VFI UPSs to 1.76 and decreased the manufacturer markup for VFD UPSs to 1.55. DOE kept the manufacturer markup for VI UPSs at 1.57 based on manufacturer feedback.

DOE included an alternative markup scenario, the pass through markup, because UPS manufacturers stated they do not expect to be able to mark up the additional cost of production in the standards cases, given the highly competitive UPS market. The pass through markup scenario assumes that UPS manufacturers are able to pass through the incremental costs of more efficient UPSs to their consumers, but without earning any additional operating profit on those higher costs. This scenario results in overall manufacturer margin compression and adverse financial impacts as UPS costs increase due to new energy conservation standards.

The pass through markup scenario represents the lower bound of industry profitability in the standards cases. This is because manufacturers are not able to markup up the additional costs necessitated by UPS energy conservation standards, as they are able to do in the preservation of gross margin markup scenario. Therefore, manufacturers earn less revenue in the pass through markup scenario than they do in the preservation of gross margin markup scenario.

DOE seeks comment on its methodology used to calculate manufacturer markups, its use of different manufacturer markups for each product class, and the specific

manufacturer markups DOE estimated for each UPS product class (see section VII.E).

3. Discussion of Comments

Interested parties commented on the assumptions and results of the July 2014 framework document. NEMA stated that if DOE sets ELs at or above the current ENERGY STAR levels for UPSs, UPS manufacturers would lose investments previously made to meet these ENERGY STAR requirements. (NEMA, No. 0015 at p. 7) DOE acknowledges that UPS energy conservation standards set at or above ENERGY STAR levels for UPSs could render some product designs obsolete. This could cause manufactures to make additional investments in product redesign and testing. DOE accounts for the one-time conversion costs that UPS manufacturers would have to make at each potential standard level as part of the MIA. Additionally, because UPS technology evolves rapidly, DOE determined that all UPSs would be redesigned in the three year time period between the publication of any UPS final rule and the compliance year of that rulemaking, so manufactures would have to redesign those products even in the no-standards case. See section V.B.2.a of this NOPR for a complete discussion of the manufacturer investments necessary to comply with the analyzed energy conservation standards.

4. Manufacturer Interviews

DOE conducted interviews with manufacturers following the publication of the July 2014 framework document in preparation for the NOPR analysis. In these interviews, DOE asked manufacturers to describe their major concerns with this UPS rulemaking. UPS manufacturers identified one key issue during these interviews, the burden of testing and certification.

UPS manufacturers stated that the costs associated with testing and certifying all of their products covered by this rulemaking could be burdensome. UPS manufacturers commented that since efficient products do not typically earn a premium in the UPS market, manufacturers do not regularly conduct efficiency testing or pursue energy-efficient certifications for the majority of their product offerings. As a result, the testing and certification required for compliance with a potential standard represents additional costs to the typical product testing conducted by UPS manufacturers. Since a potential standard would require all UPS offerings to be tested and certified, UPS manufacturers explained that this process could become expensive. The UPS test procedure NOPR (81 FR 31542) analyzes the testing and certification costs manufacturers must make to comply with the analyzed energy conservation standards.

K. Emissions Analysis

The emissions analysis consists of two components. The first component estimates the effect of potential energy conservation standards on power sector and site (where applicable) combustion emissions of CO_2, NO_X, SO_2, and Hg. The second component estimates the impacts of potential standards on emissions of two additional greenhouse gases, CH_4 and N_2O, as well as the reductions to emissions of all species due to ''upstream'' activities in the fuel production chain. These upstream activities comprise extraction, processing, and transporting fuels to the site of combustion. The associated emissions are referred to as upstream emissions.

The analysis of power sector emissions uses marginal emissions factors that were derived from data in *AEO 2015,* as described in section IV.M. Details of the methodology are described in the appendices of chapters 13 and 15 of the NOPR TSD.

Combustion emissions of CH_4 and N_2O are estimated using emissions intensity factors published by the EPA: GHG Emissions Factors Hub.[37] The FFC upstream emissions are estimated based on the methodology described in chapter 15 of the NOPR TSD. The upstream emissions include both emissions from fuel combustion during extraction, processing, and transportation of fuel, and ''fugitive'' emissions (direct leakage to the atmosphere) of CH_4 and CO_2.

The emissions intensity factors are expressed in terms of physical units per MWh or MMBtu of site energy savings. Total emissions reductions are estimated using the energy savings calculated in the national impact analysis.

For CH_4 and N_2O, DOE calculated emissions reduction in tons and also in terms of units of carbon dioxide equivalent (CO_2eq). Gases are converted to CO_2eq by multiplying each ton of gas by the gas's global warming potential (GWP) over a 100-year time horizon. Based on the Fifth Assessment Report of the Intergovernmental Panel on Climate Change,[38] DOE used GWP values of 28 for CH_4 and 265 for N_2O.

The *AEO* incorporates the projected impacts of existing air quality regulations on emissions. *AEO 2015* generally represents current legislation and environmental regulations, including recent government actions, for which implementing regulations were available as of October 31, 2014. DOE's estimation of impacts accounts for the presence of the emissions control programs discussed in the following paragraphs.

SO_2 emissions from affected electric generating units (EGUs) are subject to nationwide and regional emissions cap-and-trade programs. Title IV of the Clean Air Act sets an annual emissions cap on SO_2 for affected EGUs in the 48 contiguous States and the District of Columbia (DC). (42 U.S.C. 7651 *et seq.*) SO_2 emissions from 28 eastern States and DC were also limited under the Clean Air Interstate Rule (CAIR). 70 FR 25162 (May 12, 2005). CAIR created an allowance-based trading program that operates along with the Title IV program. In 2008, CAIR was remanded to EPA by the U.S. Court of Appeals for the District of Columbia Circuit, but it remained in effect.[39] In 2011, EPA issued a replacement for CAIR, the Cross-State Air Pollution Rule (CSAPR). 76 FR 48208 (Aug. 8, 2011). On August 21, 2012, the D.C. Circuit issued a decision to vacate CSAPR,[40] and the court ordered EPA to continue administering CAIR. On April 29, 2014, the U.S. Supreme Court reversed the judgment of the D.C. Circuit and remanded the case for further proceedings consistent with the Supreme Court's opinion.[41] On October 23, 2014, the D.C. Circuit lifted the stay of CSAPR.[42] Pursuant to this action, CSAPR went into effect (and CAIR

[37] Available at *www.epa.gov/climateleadership/center-corporate-climate-leadership-ghg-emission-factors-hub.*

[38] Intergovernmental Panel on Climate Change. Anthropogenic and Natural Radiative Forcing. In Climate Change 2013: The Physical Science Basis. Contribution of Working Group I to the Fifth Assessment Report of the Intergovernmental Panel on Climate Change. Chapter 8. 2013. Stocker, T.F., D. Qin, G.-K. Plattner, M. Tignor, S.K. Allen, J. Boschung, A. Nauels, Y. Xia, V. Bex, and P.M. Midgley, Editors. Cambridge University Press: Cambridge, United Kingdom and New York, NY, USA.

[39] See *North Carolina* v. *EPA,* 550 F.3d 1176 (D.C. Cir. 2008); *North Carolina* v. *EPA,* 531 F.3d 896 (D.C. Cir. 2008).

[40] See *EME Homer City Generation, LP* v. *EPA,* 696 F.3d 7, 38 (D.C. Cir. 2012), *cert. granted,* 81 U.S.L.W. 3567, 81 U.S.L.W. 3696, 81 U.S.L.W. 3702 (U.S. June 24, 2013) (No. 12–1182).

[41] *See EPA* v. *EME Homer City Generation,* 134 S. Ct. 1584, 1610 (U.S. 2014). The Supreme Court held in part that EPA's methodology for quantifying emissions that must be eliminated in certain States due to their impacts in other downwind States was based on a permissible, workable, and equitable interpretation of the Clean Air Act provision that provides statutory authority for CSAPR.

[42] *See Georgia* v. *EPA,* Order *(D.C. Cir. filed October 23, 2014) (No. 11–1302).*

ceased to be in effect) as of January 1, 2015.

EIA was not able to incorporate CSAPR into *AEO 2015,* so it assumes implementation of CAIR. Although DOE's analysis used emissions factors that assume that CAIR, not CSAPR, is the regulation in force, the difference between CAIR and CSAPR is not significant for the purpose of DOE's analysis of emissions impacts from energy conservation standards.

The attainment of emissions caps is typically flexible among EGUs and is enforced through the use of emissions allowances and tradable permits. Under existing EPA regulations, any excess SO_2 emissions allowances resulting from the lower electricity demand caused by the adoption of an efficiency standard could be used to permit offsetting increases in SO_2 emissions by any regulated EGU. In past rulemakings, DOE recognized that there was uncertainty about the effects of efficiency standards on SO_2 emissions covered by the existing cap-and-trade system, but it concluded that negligible reductions in power sector SO_2 emissions would occur as a result of standards.

Beginning in 2016, however, SO_2 emissions will fall as a result of the Mercury and Air Toxics Standards (MATS) for power plants. 77 FR 9304 (Feb. 16, 2012). In the MATS rule, EPA established a standard for hydrogen chloride as a surrogate for acid gas hazardous air pollutants (HAP), and also established a standard for SO_2 (a non-HAP acid gas) as an alternative equivalent surrogate standard for acid gas HAP. The same controls are used to reduce HAP and non-HAP acid gas; thus, SO_2 emissions will be reduced as a result of the control technologies installed on coal-fired power plants to comply with the MATS requirements for acid gas. *AEO 2015* assumes that, in order to continue operating, coal plants must have either flue gas desulfurization or dry sorbent injection systems installed by 2016. Both technologies, which are used to reduce acid gas emissions, also reduce SO_2 emissions. Under the MATS, emissions will be far below the cap established by CAIR, so it is unlikely that excess SO_2 emissions allowances resulting from the lower electricity demand would be needed or used to permit offsetting increases in SO_2 emissions by any regulated EGU.[43] Therefore, DOE believes that energy conservation standards will generally reduce SO_2 emissions in 2016 and beyond.

CAIR established a cap on NO_X emissions in 28 eastern States and the District of Columbia.[44] Energy conservation standards are expected to have little effect on NO_X emissions in those States covered by CAIR because excess NO_X emissions allowances resulting from the lower electricity demand could be used to permit offsetting increases in NO_X emissions from other facilities. However, standards would be expected to reduce NO_X emissions in the States not affected by the caps, so DOE estimated NO_X emissions reductions from the standards considered in this NOPR for these States.

The MATS limit mercury emissions from power plants, but they do not include emissions caps and, as such, DOE's energy conservation standards would likely reduce Hg emissions. DOE estimated mercury emissions reduction using emissions factors based on *AEO 2015,* which incorporates the MATS.

L. Monetizing Carbon Dioxide and Other Emissions Impacts

As part of the development of this proposed rule, DOE considered the estimated monetary benefits from the reduced emissions of CO_2 and NO_X that are expected to result from each of the TSLs considered. In order to make this calculation analogous to the calculation of the NPV of consumer benefit, DOE considered the reduced emissions expected to result over the lifetime of products shipped in the forecast period for each TSL. This section summarizes the basis for the monetary values used for CO_2 and NO_X emissions and presents the values considered in this NOPR.

1. Social Cost of Carbon

The SCC is an estimate of the monetized damages associated with an incremental increase in carbon emissions in a given year. It is intended to include (but is not limited to) climate-change-related changes in net agricultural productivity, human health, property damages from increased flood risk, and the value of ecosystem services. Estimates of the SCC are provided in dollars per metric ton of CO_2. A domestic SCC value is meant to reflect the value of damages in the United States resulting from a unit change in CO_2 emissions, while a global SCC value is meant to reflect the value of damages worldwide.

Under section 1(b)(6) of Executive Order 12866, ''Regulatory Planning and Review,'' 58 FR 51735 (Oct. 4, 1993), agencies must, to the extent permitted by law, ''assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.'' The purpose of the SCC estimates presented here is to allow agencies to incorporate the monetized social benefits of reducing CO_2 emissions into cost-benefit analyses of regulatory actions. The estimates are presented with an acknowledgement of the many uncertainties involved and with a clear understanding that they should be updated over time to reflect increasing knowledge of the science and economics of climate impacts.

As part of the interagency process that developed these SCC estimates, technical experts from numerous agencies met on a regular basis to consider public comments, explore the technical literature in relevant fields, and discuss key model inputs and assumptions. The main objective of this process was to develop a range of SCC values using a defensible set of input assumptions grounded in the existing scientific and economic literatures. In this way, key uncertainties and model differences transparently and consistently inform the range of SCC estimates used in the rulemaking process.

a. Monetizing Carbon Dioxide Emissions

When attempting to assess the incremental economic impacts of CO_2 emissions, the analyst faces a number of challenges. A report from the National Research Council[45] points out that any assessment will suffer from uncertainty, speculation, and lack of information about (1) future emissions of GHGs, (2) the effects of past and future emissions on the climate system, (3) the impact of changes in climate on the physical and biological environment, and (4) the

[43] DOE notes that the Supreme Court remanded EPA's 2012 rule regarding national emission standards for hazardous air pollutants from certain electric utility steam generating units. See *Michigan* v. *EPA* (Case No. 14–46, 2015). DOE has tentatively determined that the remand of the MATS rule does not change the assumptions regarding the impact of energy efficiency standards on SO_2 emissions. Further, while the remand of the MATS rule may have an impact on the overall amount of mercury emitted by power plants, it does not change the impact of the energy efficiency standards on mercury emissions. DOE will continue to monitor developments related to this case and respond to them as appropriate.

[44] CSAPR also applies to NO_X, and it supersedes the regulation of NO_X under CAIR. As stated previously, the current analysis assumes that CAIR, not CSAPR, is the regulation in force. The difference between CAIR and CSAPR with regard to DOE's analysis of NO_X emissions is slight.

[45] National Research Council. *Hidden Costs of Energy: Unpriced Consequences of Energy Production and Use.* 2009. National Academies Press: Washington, DC.

translation of these environmental impacts into economic damages. As a result, any effort to quantify and monetize the harms associated with climate change will raise questions of science, economics, and ethics and should be viewed as provisional.

Despite the limits of both quantification and monetization, SCC estimates can be useful in estimating the social benefits of reducing CO_2 emissions. The agency can estimate the benefits from reduced (or costs from increased) emissions in any future year by multiplying the change in emissions in that year by the SCC values appropriate for that year. The NPV of the benefits can then be calculated by multiplying each of these future benefits by an appropriate discount factor and summing across all affected years.

It is important to emphasize that the interagency process is committed to updating these estimates as the science and economic understanding of climate change and its impacts on society improves over time. In the meantime, the interagency group will continue to explore the issues raised by this analysis and consider public comments as part of the ongoing interagency process.

b. Development of Social Cost of Carbon Values

In 2009, an interagency process was initiated to offer a preliminary assessment of how best to quantify the benefits from reducing carbon dioxide emissions. To ensure consistency in how benefits are evaluated across Federal agencies, the Administration sought to develop a transparent and defensible method, specifically designed for the rulemaking process, to quantify avoided climate change damages from reduced CO_2 emissions. The interagency group did not undertake any original analysis. Instead, it combined SCC estimates from the existing literature to use as interim values until a more comprehensive analysis could be conducted. The outcome of the preliminary assessment by the interagency group was a set of five interim values: Global SCC estimates for 2007 (in 2006$) of $55, $33, $19, $10, and $5 per metric ton of CO_2. These interim values represented the first sustained interagency effort within the U.S. government to develop an SCC for use in regulatory analysis. The results of this preliminary effort were presented in several proposed and final rules.

c. Current Approach and Key Assumptions

After the release of the interim values, the interagency group reconvened on a regular basis to generate improved SCC estimates. Specially, the group considered public comments and further explored the technical literature in relevant fields. The interagency group relied on three integrated assessment models commonly used to estimate the SCC: The FUND, DICE, and PAGE models. These models are frequently cited in the peer-reviewed literature and were used in the last assessment of the Intergovernmental Panel on Climate Change (IPCC). Each model was given equal weight in the SCC values that were developed.

Each model takes a slightly different approach to model how changes in emissions result in changes in economic damages. A key objective of the interagency process was to enable a consistent exploration of the three models, while respecting the different approaches to quantifying damages taken by the key modelers in the field. An extensive review of the literature was conducted to select three sets of input parameters for these models: Climate sensitivity, socio-economic and emissions trajectories, and discount rates. A probability distribution for climate sensitivity was specified as an input into all three models. In addition, the interagency group used a range of scenarios for the socio-economic parameters and a range of values for the discount rate. All other model features were left unchanged, relying on the model developers' best estimates and judgments.

In 2010, the interagency group selected four sets of SCC values for use in regulatory analyses. Three sets of values are based on the average SCC from the three integrated assessment models, at discount rates of 2.5, 3, and 5 percent. The fourth set, which represents the 95th percentile SCC estimate across all three models at a 3-percent discount rate, was included to represent higher-than-expected impacts from climate change further out in the tails of the SCC distribution. The values grow in real terms over time. Additionally, the interagency group determined that a range of values from 7 percent to 23 percent should be used to adjust the global SCC to calculate domestic effects,[46] although preference is given to consideration of the global benefits of reducing CO_2 emissions. Table IV.5 presents the values in the 2010 interagency group report,[47] which is reproduced in appendix 14A of the NOPR TSD.

TABLE IV.5—ANNUAL SCC VALUES FROM 2010 INTERAGENCY REPORT, 2010–2050

[2007$ per metric ton CO_2]

Year	Discount rate			
	5%	3%	2.5%	3%
	Average	Average	Average	95th Percentile
2010	4.7	21.4	35.1	64.9
2015	5.7	23.8	38.4	72.8
2020	6.8	26.3	41.7	80.7
2025	8.2	29.6	45.9	90.4
2030	9.7	32.8	50.0	100.0
2035	11.2	36.0	54.2	109.7
2040	12.7	39.2	58.4	119.3
2045	14.2	42.1	61.7	127.8
2050	15.7	44.9	65.0	136.2

[46] It is recognized that this calculation for domestic values is approximate, provisional, and highly speculative. There is no *a priori* reason why domestic benefits should be a constant fraction of net global damages over time.

[47] United States Government–Interagency Working Group on Social Cost of Carbon. *Social Cost of Carbon for Regulatory Impact Analysis Under Executive Order 12866*. February 2010. *https://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/Social-Cost-of-Carbon-for-RIA.pdf*.

The SCC values used for this document were generated using the most recent versions of the three integrated assessment models that have been published in the peer-reviewed literature, as described in the 2013 update from the interagency working group (revised July 2015).[48] Table IV.6 shows the updated sets of SCC estimates from the latest interagency update in 5-year increments from 2010 through 2050. The full set of annual SCC estimates from 2010 through 2050 is reported in appendix 14B of the NOPR TSD. The central value that emerges is the average SCC across models at the 3-percent discount rate. However, for purposes of capturing the uncertainties involved in regulatory impact analysis, the interagency group emphasizes the importance of including all four sets of SCC values.

TABLE IV.6—ANNUAL SCC VALUES FROM 2013 INTERAGENCY UPDATE (REVISED JULY 2015), 2010–2050

[2007$ per metric ton CO_2]

Year	Discount rate			
	5%	3%	2.5%	3%
	Average	Average	Average	95th percentile
2010	10	31	50	86
2015	11	36	56	105
2020	12	42	62	123
2025	14	46	68	138
2030	16	50	73	152
2035	18	55	78	168
2040	21	60	84	183
2045	23	64	89	197
2050	26	69	95	212

It is important to recognize that a number of key uncertainties remain, and that current SCC estimates should be treated as provisional and revisable because they will evolve with improved scientific and economic understanding. The interagency group also recognizes that the existing models are imperfect and incomplete. The National Research Council report mentioned previously points out that there is tension between the goal of producing quantified estimates of the economic damages from an incremental ton of carbon and the limits of existing efforts to model these effects. There are a number of analytical challenges that are being addressed by the research community, including research programs housed in many of the Federal agencies participating in the interagency process to estimate the SCC. The interagency group intends to periodically review and reconsider those estimates to reflect increasing knowledge of the science and economics of climate impacts, as well as improvements in modeling.[49]

In summary, in considering the potential global benefits resulting from reduced CO_2 emissions, DOE used the values from the 2013 interagency report (revised July 2015), adjusted to 2015$ using the implicit price deflator for gross domestic product (GDP) from the Bureau of Economic Analysis. For each of the four sets of SCC cases specified, the values for emissions in 2015 were $12.4, $40.6, $63.2, and $118 per metric ton avoided (values expressed in 2015$). DOE derived values after 2050 based on the trend in 2010–2050 in each of the four cases.

DOE multiplied the CO_2 emissions reduction estimated for each year by the SCC value for that year in each of the four cases. To calculate a present value of the stream of monetary values, DOE discounted the values in each of the four cases using the specific discount rate that had been used to obtain the SCC values in each case.

2. Social Cost of Other Air Pollutants

As noted previously, DOE has estimated how the considered energy conservation standards would decrease power sector NO_X emissions in those 22 States not affected by the CAIR.

DOE estimated the monetized value of NO_X emissions reductions from electricity generation using benefit per ton estimates from the ''Regulatory Impact Analysis for the Clean Power Plan Final Rule,'' published in August 2015 by EPA's Office of Air Quality Planning and Standards.[50] The report includes high and low values for NO_X (as $PM_{2.5}$) for 2020, 2025, and 2030 using discount rates of 3 percent and 7 percent; these values are presented in chapter 14 of the NOPR TSD. DOE primarily relied on the low estimates to be conservative.[51] DOE assigned values for 2021–2024 and 2026–2029 using, respectively, the values for 2020 and 2025. DOE assigned values after 2030 using the value for 2030. DOE developed values specific to the end-use category for UPSs using a method

[48] United States Government–Interagency Working Group on Social Cost of Carbon. *Technical Support Document:* Technical Update of the Social Cost of Carbon for Regulatory Impact Analysis Under Executive Order 12866. May 2013. Revised July 2015. *https://www.whitehouse.gov/sites/default/files/omb/inforeg/scc-tsd-final-july-2015.pdf.*

[49] In November 2013, OMB announced a new opportunity for public comment on the interagency technical support document underlying the revised SCC estimates. 78 FR 70586. In July 2015 OMB published a detailed summary and formal response to the many comments that were received; this is available at *https://www.whitehouse.gov/blog/2015/07/02/estimating-benefits-carbon-dioxide-emissions-reductions.* It also stated its intention to seek independent expert advice on opportunities to improve the estimates, including many of the approaches suggested by commenters.

[50] Available at *www.epa.gov/cleanpowerplan/clean-power-plan-final-rule-regulatory-impact-analysis.* See Tables 4A–3, 4A–4, and 4A–5 in the report. The U.S. Supreme Court has stayed the rule implementing the Clean Power Plan until the current litigation against it concludes. *Chamber of Commerce, et al.* v. *EPA, et al.,* Order in Pending Case, 577 U.S. ____ (2016). However, the benefit-per-ton estimates established in the Regulatory Impact Analysis for the Clean Power Plan are based on scientific studies that remain valid irrespective of the legal status of the Clean Power Plan.

[51] For the monetized NO_X benefits associated with $PM_{2.5}$, the related benefits are primarily based on an estimate of premature mortality derived from the ACS study (Krewski et al. 2009), which is the lower of the two EPA central tendencies. Using the lower value is more conservative when making the policy decision concerning whether a particular standard level is economically justified. If the benefit-per-ton estimates were based on the Six Cities study (Lepuele et al. 2012), the values would be nearly two-and-a-half times larger. (See chapter [14] of the final rule TSD for further description of the studies mentioned above.)

described in appendix 14C of the NOPR TSD.

DOE multiplied the emissions reduction (in tons) in each year by the associated $/ton values, and then discounted each series using discount rates of 3 percent and 7 percent as appropriate.

DOE is evaluating appropriate monetization of avoided SO_2 and Hg emissions in energy conservation standards rulemakings. DOE has not included monetization of those emissions in the current analysis.

M. Utility Impact Analysis

The utility impact analysis estimates several effects on the electric power generation industry that would result from the adoption of new or amended energy conservation standards. The utility impact analysis estimates the changes in installed electrical capacity and generation that would result for each TSL. The analysis is based on published output from the NEMS associated with AEO 2015. NEMS produces the AEO Reference case, as well as a number of side cases that estimate the economy-wide impacts of changes to energy supply and demand. DOE uses published side cases to estimate the marginal impacts of reduced energy demand on the utility sector. These marginal factors are estimated based on the changes to electricity sector generation, installed capacity, fuel consumption and emissions in the *AEO* Reference case and various side cases. Details of the methodology are provided in the appendices to chapters 13 and 15 of the NOPR TSD.

The output of this analysis is a set of time-dependent coefficients that capture the change in electricity generation, primary fuel consumption, installed capacity and power sector emissions due to a unit reduction in demand for a given end use. These coefficients are multiplied by the stream of electricity savings calculated in the NIA to provide estimates of selected utility impacts of new or amended energy conservation standards.

Schneider Electric and ITI both commented that NEMS–BT was identified as inadequate for modeling beyond 2025 during a DOE distribution transformer rulemaking. (Schneider Electric, No. 0008 at p. 16) (ITI, No. 0010 at p. 19)

AEO 2015 has an end year of 2040. Beyond 2040, DOE extrapolates various factors. DOE acknowledges that any long-range projections are subject to considerable uncertainty, but NEMS provides a self-consistent framework that accounts for a wide range of factors in the energy sector and the larger economy.

N. Employment Impact Analysis

DOE considers employment impacts in the domestic economy as one factor in selecting a proposed standard. Employment impacts from new or amended energy conservation standards include both direct and indirect impacts. Direct employment impacts are any changes in the number of employees of manufacturers of the products subject to standards, their suppliers, and related service firms. The MIA addresses those impacts. Indirect employment impacts are changes in national employment that occur due to the shift in expenditures and capital investment caused by the purchase and operation of more-efficient appliances. Indirect employment impacts from standards consist of the net jobs created or eliminated in the national economy, other than in the manufacturing sector being regulated, caused by (1) reduced spending by end users on energy, (2) reduced spending on new energy supply by the utility industry, (3) increased consumer spending on new products to which the new standards apply, and (4) the effects of those three factors throughout the economy.

One method for assessing the possible effects on the demand for labor of such shifts in economic activity is to compare sector employment statistics developed by the Labor Department's Bureau of Labor Statistics (BLS). BLS regularly publishes its estimates of the number of jobs per million dollars of economic activity in different sectors of the economy, as well as the jobs created elsewhere in the economy by this same economic activity. Data from BLS indicate that expenditures in the utility sector generally create fewer jobs (both directly and indirectly) than expenditures in other sectors of the economy.[52] There are many reasons for these differences, including wage differences and the fact that the utility sector is more capital-intensive and less labor-intensive than other sectors. Energy conservation standards have the effect of reducing consumer utility bills. Because reduced consumer expenditures for energy likely lead to increased expenditures in other sectors of the economy, the general effect of efficiency standards is to shift economic activity from a less labor-intensive sector (*i.e.,* the utility sector) to more labor-intensive sectors (*e.g.,* the retail and service sectors). Thus, the BLS data suggest that net national employment may increase due to shifts in economic activity resulting from energy conservation standards.

DOE estimated indirect national employment impacts for the standard levels considered in this NOPR using an input/output model of the U.S. economy called Impact of Sector Energy Technologies version 3.1.1 (ImSET).[53] ImSET is a special-purpose version of the ''U.S. Benchmark National Input-Output'' (I–O) model, which was designed to estimate the national employment and income effects of energy-saving technologies. The ImSET software includes a computer-based I–O model having structural coefficients that characterize economic flows among 187 sectors most relevant to industrial, commercial, and residential building energy use.

DOE notes that ImSET is not a general equilibrium forecasting model, and understands the uncertainties involved in projecting employment impacts, especially changes in the later years of the analysis. Because ImSET does not incorporate price changes, the employment effects predicted by ImSET may over-estimate actual job impacts over the long run for this rule. Therefore, DOE generated results for near-term timeframes (2019–2024), where these uncertainties are reduced. For more details on the employment impact analysis, see chapter 16 of the NOPR TSD.

V. Analytical Results and Conclusions

The following section addresses the results from DOE's analyses with respect to the considered energy conservation standards for UPSs. It addresses the TSLs examined by DOE, the projected impacts of each of these levels if adopted as energy conservation standards for UPSs, and the standards levels that DOE is proposing to adopt in this NOPR. Additional details regarding DOE's analyses are contained in the NOPR TSD supporting this document.

A. Trial Standard Levels

DOE analyzed the benefits and burdens of four TSLs for UPSs. These TSLs were developed by combining specific efficiency levels for each of the product classes analyzed by DOE. DOE presents the results for the TSLs in this

[52] See U.S. Department of Commerce–Bureau of Economic Analysis. *Regional Multipliers: A User Handbook for the Regional Input-Output Modeling System (RIMS II).* 1997. U.S. Government Printing Office: Washington, DC. Available at *http://www.bea.gov/scb/pdf/regional/perinc/meth/rims2.pdf.*

[53] J.M. Roop, M.J. Scott, and R.W. Schultz. *ImSET 3.1: Impact of Sector Energy Technologies.* 2009. Pacific Northwest National Laboratory: Richland, WA. PNNL–18412. Available at *www.pnl.gov/main/publications/external/technical_reports/PNNL–18412.pdf.*

document, while the results for all efficiency levels that DOE analyzed are in the NOPR TSD. Table V.1 presents the TSLs and the corresponding efficiency levels for UPSs. DOE examined product classes individually.

TABLE V.1—TRIAL STANDARD LEVELS FOR UPSS

Product class	Description	Trial standard level			
		TSL 1	TSL 2	TSL 3	TSL 4
10a	VFD UPSs	EL 1	EL 1	EL 2	EL 3
10b	VI UPSs	EL 1	EL 2	EL 2	EL 3
10c	VFI UPSs	EL 1	EL 1	EL 1	EL 3

TSL 1 is the minimum possible standard considered, and also corresponds to the maximum consumer NPV for each product class. TSL 2 represents an intermediate level of performance above the baseline, with maximum NES while at a positive NPV for all product classes. TSL 3 represents an intermediate level of performance above TSL 2, and corresponds to maximum NES while at positive NPV in aggregate across all three product classes (the NPV of VFD UPSs is marginally negative). Finally, TSL 4 represents the maximum technologically feasible (''max-tech'') energy efficiency for all product classes and therefore, the maximum NES.

B. Economic Justification and Energy Savings

1. Economic Impacts on Individual Consumers

DOE analyzed the economic impacts on UPS consumers by looking at the effects potential new standards at each TSL would have on the LCC and PBP. DOE also examined the impacts of potential standards on consumer subgroups. These analyses are discussed below.

a. Life-Cycle Cost and Payback Period

In general, higher-efficiency products affect consumers in two ways: (1) Purchase price increases, and (2) annual operating costs decrease. Inputs used for calculating the LCC and PBP include total installed costs (*i.e.,* product price plus installation costs), and operating costs (*i.e.,* annual energy use, energy prices, energy price trends, repair costs, and maintenance costs). The LCC calculation also uses product lifetime and a discount rate. Chapter 8 of the NOPR TSD provides detailed information on the LCC and PBP analyses.

Table V.2 through Table V.4 show the LCC and PBP results for the TSL efficiency levels considered for each product class. In the first of each pair of tables, the simple payback is measured relative to the baseline product (EL 0). In Table V.5 through Table V.7, impacts are measured relative to the efficiency distribution in the no-standards case in the compliance year (see section IV.F.8 of this NOPR). Because some consumers purchase products with higher efficiency in the no-standards case, the average savings are less than the difference between the average LCC of EL 0 and the average LCC at each TSL. The savings refer only to consumers who are affected by a standard at a given TSL. Those who already purchase a product with efficiency at or above a given TSL are not affected. Consumers for whom the LCC increases at a given TSL experience a net cost.

TABLE V.2—AVERAGE LCC AND PBP RESULTS BY EFFICIENCY LEVEL FOR PRODUCT CLASS 10a

[VFD UPSs]

TSL	EL	Average costs (2015$)				Simple payback (years)	Average lifetime (years)
		Installed cost	First year's operating cost	Lifetime operating cost	LCC		
Residential							
	0	97	14	64	162	.....	5.0
1	1	92	6	25	117	0.0	5.0
2	1	92	6	25	117	0.0	5.0
3	2	121	4	18	139	2.3	5.0
4	3	139	3	14	153	3.8	5.0
Commercial							
	0	70	10	46	116	.....	5.0
1	1	66	4	18	84	0.0	5.0
2	1	66	4	18	84	0.0	5.0
3	2	91	3	13	104	2.8	5.0
4	3	107	2	10	117	4.5	5.0

Note: The results for each TSL are calculated assuming that all consumers use products at that efficiency level. The PBP is measured relative to the baseline (EL 0) product.

TABLE V.3—AVERAGE LCC AND PBP RESULTS BY EFFICIENCY LEVEL FOR PRODUCT CLASS 10b

[VI UPSs]

TSL	EL	Average costs (2015$)				Simple payback (years)	Average lifetime (years)
		Installed cost	First year's operating cost	Lifetime operating cost	LCC		
Residential							
	0	111	19	108	219	.....	6.3
1	1	141	9	53	193	3.0	6.3
2	2	162	6	34	196	3.9	6.3
3	2	162	6	34	196	3.9	6.3
4	3	623	4	20	643	33.2	6.3
Commercial							
	0	80	14	76	156	.....	6.3
1	1	106	7	37	143	3.6	6.3
2	2	125	4	24	149	4.7	6.3
3	2	125	4	24	149	4.7	6.3
4	3	533	3	14	547	39.8	6.3

Note: The results for each TSL are calculated assuming that all consumers use products at that efficiency level. The PBP is measured relative to the baseline (EL 0) product.

TABLE V.4—AVERAGE LCC AND PBP RESULTS BY EFFICIENCY LEVEL FOR PRODUCT CLASS 10c

[VI UPSs]

TSL	EL	Average costs (2015$)				Simple payback (years)	Average lifetime (years)
		Installed cost	First year's operating cost	Lifetime operating cost	LCC		
Residential							
	0	408	125	1066	1474	.....	10.0
1	1	460	111	948	1408	3.7	10.0
2	1	460	111	948	1408	3.7	10.0
3	1	460	111	948	1408	3.7	10.0
4	3	1180	71	609	1789	14.4	10.0
Commercial							
	0	293	86	693	986	.....	10.0
1	1	338	77	616	955	4.8	10.0
2	1	338	77	616	955	4.8	10.0
3	1	338	77	616	955	4.8	10.0
4	3	974	49	396	1371	18.5	10.0

Note: The results for each TSL are calculated assuming that all consumers use products at that efficiency level. The PBP is measured relative to the baseline (EL 0) product.

TABLE V.5—AVERAGE LCC SAVINGS RELATIVE TO THE NO-STANDARDS CASE FOR PRODUCT CLASS 10a

[VFD UPSs]

TSL	EL	Life-cycle cost savings	
		Average LCC savings* (2015$)	Percent of consumers that experience net cost
Residential			
1	1	44	0
2	1	44	0
3	2	5	37
4	3	−10	74

TABLE V.5—AVERAGE LCC SAVINGS RELATIVE TO THE NO-STANDARDS CASE FOR PRODUCT CLASS 10a—Continued
[VFD UPSs]

TSL	EL	Life-cycle cost savings	
		Average LCC savings* (2015$)	Percent of consumers that experience net cost
Commercial			
1	1	32	0
2	1	32	0
3	2	−1	38
4	3	−14	79

*The savings represent the average LCC for affected consumers.

TABLE V.6—AVERAGE LCC SAVINGS RELATIVE TO THE NO-STANDARDS CASE FOR PRODUCT CLASS 10b
[VI UPSs]

TSL	EL	Life-cycle cost savings	
		Average LCC savings* (2015$)	Percent of consumers that experience net cost
Residential			
1	1	26	6
2	2	18	35
3	2	18	35
4	3	−430	100
Commercial			
1	1	13	8
2	2	5	45
3	2	5	45
4	3	−394	100

*The savings represent the average LCC for affected consumers.

TABLE V.7—AVERAGE LCC SAVINGS RELATIVE TO THE NO-STANDARDS CASE FOR PRODUCT CLASS 10c
[VFI UPSs]

TSL	EL	Life-cycle cost savings	
		Average LCC savings* (2015$)	Percent of consumers that experience net cost
Residential			
1	1	66	3
2	1	66	3
3	1	66	3
4	3	−331	91
Commercial			
1	1	31	2
2	1	31	2
3	1	31	2
4	3	−390	100

*The savings represent the average LCC for affected consumers.

b. Consumer Subgroup Analysis

In the consumer subgroup analysis, DOE estimated the impact of the considered TSLs on low-income households and small businesses. Table V.8 through Table V.10 compares the average LCC savings and PBP at each efficiency level for low-income households, along with the average LCC savings for the entire residential sample. Table V.11 through Table V.13 compares the average LCC savings and PBP at each TSL for small businesses, along with the average LCC savings for the commercial sample. In most cases, the average LCC savings and PBP for low-income households and small businesses at the considered efficiency levels are not substantially different from the average values found for the entire residential and commercial samples, respectively. Chapter 11 of the NOPR TSD presents the complete LCC and PBP results for the subgroups.

TABLE V.8—COMPARISON OF LCC SAVINGS AND PBP FOR LOW-INCOME HOUSEHOLDS AND ALL HOUSEHOLDS FOR PRODUCT CLASS 10a

[VFD UPSs]

TSL	Average life-cycle cost savings (2015$)		Simple payback period (years)	
	Low-income households	All households	Low-income households	All households
1	47	44	0.0	0.0
2	47	44	0.0	0.0
3	7	5	2.2	2.3
4	−8	−10	3.5	3.8

TABLE V.9—COMPARISON OF LCC SAVINGS AND PBP FOR LOW-INCOME HOUSEHOLDS AND ALL HOUSEHOLDS FOR PRODUCT CLASS 10b

[VI UPSs]

TSL	Average life-cycle cost savings (2015$)		Simple payback period (years)	
	Low-income households	All households	Low-income households	All households
1	30	26	2.8	3.0
2	22	18	3.6	3.9
3	22	18	3.6	3.9
4	−426	−430	31.0	33.2

TABLE V.10—COMPARISON OF LCC SAVINGS AND PBP FOR LOW-INCOME HOUSEHOLDS AND ALL HOUSEHOLDS FOR PRODUCT CLASS 10c

[VFI UPSs]

TSL	Average life-cycle cost savings (2015$)		Simple payback period (years)	
	Low-income households	All households	Low-income households	All households
1	75	66	3.5	3.7
2	75	66	3.5	3.7
3	75	66	3.5	3.7
4	−302	−331	13.5	14.4

TABLE V.11—COMPARISON OF LCC SAVINGS AND PBP SMALL BUSINESSES AND ALL BUSINESSES FOR PRODUCT CLASS 10a

[VFD UPSs]

TSL	Average life-cycle cost savings (2015$)		Simple payback period (years)	
	Small businesses	All businesses	Small businesses	All businesses
1	31	32	0.0	0.0
2	31	32	0.0	0.0
3	−1	−1	2.8	2.8
4	−14	−14	4.5	4.5

TABLE V.12—COMPARISON OF LCC SAVINGS AND PBP SMALL BUSINESSES AND ALL BUSINESSES FOR PRODUCT CLASS 10b

[VI UPSs]

TSL	Average life-cycle cost savings (2015$)		Simple payback period (years)	
	Small businesses	All businesses	Small businesses	All businesses
1	12	13	3.6	3.6
2	3	5	4.7	4.7
3	3	5	4.7	4.7
4	−396	−394	39.8	39.8

TABLE V.13—COMPARISON OF LCC SAVINGS AND PBP SMALL BUSINESSES AND ALL BUSINESSES FOR PRODUCT CLASS 10c

[VFI UPSs]

TSL	Average life-cycle cost savings (2015$)		Simple payback period (years)	
	Small businesses	All businesses	Small businesses	All businesses
1	28	31	4.8	4.8
2	28	31	4.8	4.8
3	28	31	4.8	4.8
4	-400	-390	18.5	18.5

c. Rebuttable Presumption Payback

As discussed in section III.D.2, EPCA establishes a rebuttable presumption that an energy conservation standard is economically justified if the increased purchase cost for a product that meets the standard is less than three times the value of the first-year energy savings resulting from the standard. In calculating a rebuttable presumption payback period for each of the considered TSLs, DOE used discrete values, and, as required by EPCA, based the energy use calculation on the DOE test procedure for UPSs. In contrast, the PBPs presented in section V.B.1.a were calculated using distributions that reflect the range of energy use in the field.

TableV.14 presents the rebuttable-presumption payback periods for the considered TSLs for UPSs. While DOE examined the rebuttable-presumption criterion, it considered whether the standard levels considered for the NOPR are economically justified through a more detailed analysis of the economic impacts of those levels, pursuant to 42 U.S.C. 6295(o)(2)(B)(i), that considers the full range of impacts to the consumer, manufacturer, Nation, and environment. The results of that analysis serve as the basis for DOE to definitively evaluate the economic justification for a potential standard level, thereby supporting or rebutting the results of any preliminary determination of economic justification.

TABLE V.14—REBUTTABLE PRESUMPTION PBPS FOR PRODUCT CLASSES 10a, 10b, AND 10c

TSL	10a (VFD UPSs)	10b (VI UPSs)	10c (VFI UPSs)
Residential			
1	0.0	2.8	3.5
2	0.0	3.7	3.5
3	2.0	3.7	3.5
4	3.0	29.6	14.1
Commercial			
1	0.0	3.3	4.5
2	0.0	4.5	4.5
3	2.5	4.5	4.5
4	3.6	35.6	18.1

2. Economic Impacts on Manufacturers

DOE performed an MIA to estimate the impact of new energy conservation standards on UPS manufacturers. The following section describes the estimated impacts on UPS manufacturers at each analyzed TSL. Chapter 12 of the NOPR TSD explains the analysis in further detail.

a. Industry Cash Flow Analysis Results

Table V.15 and Table V.16 present the financial impacts (represented by changes in INPV) of analyzed standards on UPS manufacturers as well as the conversion costs that DOE estimates

UPS manufacturers would incur at each TSL. To evaluate the range of cash-flow impacts on the UPS industry, DOE modeled two markup scenarios that correspond to the range of anticipated market responses to new standards. Each scenario results in a unique set of cash flows and corresponding industry values at each TSL.

To assess the upper (less severe) bound of the range of potential impacts on UPS manufacturers, DOE modeled a preservation of gross margin markup scenario. This scenario assumes that in the standards cases, manufacturers would be able to fully pass on higher production costs required to produce more efficient products to their consumers. Specifically, the industry would be able to maintain its average no-standards case gross margin (as a percentage of revenue) despite the higher product costs in the standards cases. In general, the larger the product price increases, the less likely manufacturers are to achieve the cash flow from operations calculated in this scenario because it is less likely that manufacturers would be able to fully mark up these larger cost increases.

To assess the lower (more severe) bound of the range of potential impacts on manufacturers, DOE modeled the pass through markup scenario. In this scenario DOE assumes that manufacturers are able to pass through the incremental costs of more efficient UPSs to their customers, but without earning any additional operating profit on those higher costs. This scenario represents the lower bound of the range of potential impacts on manufacturers because manufacture margins are compressed as a result of this markup scenario.

TABLE V.15—MANUFACTURER IMPACT ANALYSIS FOR UNINTERRUPTIBLE POWER SUPPLIES—PRESERVATION OF GROSS MARGIN MARKUP SCENARIO

	Units	No standards case	Trial standard level			
			1	2	3	4
INPV	2015$ millions	2,555	2,746	2,849	2,983	7,400
Change in INPV	2015$ millions		191	295	428	4,845
	%		7.5	11.5	16.8	189.7
Product Conversion Costs	2015$ millions		16	20	20	23
Capital Conversion Costs	2015$ millions					
Total Conversion Costs	2015$ millions		16	20	20	23

TABLE V.16—MANUFACTURER IMPACT ANALYSIS FOR UNINTERRUPTIBLE POWER SUPPLIES—PASS THROUGH MARKUP SCENARIO

	Units	No standards case	Trial standard level			
			1	2	3	4
INPV	2015$ millions	2,555	2,166	1,957	1,619	(667)
Change in INPV	2015$ millions		(389)	(598)	(936)	(3,222)
	%		(15.2)	(23.4)	(36.6)	(126.1)
Product Conversion Costs	2015$ millions		16	20	20	23
Capital Conversion Costs	2015$ millions					
Total Conversion Costs	2015$ millions		16	20	20	23

* Numbers in parentheses indicate negative numbers.

TSL 1 sets the efficiency level at EL 1 for all UPSs. At TSL 1, DOE estimates impacts on INPV to range from −$389 million to $191 million, or a change in INPV of −15.2 percent to 7.5 percent. At this TSL, industry free cash flow is estimated to decrease by approximately 6.3 percent to $81 million, compared to the no-standards case value of $86 million in 2018, the year leading up to the proposed standard.

DOE does not expect that UPS manufacturers will incur any capital conversion costs at any of the TSLs. DOE does expect that manufacturers will incur product conversion costs of $16.2 million at TSL 1, primarily driven by testing and certifying all covered UPSs as well as by increased R&D efforts necessary to redesign UPSs that do not meet efficiency levels required at TSL 1.

At TSL 1, the shipment-weighted-average MPCs increase by approximately 11 percent for VFI UPSs and 21 percent for VI UPSs and decrease by approximately 3 percent for VFD UPSs relative to the no-standards case MPCs in 2019, the expected compliance year of the standards. In the preservation of gross margin markup scenario, manufacturers are able to recover their $16.2 million in conversion costs over the course of the analysis period through the increases in MPCs for VFI and VI UPSs causing a slightly positive change in INPV at TSL 1 under the preservation of gross margin markup scenario.

Under the pass through markup scenario, the MPC increases at TSL 1 result in reductions in manufacturer markups from 1.76 in the no-standards case to 1.67 for VFI UPSs at TSL 1 and from 1.57 in the no-standards case to 1.44 for VI UPSs at TSL 1. The MPC decrease for VFD UPSs at TSL 1 results in an increase in manufacturer markup from 1.55 in the no-standards case to 1.57 at TSL 1. The reductions in manufacturer markups for VFI and VI UPSs and $16.2 million in conversion costs incurred by manufacturers cause a moderately negative change in INPV at TSL 1 under the pass through markup scenario.

TSL 2 sets the efficiency level at EL 1 for VFI and VFD UPSs and EL 2 for VI UPSs. At TSL 2, DOE estimates impacts on INPV to range from −$598 million to $295 million, or a change in INPV of −23.4 percent to 11.5 percent. At this TSL, industry free cash flow is estimated to decrease by approximately 7.6 percent to $80 million, compared to the no-standards case value of $86

million in 2018, the year leading up to the proposed standard.

DOE expects that product conversion costs will rise from $16.2 million at TSL 1 to $19.6 million at TSL 2. Product conversion costs incurred at TSL 2 are primarily driven by testing and certifying all covered UPSs as well as by increased R&D efforts necessary to redesign UPSs that do not meet efficiency levels required at TSL 2 and VI UPSs to have best-in-market efficiency.

At TSL 2, the shipment-weighted-average MPCs increase by approximately 11 percent for VFI UPSs and 41 percent for VI UPSs and decrease by approximately 3 percent for VFD UPSs relative to the no-standards case MPCs in 2019, the expected compliance year of the standards. In the preservation of gross margin markup scenario, manufacturers are able to recover their $19.6 million in conversion costs over the course of the analysis period through the increases in MPCs for VFI and VI UPSs causing a moderately positive change in INPV at TSL 2 under the preservation of gross margin markup scenario.

Under the pass through markup scenario at TSL 2, the MPC increases result in reductions in manufacturer markups from 1.76 in the no-standards case to 1.67 for VFI UPSs at TSL 2 and from 1.57 in the no-standards case to 1.37 for VI UPSs at TSL 2. The MPC decrease for VFD UPSs at TSL 2 results in an increase in manufacturer markup from 1.55 in the no-standards case to 1.57 in the standards case at TSL 2. The reductions in manufacturer markups for VFI and VI UPSs and $19.6 million in conversion costs cause a significantly negative change in INPV at TSL 2 under the pass through markup scenario.

TSL 3 sets the efficiency level at EL 1 for VFI UPSs and EL 2 for VI and VFD UPSs. At TSL 3, DOE estimates impacts on INPV to range from −$936 million to $428 million, or a change in INPV of −36.6 percent to 16.8 percent. At this TSL, industry free cash flow is estimated to decrease by approximately 8.0 percent to $80 million, compared to the no-standards case value of $86 million in 2018, the year leading up to the proposed standard.

DOE expects that product conversion costs will rise slightly from $19.6 million at TSL 2 to $20.4 million at TSL 3. Product conversion costs incurred at TSL 3 are primarily driven by testing and certifying all covered UPSs as well as by increased R&D efforts necessary to redesign UPSs that do not meet efficiency levels required at TSL 3 and VI and VFD UPSs to have best-in-market efficiency at TSL 3.

At TSL 3, the shipment-weighted-average MPCs increase by approximately 11 percent for VFI UPSs, 41 percent for VI UPSs, and 24 percent for VFD UPSs relative to the no-standards case MPCs in 2019, the expected compliance year of the standards. In the preservation of gross margin markup scenario, manufacturers are able to recover their $20.4 million in conversion costs over the course of the analysis period through the increases in MPCs causing a moderately positive change in INPV at TSL 3 under the preservation of gross margin markup scenario.

Under the pass through markup scenario at TSL 3, the increases in shipment-weighted-average MPCs result in reductions in manufacturer markups, from 1.76 in the no-standards case to 1.67 for VFI UPSs at TSL 3, from 1.57 in the no-standards case to 1.37 for VI UPSs at TSL 3, and from 1.55 in the no-standards case to 1.43 for VFD UPSs at TSL 3. These reductions in manufacturer markups and $20.4 million in conversion costs incurred by manufacturers cause a significantly negative change in INPV at TSL 3 under the pass through markup scenario.

TSL 4 sets the efficiency level at EL 3 for all UPSs, which represents max-tech. At TSL 4, DOE estimates impacts on INPV to range from −$3,222 million to $4,845 million, or a change in INPV of −126.1 percent to 189.7 percent. At this TSL, industry free cash flow is estimated to decrease by approximately 9.0 percent to $79 million, compared to the no-standards case value of $86 million in 2018, the year leading up to the proposed standard.

DOE expects that product conversion costs will rise from $20.4 million at TSL 3 to $23.0 million at TSL 4. Product conversion costs incurred at TSL 4 are primarily driven by testing and certifying all covered UPSs as well as by increased R&D efforts necessary to redesign UPSs that do not meet efficiency levels required at TSL 4 to have best-in-market efficiency and to use the most efficient materials and semiconductor components available.

At TSL 4, the shipment-weighted-average MPCs increase significantly by approximately 209 percent for VFI UPSs, 504 percent for VI UPSs, and 45 percent for VFD UPSs relative to the no-standards case MPCs in 2019, the expected compliance year of the standards. In the preservation of gross margin markup scenario, manufacturers are able to recover their $23.0 million in conversion costs over the course of the analysis period through the increases in MPCs causing a significantly positive change in INPV at TSL 4 under the preservation of gross margin markup scenario.

Under the pass through markup scenario at TSL 4, the MPC increases result in reductions in manufacturer markups, from 1.76 in the no-standards case to 1.30 for VFI UPSs at TSL 4, from 1.57 in the no-standards case to 1.30 for VI UPSs at TSL 4, and from 1.55 in the no-standards case to 1.36 for VFD UPSs at TSL 4. These reductions in manufacturer markups and $23.0 million in conversion costs incurred by manufacturers cause a significantly negative change in INPV at TSL 4 under the pass through markup scenario.

b. Impacts on Employment

As part of the direct employment impact analysis, DOE attempted to quantify the number of domestic workers involved in UPS production. Manufacturer interviews and DOE's research indicate that all UPS components that would be modified to improve the efficiency of UPSs are manufactured abroad. DOE was able to identify a handful of UPS manufacturers that do assemble these UPS components domestically. However, based on manufacturer interviews, DOE does not believe that there would be an impact on the amount of domestic workers involved in the assembly of UPSs due to new energy conservation standards. While the components of UPS configurations may change, DOE estimates that the same amount of labor would be needed to assemble these products. Therefore, DOE did not conduct a quantitative domestic manufacturing employment impact analysis on UPS manufacturers for this rulemaking.

DOE also recognizes there are several UPS and UPS component manufacturers that have employees in the U.S. that work on design, technical support, sales, training, testing, certification, and other requirements. However, in interviews, manufacturers generally did not expect any negative changes in the domestic employment of the design, technical support, or other departments of UPS and UPS component manufacturers located in the U.S. in response to new energy conservation standards.

DOE seeks comment on its determination that all UPS manufacturing takes place abroad. Additionally, DOE seeks comment on the presence of any domestic UPS manufacturing beyond assembly, R&D, testing, and certification, and if there are any potential negative impacts to domestic employment that could arise due to energy conservation standards on UPSs that are not fully captured by the

direct employment impact analysis (see section VII.E).

c. Impacts on Manufacturing Capacity

UPS manufacturers stated that they did not anticipate any capacity constraints at any of the analyzed ELs, given a three-year timeframe from the publication of a final rule and the compliance year.

DOE seeks comment on any potential UPS and UPS component manufacturer capacity constraints caused by the proposed standards in this NOPR (see section VII.E).

d. Impacts on Subgroups of Manufacturers

Using average cost assumptions to develop an industry cash-flow estimate may not be adequate for assessing differential impacts among manufacturer subgroups. Small manufacturers, niche product manufacturers, and manufacturers exhibiting cost structures substantially different from the industry average could be affected disproportionately. lDOE identified one manufacturer subgroup that it believes could be disproportionally impacted by energy conservation standards and would require a separate analysis in the MIA, small businesses. DOE analyzes the impacts on small businesses in a separate analysis in section VI.B of this NOPR as part of the Regulatory Flexibility Analysis. DOE did not identify any other adversely impacted manufacturer subgroups for this rulemaking based on the results of the industry characterization.

DOE seeks comment on any other manufacturer subgroups that DOE should analyze and/or types of UPS manufacturers for the manufacturer subgroup analysis, including the identification of UPS manufacturer subgroups that should be analyzed separately (see section VII.E).

e. Cumulative Regulatory Burden

One aspect of assessing manufacturer burden involves considering the cumulative impact of multiple DOE standards and the regulatory actions of other Federal agencies and States that affect the manufacturers of a covered product. A standard level is not economically justified if it contributes to an unacceptable cumulative regulatory burden. While any one regulation may not impose a significant burden on manufacturers, the combined effects of several existing or impending regulations may have serious consequences for some manufacturers, groups of manufacturers, or an entire industry. Assessing the impact of a single regulation may overlook this cumulative regulatory burden. In addition to energy conservation standards, other regulations can significantly affect manufacturers' financial operations. Multiple regulations affecting the same manufacturer can strain profits and lead companies to abandon product lines or markets with lower expected future returns than competing products. For these reasons, DOE conducts an analysis of cumulative regulatory burden as part of its rulemakings pertaining to appliance efficiency.

Some UPS manufacturers could also make other products that could be subject to energy conservation standards set by DOE. DOE looks at these regulations that could affect UPS manufacturers that will take effect approximately 3 years before or after the estimated 2019 compliance date of any amended energy conservation standards for UPSs. These energy conservation standards include external power supplies that have a compliance date in 2016 [54] and battery chargers that have a compliance date in 2018.[55]

The compliance dates and expected industry conversion costs of relevant energy conservation standards are indicated in Table V.17. DOE notes that very few of the products listed in Table V.17 are manufactured domestically.

TABLE V.17—COMPLIANCE DATES AND EXPECTED CONVERSION EXPENSES OF FEDERAL ENERGY CONSERVATION STANDARDS AFFECTING UNINTERRUPTIBLE POWER SUPPLY MANUFACTURERS

Federal energy conservation standards	Number of manufacturers *	Compliance date	Estimated INPV (no new standards case)	Estimated total industry conversion expense	Number of manufacturers from today's rule affected **
External Power Supplies 79 FR 7846 (February 10, 2014).	679	2016	$274 million (2012$)	$43.3 million (2012$)	7
Battery Chargers ..... XX FR XXX (Month, Day, 2016).	107	† 2018	$79,904 million (2013$)	$19.5 million (2013$)	3

* The number of manufacturers listed in the final rule for the energy conservation standard that is contributing to cumulative regulatory burden.
** The number of manufacturers producing UPSs that are affected by the listed energy conservation standards.
† The final rule for this energy conservation standard has not been published. The data points in the table are estimates from the pre-publication stage.

DOE discusses these and other requirements and includes the full details of the cumulative regulatory burden analysis in chapter 12 of the NOPR TSD. DOE will continue to evaluate its approach to assessing cumulative regulatory burden for use in future rulemakings to ensure that it is effectively capturing the overlapping impacts of its regulations. In particular, DOE will assess whether looking at rules where any portion of the compliance period potentially overlaps with the compliance period for the subject rulemaking would yield a more accurate reflection of cumulative regulatory burden.

DOE seeks comment on the compliance costs of any other regulations on products that UPS manufacturers also manufacture, especially if compliance with those regulations is required within three years before or after the estimated compliance date of this proposed standard (2019) (see section VII.E). Additionally, DOE welcomes comment on how it analyzes and considers cumulative regulatory burden.

[54] Energy conservation standards for external power supplies that become effective on February 10, 2016. 79 FR 7846. [Docket Number EERE–2008–BT–STD–0005–0219]

[55] Energy conservation standards for battery chargers will become effective on June 13, 2018. 81 FR 38266. [Docket Number EERE–2008–BT–STD–0005]

3. National Impact Analysis

a. Significance of Energy Savings

To estimate the energy savings attributable to potential standards for UPSs, DOE compared their energy consumption under the no-standards case to their anticipated energy consumption under each TSL. The savings are measured over the entire lifetime of products purchased in the 30-year period that begins in the year of anticipated compliance with amended standards (2019–2048). Table V.18 present DOE's projections of the national energy savings for each TSL considered for UPSs. The savings were calculated using the approach described in section IV.H of this NOPR.

TABLE V.18—CUMULATIVE NATIONAL PRIMARY ENERGY SAVINGS FOR UPSS SHIPPED IN 2019–2048 (quads) *

Product class	Description	Trial standard level			
		1	2	3	4
10a	VFD UPS	0.24	0.24	0.31	0.36
10b	VI UPS	0.41	0.59	0.59	0.73
10c	VFI UPS	0.31	0.31	0.31	1.44
Total *	.....	0.95	1.13	1.20	2.53

* Numbers may not add to totals, due to rounding.

TABLE V.19—CUMULATIVE NATIONAL ENERGY SAVINGS INCLUDING FULL-FULL-CYCLE FOR UPSS SHIPPED IN 2019–2048 (quads) *

Product class	Description	Trial standard level			
		1	2	3	4
10a	VFD UPS	0.25	0.25	0.32	0.38
10b	VI UPS	0.42	0.61	0.61	0.76
10c	VFI UPS	0.33	0.33	0.33	1.51
Total *	.....	1.00	1.18	1.26	2.65

* Numbers may not add to totals, due to rounding.

OMB Circular A–4 [56] requires agencies to present analytical results, including separate schedules of the monetized benefits and costs that show the type and timing of benefits and costs. Circular A–4 also directs agencies to consider the variability of key elements underlying the estimates of benefits and costs. For this rulemaking, DOE undertook a sensitivity analysis using nine, rather than 30, years of product shipments. The choice of a 9-year period is a proxy for the timeline in EPCA for the review of certain energy conservation standards and potential revision of and compliance with such revised standards.[57] The review timeframe established in EPCA is generally not synchronized with the product lifetime, product manufacturing cycles, or other factors specific to UPSs. Thus, such results are presented for informational purposes only and are not indicative of any change in DOE's analytical methodology. The NES sensitivity analysis results based on a 9-year analytical period are presented in Table V.20. The impacts are counted over the lifetime of UPSs purchased in 2019–2027.

TABLE V.20—CUMULATIVE NATIONAL PRIMARY ENERGY SAVINGS FOR UPSS; 9 YEARS OF SHIPMENTS (2019–2027) (quads) *

Product class	Description	Trial standard level			
		1	2	3	4
10a	VFD UPS	0.06	0.06	0.07	0.09
10b	VI UPS	0.10	0.14	0.14	0.17
10c	VFI UPS	0.07	0.07	0.07	0.34
Total *	.....	0.23	0.27	0.29	0.60

* Numbers may not add to totals, due to rounding.

[56] U.S. Office of Management and Budget. Circular A–4: Regulatory Analysis. September 17, 2003. *www.whitehouse.gov/omb/circulars_a004_a-4/.*

[57] Section 325(m) of EPCA requires DOE to review its standards at least once every 6 years, and requires, for certain products, a 3-year period after any new standard is promulgated before compliance is required, except that in no case may any new standards be required within 6 years of the compliance date of the previous standards. While adding a 6-year review to the 3-year compliance period adds up to 9 years, DOE notes that it may undertake reviews at any time within the 6 year period and that the 3-year compliance date may yield to the 6-year backstop. A 9-year analysis period may not be appropriate given the variability that occurs in the timing of standards reviews and the fact that for some products, the compliance period is 5 years rather than 3 years.

TABLE V.21—CUMULATIVE NATIONAL ENERGY SAVINGS INCLUDING FULL-FUEL-CYCLE FOR UPSS; 9 YEARS OF SHIPMENTS (2019–2027) (quads) *

Product class	Description	Trial standard level			
		1	2	3	4
10a	VFD UPS	0.06	0.06	0.08	0.09
10b	VI UPS	0.10	0.15	0.15	0.18
10c	VFI UPS	0.08	0.08	0.08	0.35
Total *	.....	0.24	0.28	0.30	0.62

* Numbers may not add to totals, due to rounding.

b. Net Present Value of Consumer Costs and Benefits

DOE estimated the cumulative NPV of the total costs and savings for consumers that would result from the TSLs considered for UPSs. In accordance with OMB's guidelines on regulatory analysis,[58] DOE calculated NPV using both a 7-percent and a 3-percent real discount rate. Table V.22 shows the consumer NPV results with impacts counted over the lifetime of products purchased in 2019–2048.

TABLE V.22—CUMULATIVE NET PRESENT VALUE OF CONSUMER BENEFITS FOR UPSS SHIPPED IN 2019–2048

Discount rate	Trial standard level (billion 2015$)			
	1	2	3	4
3 percent	4.8	4.4	2.4	−51
7 percent	2.2	1.9	0.75	−29

The NPV results based on the aforementioned 9-year analytical period are presented in Table V.23. The impacts are counted over the lifetime of products purchased in 2019–2027. As mentioned previously, such results are presented for informational purposes only and are not indicative of any change in DOE's analytical methodology or decision criteria.

TABLE V.23—CUMULATIVE NET PRESENT VALUE OF CONSUMER BENEFITS FOR [UPSS]; 9 YEARS OF SHIPMENTS (2019–2027)

Discount rate	Trial standard level (billion 2015$)			
	1	2	3	4
3 percent	1.4	1.2	0.61	−16
7 percent	0.89	0.75	0.26	−13

The above results reflect the use of no price trend for UPSs over the analysis period (see section IV.F.1 of this document).

c. Indirect Impacts on Employment

DOE expects energy conservation standards for UPSs to reduce energy bills for consumers of those products, with the resulting net savings being redirected to other forms of economic activity. These expected shifts in spending and economic activity could affect the demand for labor. As described in section IV.N of this document, DOE used an input/output model of the U.S. economy to estimate indirect employment impacts of the TSLs that DOE considered in this rulemaking. DOE understands that there are uncertainties involved in projecting employment impacts, especially changes in the later years of the analysis. Therefore, DOE generated results for near-term timeframes (2016–2048), where these uncertainties are reduced.

The results suggest that the proposed standards are likely to have a negligible impact on the net demand for labor in the economy. The net change in jobs is so small that it would be imperceptible in national labor statistics and might be offset by other, unanticipated effects on employment. Chapter 16 of the NOPR TSD presents detailed results regarding anticipated indirect employment impacts.

4. Impact on Utility or Performance of Products

Based on testing conducted in support of this proposed rule, discussed in section IV.C.1.b of this NOPR, DOE has tentatively concluded that the standards proposed in this NOPR would not reduce the utility or performance of the UPSs under consideration in this rulemaking. Manufacturers of these products currently offer units that meet or exceed the proposed standards.

5. Impact of Any Lessening of Competition

As discussed in section III.D.1.e, the Attorney General determines the impact, if any, of any lessening of competition likely to result from a

[58] U.S. Office of Management and Budget, ''Circular A–4: Regulatory Analysis,'' section E, (Sept. 17, 2003) (Available at: *http://www.whitehouse.gov/omb/circulars_a004_a-4/*).

proposed standard, and transmits such determination in writing to the Secretary, together with an analysis of the nature and extent of such impact. To assist the Attorney General in making this determination, DOE has provided DOJ with copies of this NOPR and the accompanying TSD for review. DOE will consider DOJ's comments on the proposed rule in determining whether to proceed to a final rule. DOE will publish and respond to DOJ's comments in that document. DOE invites comment from the public regarding the competitive impacts that are likely to result from this proposed rule. In addition, stakeholders may also provide comments separately to DOJ regarding these potential impacts. See the **ADDRESSES** section for information to send comments to DOJ.

6. Need of the Nation To Conserve Energy

Enhanced energy efficiency, where economically justified, improves the Nation's energy security, strengthens the economy, and reduces the environmental impacts (costs) of energy production. Reduced electricity demand due to energy conservation standards is also likely to reduce the cost of maintaining the reliability of the electricity system, particularly during peak-load periods. As a measure of this reduced demand, chapter 15 in the NOPR TSD presents the estimated reduction in generating capacity, relative to the no-standards case, for the TSLs that DOE considered in this rulemaking.

Energy conservation resulting from new standards for UPSs is expected to yield environmental benefits in the form of reduced emissions of air pollutants and greenhouse gases. Table V.24 provides DOE's estimate of cumulative emissions reductions expected to result from the TSLs considered in this rulemaking. The table includes both power sector emissions and upstream emissions. The emissions were calculated using the multipliers discussed in section IV.K. DOE reports annual emissions reductions for each TSL in chapter 13 of the NOPR TSD.

TABLE V.24—CUMULATIVE EMISSIONS REDUCTION FOR UPSS SHIPPED IN 2019–2048

	Trial standard level			
	1	2	3	4
Power Sector Emissions				
CO_2 (*million metric tons*)	57.4	68.2	72.6	152
SO_2 (*thousand tons*)	33.8	40.2	42.8	89.2
NO_X (*thousand tons*)	63.5	75.5	80.4	169
Hg (*tons*)	0.126	0.149	0.159	0.332
CH_4 (*thousand tons*)	4.84	5.76	6.14	12.8
N_2O (*thousand tons*)	0.685	0.815	0.868	1.81
Upstream Emissions				
CO_2 (*million metric tons*)	3.20	3.80	4.04	8.52
SO_2 (*thousand tons*)	0.595	0.707	0.752	1.58
NO_X (*thousand tons*)	45.8	54.4	57.9	122
Hg (*tons*)	0.0013	0.0016	0.0017	0.0035
CH_4 (*thousand tons*)	253	301	320	674
N_2O (*thousand tons*)	0.029	0.035	0.037	0.078
Total FFC Emissions				
CO_2 (*million metric tons*)	60.5	72.0	76.7	160.6
SO_2 (*thousand tons*)	34.3	40.9	43.5	90.7
NO_X (*thousand tons*)	109	130	138	291
Hg (*tons*)	0.127	0.151	0.161	0.335
CH_4 (*thousand tons*)	258	306	326	686
CH_4 (*thousand tons CO_2eq*)*	7220	8580	9120	19200
N_2O (*thousand tons*)	0.714	0.850	0.905	1.89
N_2O (*thousand tons CO_2eq*)*	189	225	240	500

* CO_2eq is the quantity of CO_2 that would have the same global warming potential (GWP).

As part of the analysis for this proposed rule, DOE estimated monetary benefits likely to result from the reduced emissions of CO_2 and NO_X that DOE estimated for each of the considered TSLs for UPSs. As discussed in section IV.L of this document, for CO_2, DOE used the most recent values for the SCC developed by an interagency process. The four sets of SCC values for CO_2 emissions reductions in 2015 resulting from that process (expressed in 2015$) are represented by $12.4/metric ton (the average value from a distribution that uses a 5-percent discount rate), $40.6/metric ton (the average value from a distribution that uses a 3-percent discount rate), $63.2/metric ton (the average value from a distribution that uses a 2.5-percent discount rate), and $118/metric ton (the 95th-percentile value from a distribution that uses a 3-percent discount rate). The values for later years are higher due to increasing damages (public health, economic and environmental) as the projected magnitude of climate change increases.

Table V.25 presents the global value of CO_2 emissions reductions at each TSL. For each of the four cases, DOE calculated a present value of the stream of annual values using the same discount rate as was used in the studies upon which the dollar-per-ton values are based. DOE calculated domestic values as a range from 7 percent to 23 percent of the global values; these results are presented in chapter 14 of the NOPR TSD.

TABLE V.25—ESTIMATES OF GLOBAL PRESENT VALUE OF CO_2 EMISSIONS REDUCTION FOR UPSS SHIPPED IN 2019–2048

TSL	SCC case * (million 2015$)			
	5% discount rate, average	3% discount rate, average	2.5% discount rate, average	3% discount rate, 95th percentile
Power Sector Emissions				
1	445	1960	3080	5960
2	530	2330	3670	7100
3	565	2480	3910	7560
4	1170	5160	8130	15700
Upstream Emissions				
1	24.3	108	170	329
2	29.0	129	203	392
3	30.9	137	216	417
4	64.0	286	451	871
Total FFC Emissions				
1	469	2070	3250	6290
2	559	2460	3870	7490
3	596	2620	4120	7980
4	1230	5440	8580	16600

* For each of the four cases, the corresponding SCC value for emissions in 2015 is $12.4, $40.6, $63.2, and $118 per metric ton (2014$). The values are for CO_2 only (*i.e.,* not CO_{2eq} of other greenhouse gases).

DOE is well aware that scientific and economic knowledge about the contribution of CO_2 and other GHG emissions to changes in the future global climate and the potential resulting damages to the world economy continues to evolve rapidly. Thus, any value placed on reduced CO_2 emissions in this rulemaking is subject to change. DOE, together with other Federal agencies, will continue to review various methodologies for estimating the monetary value of reductions in CO_2 and other GHG emissions. This ongoing review will consider the comments on this subject that are part of the public record for this and other rulemakings, as well as other methodological assumptions and issues. However, consistent with DOE's legal obligations, and taking into account the uncertainty involved with this particular issue, DOE has included in this proposed rule the most recent values and analyses resulting from the interagency review process.

DOE also estimated the cumulative monetary value of the economic benefits associated with NO_X emissions reductions anticipated to result from the considered TSLs for UPSs. The dollar-per-ton values that DOE used are discussed in section IV.L of this document. Table V.26 presents the cumulative present values for NO_X emissions for each TSL calculated using 7-percent and 3-percent discount rates. This table presents values that use the low dollar-per-ton values, which reflect DOE's primary estimate. Results that reflect the range of NO_X dollar-per-ton values are presented in Table V.28.

TABLE V.26—ESTIMATES OF PRESENT VALUE OF NO_X EMISSIONS REDUCTION FOR UPSS SHIPPED IN 2019–2048 *

TSL	Million 2015$	
	3% discount rate	7% discount rate
Power Sector Emissions		
1	136	62.6
2	162	74.8
3	172	79.9
4	355	161
Upstream Emissions		
1	94.6	42.5
2	113	50.8
3	120	54.2
4	249	109.9
Total FFC Emissions		
1	230	105
2	274	126
3	292	134
4	603	271

* Results are based on the low benefit-per-ton values.

7. Other Factors

The Secretary of Energy, in determining whether a standard is economically justified, may consider any other factors that the Secretary deems to be relevant. (42 U.S.C. 6295(o)(2)(B)(i)(VII)) No other factors were considered in this analysis.

8. Summary of National Economic Impacts

The NPV of the monetized benefits associated with emissions reductions can be viewed as a complement to the NPV of the consumer savings calculated for each TSL considered in this rulemaking. Table V.27 presents the NPV values that result from adding the estimates of the potential economic benefits resulting from reduced CO_2 and NO_X emissions in each of four valuation scenarios to the NPV of consumer savings calculated for each TSL considered in this rulemaking, at both a 7-percent and 3-percent discount rate. The CO_2 values used in the columns of each table correspond to the 2015 values in the four sets of SCC values discussed above.

TABLE V.27—NET PRESENT VALUE OF CONSUMER SAVINGS COMBINED WITH PRESENT VALUE OF MONETIZED BENEFITS FROM CO_2 AND NO_X EMISSIONS REDUCTIONS

TSL	Consumer NPV at 3% discount rate added with: (billion 2015$)			
	SCC case $12.4/t and 3% low NO_X values	SCC case $40.6/ tand 3% low NO_X values	SCC case $63.2/t and 3% low NO_X values	SCC case $118/t and 3% low NO_X values
1	5.51	7.11	8.30	11.3
2	5.23	7.14	8.55	12.2
3	3.29	5.32	6.82	10.7
4	(49.4)	(45.2)	(42.0)	(34.0)
TSL	Consumer NPV at 7% discount rate added with: (billion 2015$)			
	SCC case $12.4/t and 7% low NO_X values	SCC case $40.6/t and 7% low NO_X values	SCC case $63.2/t and 7% low NO_X values	SCC case $118/t and 7% low NO_X values
1	2.75	4.35	5.53	8.57
2	2.55	4.46	5.87	9.48
3	1.48	3.50	5.01	8.86
4	(28.0)	(23.7)	(20.6)	(12.6)

Parentheses indicate negative (−) values.
Note: The SCC case values represent the global SCC in 2015, in [2015]$ per metric ton (t), for each case.

In considering the above results, two issues are relevant. First, the national operating cost savings are domestic U.S. monetary savings that occur as a result of market transactions, while the value of CO_2 reductions is based on a global value. Second, the assessments of operating cost savings and the SCC are performed with different methods that use different time frames for analysis. The national operating cost savings is measured for the lifetime of products shipped in 2019–2048. Because CO_2 emissions have a very long residence time in the atmosphere,[59] the SCC values in future years reflect future CO_2-emissions impacts that continue beyond 2100.

C. Conclusion

When considering proposed standards, the new or amended energy conservation standards that DOE adopts for any type (or class) of covered product must be designed to achieve the maximum improvement in energy efficiency that the Secretary determines is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A)) In determining whether a standard is economically justified, the Secretary must determine whether the benefits of the standard exceed its burdens by, to the greatest extent practicable, considering the seven statutory factors discussed previously. (42 U.S.C. 6295(o)(2)(B)(i)) The new or amended standard must also result in significant conservation of energy. (42 U.S.C. 6295(o)(3)(B))

For this NOPR, DOE considered the impacts of new standards for UPSs at each TSL, beginning with the maximum technologically feasible level, to determine whether that level was economically justified. Where the max-tech level was not justified, DOE then considered the next most efficient level and undertook the same evaluation until it reached the highest efficiency level that is both technologically feasible and economically justified and saves a significant amount of energy.

To aid the reader as DOE discusses the benefits and/or burdens of each TSL, tables in this section present a summary of the results of DOE's quantitative analysis for each TSL. In addition to the quantitative results presented in the tables, DOE also considers other burdens and benefits that affect economic justification. These include the impacts on identifiable subgroups of consumers who may be disproportionately affected by a national standard and impacts on employment.

DOE also notes that the economics literature provides a wide-ranging discussion of how consumers trade off upfront costs and energy savings in the absence of government intervention. Much of this literature attempts to explain why consumers appear to undervalue energy efficiency improvements. There is evidence that consumers undervalue future energy savings as a result of (1) a lack of information, (2) a lack of sufficient salience of the long-term or aggregate benefits, (3) a lack of sufficient savings to warrant delaying or altering purchases, (4) excessive focus on the short term, in the form of inconsistent weighting of future energy cost savings relative to available returns on other investments, (5) computational or other difficulties associated with the evaluation of relevant tradeoffs, and (6) a divergence in incentives (for example, between renters and owners, or builders and purchasers). Having less than perfect foresight and a high degree of uncertainty about the future, consumers may trade off these types of investments at a higher than expected rate between current consumption and uncertain future energy cost savings.

In DOE's current regulatory analysis, potential changes in the benefits and costs of a regulation due to changes in consumer purchase decisions are included in two ways. First, if consumers forego the purchase of a product in the standards case, this decreases sales for product manufacturers, and the impact on manufacturers attributed to lost revenue is included in the MIA. Second, DOE accounts for energy savings attributable only to products actually used by consumers in the standards case; if a regulatory option decreases the number of products purchased by consumers, this decreases the potential energy savings from an energy conservation standard. DOE provides estimates of shipments and changes in the volume of product purchases in chapter 9 of the NOPR TSD. However, DOE's current analysis does not explicitly control for

[59] The atmospheric lifetime of CO_2 is estimated of the order of 30–95 years. Jacobson, M. Z. Correction to ''Control of fossil-fuel particulate black carbon and organic matter, possibly the most effective method of slowing global warming.'' *J. Geophys. Res.* 2005. 110: D14105. doi:10.1029/2005JD005888.

heterogeneity in consumer preferences, preferences across subcategories of products or specific features, or consumer price sensitivity variation according to household income.[60]

While DOE is not prepared at present to provide a fuller quantifiable framework for estimating the benefits and costs of changes in consumer purchase decisions due to an energy conservation standard, DOE is committed to developing a framework that can support empirical quantitative tools for improved assessment of the consumer welfare impacts of appliance standards. DOE has posted a paper that discusses the issue of consumer welfare impacts of appliance energy conservation standards, and potential enhancements to the methodology by which these impacts are defined and estimated in the regulatory process.[61] DOE welcomes comments on how to more fully assess the potential impact of energy conservation standards on consumer choice and how to quantify this impact in its regulatory analysis in future rulemakings.

1. Benefits and Burdens of TSLs Considered for UPS Standards

Table V.28 and Table V.29 summarize the quantitative impacts estimated for each TSL for UPSs. The national impacts are measured over the lifetime of UPSs purchased in the 30-year period that begins in the anticipated year of compliance with amended standards (2019–2048). The energy savings, emissions reductions, and value of emissions reductions refer to full-fuel-cycle results. The efficiency levels contained in each TSL are described in section V.A of this NOPR.

TABLE V.28—SUMMARY OF ANALYTICAL RESULTS FOR UPS TSLS: NATIONAL IMPACTS

Category	TSL 1	TSL 2	TSL 3	TSL 4
Cumulative FFC National Energy Savings (quads)				
	1.00	1.18	1.26	2.65.
NPV of Consumer Costs and Benefits (billion 2015$)				
3% discount rate	4.81	4.40	2.41	(51.2).
7% discount rate	2.17	1.87	0.749	(29.5).
Cumulative FFC Emissions Reduction (Total FFC Emissions)				
CO_2 (*million metric tons*)	60.5	72.0	76.7	161.
SO_2 (*thousand tons*)	34.3	40.9	43.5	90.7.
NO_X (*thousand tons*)	109	130	138	291.
Hg (*tons*)	0.127	0.151	0.161	0.335.
CH_4 (*thousand tons*)	258	306	326	686.
CH_4 (*thousand tons CO_2eq*)*.	7,220	8,580	9,120	19,200.
N_2O (*thousand tons*)	0.714	0.850	0.905	1.89.
N_2O (*thousand tons CO_2eq*)*.	189	225	240	500.
Value of Emissions Reduction (Total FFC Emissions)				
CO_2 (*billion 2015$*)**	0.469 to 6.29	0.559 to 7.49	0.596 to 7.98	1.229 to 16.6.
NO_X—3% discount rate (*million 2015$*).	230 to 525	274 to 625	292 to 667	603 to 1380.
NO_X—7% discount rate (*million 2015$*).	105 to 237	126 to 283	134 to 302	271 to 611.

Parentheses indicate negative (−) values.
* CO_2eq is the quantity of CO_2 that would have the same global warming potential (GWP).
** Range of the economic value of CO_2 reductions is based on estimates of the global benefit of reduced CO_2 emissions.

TABLE V.29—SUMMARY OF ANALYTICAL RESULTS FOR UPS TSLS: MANUFACTURER AND CONSUMER IMPACTS

Category	TSL 1*	TSL 2*	TSL 3*	TSL 4*
Manufacturer Impacts				
Industry NPV (2015$ millions) (No-standards case INPV = 2,555)	2,166–2,746	1,957–2,849	1,619–2,983	(667)–7,400
Industry NPV Change:				
(2015$ millions)	(389)–191	(598)–295	(936)–428	(3,222)–4,845
(%)	(0.2)–0.1	(0.2)–0.1	(0.4)–0.2	(1.3)–1.9
Consumer Average LCC Savings (2015$)				
10a (VFD UPSs)	33	33	(0.08)	(13)
10b (VI UPSs)	14	6.1	6.1	(400)

[60] P.C. Reiss and M.W. White. Household Electricity Demand, Revisited. *Review of Economic Studies.* 2005. 72(3): pp., 853–883. doi: *http://restud.oxfordjournals.org/content/72/3/853.*

[61] Sanstad, A.H. Notes on the Economics of Household Energy Consumption and Technology Choice. 2010. Lawrence Berkeley National Laboratory. *https://www1.eere.energy.gov/buildings/appliance_standards/pdfs/consumer_ee_theory.pdf.*

TABLE V.29—SUMMARY OF ANALYTICAL RESULTS FOR UPS TSLS: MANUFACTURER AND CONSUMER IMPACTS—Continued

Category	TSL 1 *	TSL 2 *	TSL 3 *	TSL 4 *
10c (VFI UPSs)	35	35	35	(380)
Consumer Simple PBP (years)				
10a (VFD UPSs)	0.0	0.0	2.7	4.4
10b (VI UPSs)	3.5	4.6	4.6	39
10c (VFI UPSs)	4.7	4.7	4.7	18
Percent of Consumers That Experience a Net Cost				
10a (VFD UPSs)	0%	0%	38%	79%
10b (VI UPSs)	7.6%	44%	44%	100%
10c (VFI UPSs)	2.3%	2.3%	2.3%	99%

* Parentheses indicate negative (−) values.

DOE first considered TSL 4, which represents the max-tech efficiency levels. TSL 4 would save an estimated 2.65 quads of energy, an amount DOE considers significant. Under TSL 4, the NPV of consumer benefit would be −$29.5 billion using a discount rate of 7 percent, and −$51.2 billion using a discount rate of 3 percent.

The cumulative emissions reductions at TSL 4 are 161 Mt of CO_2, 90.7 thousand tons of SO_2, 291 thousand tons of NO_X, 0.335 ton of Hg, 686 thousand tons of CH_4, and 1.89 thousand tons of N_2O. The estimated monetary value of the CO_2 emissions reduction at TSL 4 ranges from $1.23 billion to $16.6 billion.

At TSL 4, the average LCC impact is a savings of −$13 for VFD UPSs, −$400 for VI UPSs, and −$380 for VFI UPSs. The simple payback period is 4.4 years for VFD UPSs, 39 years for VI UPSs, and 18 years for VFI UPSs. The fraction of consumers experiencing a net LCC cost is 79 percent for VFD UPSs, 100 percent for VI UPSs, and 99 percent for VFI UPSs.

At TSL 4, the projected change in INPV ranges from a decrease of $3,222 million to an increase of $4,845 million, which represents a decrease of 126.1 percent to an increase of 189.7 percent, respectively.

The Secretary tentatively concludes that at TSL 4 for UPSs, the benefits of energy savings, emission reductions, and the estimated monetary value of the emissions reductions would be outweighed by the negative NPV of consumer benefits, economic burden on most consumers, and the impacts on manufacturers, including the conversion costs and profit margin impacts that could result in a large reduction in INPV. Consequently, the Secretary has tentatively concluded that TSL 4 is not economically justified.

DOE then considered TSL 3, which would save an estimated 1.26 quads of energy, an amount DOE considers significant. Under TSL 3, the NPV of consumer benefit would be $749 million using a discount rate of 7 percent, and $2.41 billion using a discount rate of 3 percent.

The cumulative emissions reductions at TSL 3 are 76.7 Mt of CO_2, 43.5 thousand tons of SO_2, 138 thousand tons of NO_X, 0.161 tons of Hg, 326 thousand tons of CH_4, and 0.905 thousand tons of N_2O. The estimated monetary value of the CO_2 emissions reduction at TSL 3 ranges from $0.596 billion to $7.98 billion.

At TSL 3, the average LCC impact is a savings of −$0.08 for VFD UPSs, $6.1 for VI UPSs, and $35 for VFI UPSs. The simple payback period is 2.7 years for VFD UPSs, 4.6 years for VI UPSs, and 4.7 years for VFI UPSs. The fraction of consumers experiencing a net LCC cost is 38 percent for VFD UPSs, 44 percent for VI UPSs, and 2.3 percent for VFI UPSs.

At TSL 3, the projected change in INPV ranges from a decrease of $936 million to an increase of $428 million, which represents a decrease of 36.6 percent to an increase of 16.8 percent, respectively.

After considering the analysis and weighing the benefits and burdens, the Secretary has tentatively concluded that at TSL 3 for UPSs, the benefits of energy savings, overall positive NPV of consumer benefits, emissions reductions, and the estimated monetary value of the emissions reductions would be outweighed by the negative impacts on some consumers and potential negative impacts on manufacturers, including the conversion costs that could result in a reduction in INPV for manufacturers. In particular, the average LCC is negative for the VFD UPS product class. Consequently, the Secretary has tentatively concluded that TSL 3 is not economically justified.

DOE then considered TSL 2, which would save an estimated 1.18 quads of energy, an amount DOE considers significant. Under TSL 2, the NPV of consumer benefit would be $1.87 billion using a discount rate of 7 percent, and $4.40 billion using a discount rate of 3 percent.

The cumulative emissions reductions at TSL 2 are 72.0 Mt of CO_2, 40.9 thousand tons of SO_2, 130 thousand tons of NO_X, 0.151 tons of Hg, 306 thousand tons of CH_4, and 0.850 thousand tons of N_2O. The estimated monetary value of the CO_2 emissions reduction at TSL 2 ranges from $0.559 billion to $7.49 billion.

At TSL 2, the average LCC impact is a savings of $33 for VFD UPSs, $6.1 for VI UPSs, and $35 for VFI UPSs. The simple payback period is immediate for VFD UPSs, 4.6 years for VI UPSs, and 4.7 years for VFI UPSs. The fraction of consumers experiencing a net LCC cost is 0 percent for VFD UPSs, 44 percent for VI UPSs, and 2.3 percent for VFI UPSs.

At TSL 2, the projected change in INPV ranges from a decrease of $598 million to an increase of $295 million, which represents a decrease of 23.4 percent to an increase of 11.5 percent, respectively.

After considering the analysis and weighing the benefits and burdens, the Secretary has tentatively concluded that at TSL 2 for UPSs, the benefits of energy savings, positive NPV of consumer benefits, emission reductions, the estimated monetary value of the emissions reductions, and positive average LCC savings would outweigh the negative impacts on some consumers and on manufacturers, including the conversion costs that could result in a reduction in INPV for manufacturers. Accordingly, the

Secretary has tentatively concluded that TSL 2 would offer the maximum improvement in efficiency that is technologically feasible and economically justified, and would result in the significant conservation of energy.

Therefore, based on the above considerations, DOE proposes to adopt the energy conservation standards for UPSs at TSL 2. The proposed amended energy conservation standards for UPSs are shown in Table V.30.

Table V.30 Proposed Energy Conservation Standards for UPSs

Product Class		Rated Output Power	Minimum Efficiency
10a	VFD UPS	$0\ W < P_{rated} \leq 300\ W$	-1.09E-06 * P_{rated}^2 + 6.50E-04 * P_{rated} + 0.876
		$300\ W < P_{rated} \leq 700\ W$	-5.63E-08 * P_{rated}^2 + 7.61E-05 * P_{rated} + 0.955
		$P_{rated} > 700\ W$	-6.22E-09 * P_{rated}^2 + 3.91E-06 * P_{rated} + 0.981
10b	VI UPS	$0\ W < P_{rated} \leq 300\ W$	-6.45E-07 * P_{rated}^2 + 3.80E-04 * P_{rated} + 0.929
		$300\ W < P_{rated} \leq 700\ W$	-3.94E-08 * P_{rated}^2 + 4.87E-05 * P_{rated} + 0.974
		$P_{rated} > 700\ W$	-2.28E-09 * P_{rated}^2 – 7.40E-07 * P_{rated} + 0.990
10c	VFI UPS	$0\ W < P_{rated} \leq 300\ W$	-3.13E-06 * P_{rated}^2 + 1.96E-03 * P_{rated} + 0.544
		$300\ W < P_{rated} \leq 700\ W$	-2.60E-07 * P_{rated}^2 + 3.65E-04 * P_{rated} + 0.765
		$P_{rated} > 700\ W$	-1.70E-08 * P_{rated}^2 + 3.85E-05 * P_{rated} + 0.877

2. Summary of Annualized Benefits and Costs of the Proposed Standards

The benefits and costs of the proposed standards can also be expressed in terms of annualized values. The annualized net benefit is the sum of (1) the annualized national economic value (expressed in 2015$) of the benefits from operating products that meet the proposed standards (consisting primarily of operating cost savings from using less energy, minus increases in product purchase costs) and (2) the annualized monetary value of the benefits of CO_2 and NO_X emission reductions.[62]

Table V.31 shows the annualized values for UPSs under TSL 2, expressed in 2015$. The results under the primary estimate are as follows.

Using a 7-percent discount rate for benefits and costs other than CO_2 reduction (for which DOE used a 3-percent discount rate along with the average SCC series corresponding to a value of $40.6/t in 2015 (2015$)), the estimated cost of the proposed standards for UPSs is $234 million per year in increased equipment costs, while the estimated annual benefits are $406 million in reduced equipment operating costs, $133 million in CO_2 reductions, and $11.6 million in reduced NO_X emissions. In this case, the net benefit amounts to $317 million per year.

Using a 3-percent discount rate for all benefits and costs and the average SCC series corresponding to a value of $40.6/t in 2015 (2015$), the estimated cost of the proposed standards for UPSs is $250 million per year in increased equipment costs, while the estimated annual benefits are $488 million in reduced operating costs, $133 million in CO_2 reductions, and $14.8 million in reduced NO_X emissions. In this case, the net benefit amounts to $386 million per year.

TABLE V.31—ANNUALIZED BENEFITS AND COSTS OF PROPOSED ENERGY CONSERVATION STANDARDS FOR UPSS (TSL 2)

	Discount rate (%)	*million 2015$/year*		
		Primary estimate *	Low net benefits estimate *	High net benefits estimate *
Benefits				
Consumer Operating Cost Savings.	7	406	348	462.
	3	488	413	565.
CO_2 Reduction Monetized Value ($12.4/t case) **.	5	40.1	35.5	44.4.
CO_2 Reduction Monetized Value ($40.6/t case) **.	3	133	117	148.

[62] To convert the time-series of costs and benefits into annualized values, DOE calculated a present value in 2015, the year used for discounting the NPV of total consumer costs and savings. For the benefits, DOE calculated a present value associated with each year's shipments in the year in which the shipments occur (2020, 2030, *etc.*), and then discounted the present value from each year to 2015. The calculation uses discount rates of 3 and 7 percent for all costs and benefits except for the value of CO_2 reductions, for which DOE used case-specific discount rates. Using the present value, DOE then calculated the fixed annual payment over a 30-year period, starting in the compliance year that yields the same present value.

TABLE V.31—ANNUALIZED BENEFITS AND COSTS OF PROPOSED ENERGY CONSERVATION STANDARDS FOR UPSS (TSL 2)—Continued

	Discount rate (%)	*million 2015$/year*		
		Primary estimate *	Low net benefits estimate *	High net benefits estimate *
CO_2 Reduction Monetized Value ($63.2/t case) **.	2.5	194	171	216.
CO_2 Reduction Monetized Value ($118/t case) **.	3	405	357	451.
NO_X Reduction Monetized Value ‡.	7	11.6	10.4	28.6.
	3	14.8	13.1	37.5.
Total Benefits ‡	7 plus CO_2 range	458 to 823	394 to 716	535 to 941.
	7	551	476	638.
	3 plus CO_2 range	543 to 908	462 to 783	647 to 1,050.
	3	636	544	751.
Costs				
Consumer Incremental Product Costs.	7	234	209	256.
	3	250	221	277.
Net Benefits				
Total ‡	7 plus CO_2 range	224 to 589	185 to 507	278 to 685.
	7	317	267	382.
	3 plus CO_2 range	293 to 658	241 to 563	369 to 776.
	3	386	323	473.

* This table presents the annualized costs and benefits associated with UPSs shipped in 2019 – 2048. These results include benefits to consumers which accrue after 2048 from the products purchased in 2019–2048. The results account for the incremental variable and fixed costs incurred by manufacturers due to the standard, some of which may be incurred in preparation for the rule. The Primary, Low Net Benefits, and High Net Benefits Estimates utilize projections of energy prices from the *AEO 2015* Reference case, Low Economic Growth case, and High Economic Growth case, respectively. Note that the Benefits and Costs may not sum to the Net Benefits due to rounding.

** The CO_2 values represent global monetized values of the SCC, in 2015$ per metric ton (t), in 2015 under several scenarios of the updated SCC values. The first three cases use the averages of SCC distributions calculated using 5-percent, 3-percent, and 2.5-percent discount rates, respectively. The fourth case represents the 95th percentile of the SCC distribution calculated using a 3-percent discount rate. The SCC time series incorporate an escalation factor.

† DOE estimated the monetized value of NO_X emissions reductions associated with electricity savings using benefit per ton estimates from the ''Regulatory Impact Analysis for the Clean Power Plan Final Rule,'' published in August 2015 by EPA's Office of Air Quality Planning and Standards. (Available at *www.epa.gov/cleanpowerplan/clean-power-plan-final-rule-regulatory-impact-analysis.)* See section IV.L for further discussion. For DOE's Primary Estimate and Low Net Benefits Estimate, DOE used a national benefit-per-ton estimate for NO_X emitted from the Electric Generating Unit sector based on an estimate of premature mortality derived from the ACS study (Krewski et al. 2009). For DOE's High Net Benefits Estimate, the benefit-per-ton estimates were based on the Six Cities study (Lepuele et al. 2011), which are nearly two-and-a-half times larger than those from the ACS study.

‡ Total Benefits for both the 3% and 7% cases are derived using the series corresponding to the average SCC with a 3-percent discount rate ($40.6/t case). In the rows labeled ''7% plus CO_2 range'' and ''3% plus CO_2 range,'' the operating cost and NO_X benefits are calculated using the labeled discount rate, and those values are added to the full range of CO_2 values.

VI. Procedural Issues and Regulatory Review

A. Review Under Executive Orders 12866 and 13563

Section 1(b)(1) of Executive Order 12866, ''Regulatory Planning and Review,'' 58 FR 51735 (Oct. 4, 1993), requires each agency to identify the problem that it intends to address, including, where applicable, the failures of private markets or public institutions that warrant new agency action, as well as to assess the significance of that problem. The problems that the proposed standards set forth in this NOPR are intended to address are as follows:

(1) Insufficient information and the high costs of gathering and analyzing relevant information leads some consumers to miss opportunities to make cost-effective investments in energy efficiency.

(2) In some cases, the benefits of more-efficient equipment are not realized due to misaligned incentives between purchasers and users. An example of such a case is when the equipment purchase decision is made by a building contractor or building owner who does not pay the energy costs.

(3) There are external benefits resulting from improved energy efficiency of appliances and equipment that are not captured by the users of such products. These benefits include externalities related to public health, environmental protection, and national energy security that are not reflected in energy prices, such as reduced emissions of air pollutants and greenhouse gases that impact human health and global warming. DOE attempts to quantify some of the external benefits through use of social cost of carbon values.

The Administrator of the Office of Information and Regulatory Affairs (OIRA) in the OMB has determined that the proposed regulatory action is a significant regulatory action under section (3)(f) of Executive Order 12866. Accordingly, pursuant to section 6(a)(3)(B) of the Order, DOE has provided to OIRA: (i) The text of the draft regulatory action, together with a reasonably detailed description of the need for the regulatory action and an explanation of how the regulatory action will meet that need; and (ii) An assessment of the potential costs and benefits of the regulatory action, including an explanation of the manner in which the regulatory action is

consistent with a statutory mandate. DOE has included these documents in the rulemaking record.

In addition, the Administrator of OIRA has determined that the proposed regulatory action is an ''economically'' significant regulatory action under section (3)(f)(1) of Executive Order 12866. Accordingly, pursuant to section 6(a)(3)(C) of the Order, DOE has provided to OIRA an assessment, including the underlying analysis, of benefits and costs anticipated from the regulatory action, together with, to the extent feasible, a quantification of those costs; and an assessment, including the underlying analysis, of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation, and an explanation why the planned regulatory action is preferable to the identified potential alternatives. These assessments can be found in the technical support document for this rulemaking.

DOE has also reviewed this regulation pursuant to Executive Order 13563, issued on January 18, 2011. 76 FR 3281 (Jan. 21, 2011). Executive Order 13563 is supplemental to and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, agencies are required by Executive Order 13563 to: (1) Propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify); (2) tailor regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations; (3) select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity); (4) to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and (5) identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.

DOE emphasizes as well that Executive Order 13563 requires agencies to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible. In its guidance, OIRA has emphasized that such techniques may include identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes. For the reasons stated in the preamble, DOE believes that this NOPR is consistent with these principles, including the requirement that, to the extent permitted by law, benefits justify costs and that net benefits are maximized.

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis (IRFA) for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by Executive Order 13272, ''Proper Consideration of Small Entities in Agency Rulemaking,'' 67 FR 53461 (Aug. 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the Office of the General Counsel's Web site (*http://energy.gov/gc/office-general-counsel*).

For manufacturers of UPSs, the Small Business Administration (SBA) has set a size threshold, which defines those entities classified as ''small businesses'' for the purposes of the statute. DOE used the SBA's small business size standards to determine whether any small entities would be subject to the requirements of the rule. See 13 CFR part 121. The size standards are listed by North American Industry Classification System (NAICS) code and industry description and are available at *https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf*

UPS manufacturing is classified under NAICS 335999, ''All Other Miscellaneous Electrical Equipment and Component Manufacturing.'' The SBA sets a threshold of 500 employees or less for an entity to be considered as a small business manufacturer of those product classes.

To estimate the number of companies that could be small businesses that manufacture or sell UPSs covered by this rulemaking, DOE conducted a market survey using publicly available information. DOE first attempted to identify all potential UPS manufacturers by researching certification databases (*e.g.,* DOE's Compliance Database and EPA's ENERGY STAR,[63]) retailer Web sites, individual company Web sites, and the SBA's database. DOE then attempted to gather information on the location and number of employees to determine if these companies met SBA's definition of a small business for each potential UPS manufacturer by reaching out directly to those potential small businesses and using market research tools (*e.g., www.hoovers.com*, *www.manta.com*, *www.glassdoor.com*, *www.linkedin.com*, etc.). DOE also asked stakeholders and industry representatives if they were aware of any small businesses during manufacturer interviews. DOE used information from these sources to create a list of companies that potentially manufacture or sell UPSs and would be impacted by this rulemaking. DOE eliminated companies that do not meet the definition of a ''small business,'' or are completely foreign owned and operated.

DOE initially identified a total of 48 potential companies that sell UPSs in the United States. Of these, DOE estimated that 12 are small business. After reviewing publicly available information on these potential small UPS businesses, DOE determined that none of these businesses manufacture the UPSs that they sell in the United States or are subsidiaries of the foreign companies that manufacture UPSs. Additionally it is not thought that DOE's regulation of UPSs will put small businesses in the U.S. that purchase UPSs from foreign manufacturers at a competitive disadvantage in the marketplace, because these companies are not responsible for the conversion costs to comply with standards as these UPS companies do not own the manufacturing facilities and tooling used to produce UPSs. Because there are no domestic small business UPS manufacturers, DOE's UPS regulation will not have a direct effect on U.S. small business in this manufacturing space. As such, DOE certifies that this proposed rulemaking will not have a significant economic impact on a substantial number of small entities, and the preparation of an IRFA is not warranted.

DOE will provide its certification and supporting statement of factual basis to the Chief Counsel for Advocacy of the SBA for review under 5 U.S.C. 605(b). DOE seeks comment on its tentative conclusion that the proposed standard will not have a significant impact on a substantial number of small entities.

[63] ENERGY STAR. Energy Star Certified Products. Last accessed May 4, 2015. < *http://www.energystar.gov/*>.

C. Review Under the Paperwork Reduction Act

Manufacturers of UPSs must certify to DOE that their products comply with any applicable energy conservation standards. In certifying compliance, manufacturers must test their products according to the DOE test procedure for UPSs, including any amendments adopted for that test procedure. DOE has established regulations for the certification and recordkeeping requirements for all covered consumer products and commercial equipment. 76 FR 12422 (March 7, 2011). The collection-of-information requirement for the certification and recordkeeping is subject to review and approval by OMB under the Paperwork Reduction Act (PRA). This requirement has been approved by OMB under OMB control number 1910–1400. DOE requested OMB approval of an extension of this information collection for three years, specifically including the collection of information for battery chargers, and estimated that the annual number of burden hours under this extension is 30 hours per company. In response to DOE's request, OMB approved DOE's information collection requirements covered under OMB control number 1910–1400 through November 30, 2017. 80 FR 5099 (January 30, 2015).

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

D. Review Under the National Environmental Policy Act of 1969

Pursuant to the National Environmental Policy Act (NEPA) of 1969, DOE has determined that the proposed rule fits within the category of actions included in Categorical Exclusion (CX) B5.1 and otherwise meets the requirements for application of a CX. (See 10 CFR part 1021, App. B, B5.1(b); 1021.410(b) and App. B, B(1)–(5).) The proposed rule fits within this category of actions because it is a rulemaking that establishes energy conservation standards for consumer products or industrial equipment, and for which none of the exceptions identified in CX B5.1(b) apply. Therefore, DOE has made a CX determination for this rulemaking, and DOE does not need to prepare an Environmental Assessment or Environmental Impact Statement for this proposed rule. DOE's CX determination for this proposed rule is available at *http://energy.gov/nepa/categorical-exclusion-cx-determinations-cx/*.

E. Review Under Executive Order 13132

Executive Order 13132, ''Federalism,'' 64 FR 43255 (Aug. 10, 1999), imposes certain requirements on Federal agencies formulating and implementing policies or regulations that preempt State law or that have Federalism implications. The Executive Order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive Order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have Federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. 65 FR 13735. DOE has examined this proposed rule and has tentatively determined that it would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. EPCA governs and prescribes Federal preemption of State regulations as to energy conservation for the products that are the subject of this proposed rule. States can petition DOE for exemption from such preemption to the extent, and based on criteria, set forth in EPCA. (42 U.S.C. 6297) Therefore, no further action is required by Executive Order 13132.

F. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, ''Civil Justice Reform,'' imposes on Federal agencies the general duty to adhere to the following requirements (1) eliminate drafting errors and ambiguity, (2) write regulations to minimize litigation, (3) provide a clear legal standard for affected conduct rather than a general standard, and (4) promote simplification and burden reduction. 61 FR 4729 (Feb. 7, 1996). Regarding the review required by section 3(a), section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) clearly specifies the preemptive effect, if any, (2) clearly specifies any effect on existing Federal law or regulation, (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction, (4) specifies the retroactive effect, if any, (5) adequately defines key terms, and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this proposed rule meets the relevant standards of Executive Order 12988.

G. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. Public Law 104–4, sec. 201 (codified at 2 U.S.C. 1531). For a proposed regulatory action likely to result in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a), (b)) The UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a proposed ''significant intergovernmental mandate,'' and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect them. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820. DOE's policy statement is also available at *http://energy.gov/sites/prod/files/gcprod/documents/umra_97.pdf*.

Although this proposed rule does not contain a Federal intergovernmental mandate, it may require expenditures of $100 million or more in any one year by the private sector. Such expenditures may include: (1) investment in research and development and in capital expenditures by UPS manufacturers in the years between the final rule and the

compliance date for the new standards, and (2) incremental additional expenditures by consumers to purchase higher-efficiency UPS, starting at the compliance date for the applicable standard.

Section 202 of UMRA authorizes a Federal agency to respond to the content requirements of UMRA in any other statement or analysis that accompanies the proposed rule. (2 U.S.C. 1532(c)) The content requirements of section 202(b) of UMRA relevant to a private sector mandate substantially overlap the economic analysis requirements that apply under section 325(o) of EPCA and Executive Order 12866. The **SUPPLEMENTARY INFORMATION** section of this NOPR and the TSD for this proposed rule respond to those requirements.

Under section 205 of UMRA, the Department is obligated to identify and consider a reasonable number of regulatory alternatives before promulgating a rule for which a written statement under section 202 is required. (2 U.S.C. 1535(a)) DOE is required to select from those alternatives the most cost-effective and least burdensome alternative that achieves the objectives of the proposed rule unless DOE publishes an explanation for doing otherwise, or the selection of such an alternative is inconsistent with law. As required by 42 U.S.C. 6295(d), (f), and (o), 6313(e), and 6316(a), this proposed rule would establish new energy conservation standards for UPS that are designed to achieve the maximum improvement in energy efficiency that DOE has determined to be both technologically feasible and economically justified. A full discussion of the alternatives considered by DOE is presented in chapter 17 of the TSD for this proposed rule.

H. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Public Law 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. This rule would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

I. Review Under Executive Order 12630

Pursuant to Executive Order 12630, ''Governmental Actions and Interference with Constitutionally Protected Property Rights,'' 53 FR 8859 (March 15, 1988), DOE has determined that this proposed rule would not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

J. Review Under the Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note) provides for Federal agencies to review most disseminations of information to the public under information quality guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's guidelines were published at 67 FR 62446 (Oct. 7, 2002). DOE has reviewed this NOPR under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

K. Review Under Executive Order 13211

Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,'' 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to OIRA at OMB, a Statement of Energy Effects for any proposed significant energy action. A ''significant energy action'' is defined as any action by an agency that promulgates or is expected to lead to promulgation of a final rule, and that (1) is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy, or (3) is designated by the Administrator of OIRA as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use.

DOE has tentatively concluded that this regulatory action, which proposes new energy conservation standards for UPS, is not a significant energy action because the proposed standards are not likely to have a significant adverse effect on the supply, distribution, or use of energy, nor has it been designated as such by the Administrator at OIRA. Accordingly, DOE has not prepared a Statement of Energy Effects on this proposed rule.

L. Review Under the Information Quality Bulletin for Peer Review

On December 16, 2004, OMB, in consultation with the Office of Science and Technology Policy (OSTP), issued its Final Information Quality Bulletin for Peer Review (the Bulletin). 70 FR 2664 (Jan. 14, 2005). The Bulletin establishes that certain scientific information shall be peer reviewed by qualified specialists before it is disseminated by the Federal Government, including influential scientific information related to agency regulatory actions. The purpose of the bulletin is to enhance the quality and credibility of the Government's scientific information. Under the Bulletin, the energy conservation standards rulemaking analyses are ''influential scientific information,'' which the Bulletin defines as ''scientific information the agency reasonably can determine will have, or does have, a clear and substantial impact on important public policies or private sector decisions.'' *Id.* at FR 2667.

In response to OMB's Bulletin, DOE conducted formal in-progress peer reviews of the energy conservation standards development process and analyses and has prepared a Peer Review Report pertaining to the energy conservation standards rulemaking analyses. Generation of this report involved a rigorous, formal, and documented evaluation using objective criteria and qualified and independent reviewers to make a judgment as to the technical/scientific/business merit, the actual or anticipated results, and the productivity and management effectiveness of programs and/or projects. The ''Energy Conservation Standards Rulemaking Peer Review Report'' dated February 2007 has been disseminated and is available at the following Web site: *www.energy.gov/eere/buildings/peer-review*.

VII. Public Participation

A. Attendance at the Public Meeting

The time, date, and location of the public meeting are listed in the DATES and **ADDRESSES** sections at the beginning of this proposed rule. If you plan to attend the public meeting, please notify the Appliance and Equipment Standards Staff at (202) 586–6636 or *Appliance_Standards_Public_Meetings@ee.doe.gov*.

Please note that foreign nationals visiting DOE Headquarters are subject to advance security screening procedures which require advance notice prior to attendance at the public meeting. If a foreign national wishes to participate in the public meeting, please inform DOE

of this fact as soon as possible by contacting Ms. Regina Washington at (202) 586–1214 or by email (*Regina.Washington@ee.doe.gov)* so that the necessary procedures can be completed.

DOE requires visitors to have laptops and other devices, such as tablets, checked upon entry into the Forrestal Building. Any person wishing to bring these devices into the building will be required to obtain a property pass. Visitors should avoid bringing these devices, or allow an extra 45 minutes to check in. Please report to the visitor's desk to have devices checked before proceeding through security.

Due to the REAL ID Act implemented by the Department of Homeland Security (DHS), there have been recent changes regarding identification (ID) requirements for individuals wishing to enter Federal buildings from specific States and U.S. territories. As a result, driver's licenses from several States or territory will not be accepted for building entry, and instead, one of the alternate forms of ID listed below will be required. DHS has determined that regular driver's licenses (and ID cards) from the following jurisdictions are not acceptable for entry into DOE facilities: Alaska, American Samoa, Arizona, Louisiana, Maine, Massachusetts, Minnesota, New York, Oklahoma, and Washington. Acceptable alternate forms of Photo-ID include: U.S. Passport or Passport Card; an Enhanced Driver's License or Enhanced ID-Card issued by the States of Minnesota, New York, or Washington (Enhanced licenses issued by these States are clearly marked Enhanced or Enhanced Driver's License); a military ID or other Federal government-issued Photo-ID card.

In addition, you can attend the public meeting via webinar. Webinar registration information, participant instructions, and information about the capabilities available to webinar participants will be published on DOE's Web site at *https://www1.eere.energy.gov/buildings/appliance_standards/standards.aspx?productid=26*. Participants are responsible for ensuring their systems are compatible with the webinar software.

B. Procedure for Submitting Prepared General Statements for Distribution

Any person who has plans to present a prepared general statement may request that copies of his or her statement be made available at the public meeting. Such persons may submit requests, along with an advance electronic copy of their statement in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format, to the appropriate address shown in the **ADDRESSES** section at the beginning of this proposed rule. The request and advance copy of statements must be received at least one week before the public meeting and may be emailed, hand-delivered, or sent by mail. DOE prefers to receive requests and advance copies via email. Please include a telephone number to enable DOE staff to make follow-up contact, if needed.

C. Conduct of the Public Meeting

DOE will designate a DOE official to preside at the public meeting and may also use a professional facilitator to aid discussion. The meeting will not be a judicial or evidentiary-type public hearing, but DOE will conduct it in accordance with section 336 of EPCA. (42 U.S.C. 6306) A court reporter will be present to record the proceedings and prepare a transcript. DOE reserves the right to schedule the order of presentations and to establish the procedures governing the conduct of the public meeting. There shall not be discussion of proprietary information, costs or prices, market share, or other commercial matters regulated by U.S. anti-trust laws. After the public meeting, interested parties may submit further comments on the proceedings, as well as on any aspect of the rulemaking, until the end of the comment period.

The public meeting will be conducted in an informal, conference style. DOE will present summaries of comments received before the public meeting, allow time for prepared general statements by participants, and encourage all interested parties to share their views on issues affecting this rulemaking. Each participant will be allowed to make a general statement (within time limits determined by DOE), before the discussion of specific topics. DOE will allow, as time permits, other participants to comment briefly on any general statements.

At the end of all prepared statements on a topic, DOE will permit participants to clarify their statements briefly and comment on statements made by others. Participants should be prepared to answer questions by DOE and by other participants concerning these issues. DOE representatives may also ask questions of participants concerning other matters relevant to this rulemaking. The official conducting the public meeting will accept additional comments or questions from those attending, as time permits. The presiding official will announce any further procedural rules or modification of the above procedures that may be needed for the proper conduct of the public meeting.

A transcript of the public meeting will be included in the docket, which can be viewed as described in the *Docket* section at the beginning of this document and will be accessible on the DOE Web site. In addition, any person may buy a copy of the transcript from the transcribing reporter.

D. Submission of Comments

DOE will accept comments, data, and information regarding this proposed rule before or after the public meeting, but no later than the date provided in the **DATES** section at the beginning of this proposed rule. Interested parties may submit comments, data, and other information using any of the methods described in the **ADDRESSES** section at the beginning of this document.

Submitting comments via *www.regulations.gov*. The *www.regulations.gov* Web page will require you to provide your name and contact information. Your contact information will be viewable to DOE Building Technologies staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment.

However, your contact information will be publicly viewable if you include it in the comment itself or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment. Otherwise, persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to *www.regulations.gov* information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as Confidential Business Information (CBI)). Comments submitted through *www.regulations.gov* cannot be claimed as CBI. Comments received through the Web site will waive any CBI claims for the information submitted. For information on submitting CBI, see the Confidential Business Information section below.

DOE processes submissions made through *www.regulations.gov* before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that *www.regulations.gov* provides after you have successfully uploaded your comment.

Submitting comments via email, hand delivery/courier, or mail. Comments and documents submitted via email, hand delivery/courier, or mail also will be posted to *www.regulations.gov*. If you do not want your personal contact information to be publicly viewable, do not include it in your comment or any accompanying documents. Instead, provide your contact information in a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. The cover letter will not be publicly viewable as long as it does not include any comments.

Include contact information each time you submit comments, data, documents, and other information to DOE. If you submit via mail or hand delivery/courier, please provide all items on a CD, if feasible, in which case it is not necessary to submit printed copies. No telefacsimiles (faxes) will be accepted.

Comments, data, and other information submitted to DOE electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are not secured, that are written in English, and that are free of any defects or viruses. Documents should not contain special characters or any form of encryption and, if possible, they should carry the electronic signature of the author.

Campaign form letters. Please submit campaign form letters by the originating organization in batches of between 50 to 500 form letters per PDF or as one form letter with a list of supporters' names compiled into one or more PDFs. This reduces comment processing and posting time.

Confidential Business Information. Pursuant to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email, postal mail, or hand delivery/courier two well-marked copies: One copy of the document marked ''confidential'' including all the information believed to be confidential, and one copy of the document marked ''non-confidential'' with the information believed to be confidential deleted. Submit these documents via email or on a CD, if feasible. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

Factors of interest to DOE when evaluating requests to treat submitted information as confidential include (1) a description of the items, (2) whether and why such items are customarily treated as confidential within the industry, (3) whether the information is generally known by or available from other sources, (4) whether the information has previously been made available to others without obligation concerning its confidentiality, (5) an explanation of the competitive injury to the submitting person that would result from public disclosure, (6) when such information might lose its confidential character due to the passage of time, and (7) why disclosure of the information would be contrary to the public interest.

It is DOE's policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

E. Issues on Which DOE Seeks Comment

Although DOE welcomes comments on any aspect of this proposal, DOE is particularly interested in receiving comments and views of interested parties concerning the following issues:

(1) DOE requests comments on the potential technology options identified for improving the efficiency of UPSs. See section IV.A.2 for further detail.

(2) DOE requests comment on its screening analysis used to select the most viable options for consideration in setting this proposed standards. See section IV.B.2 for further detail.

(3) DOE requests comment on the ELs selected for each product class for its analysis. See section IV.C.2 for further detail.

(4) DOE requests comment on its understanding of why less efficient UPSs continue to exist in the market place at a price higher than more efficient units. See section IV.C.3 for further detail.

(5) DOE requests further comment on the average loading conditions for UPS product classes. See section IV.E for further detail.

(6) DOE requests additional information on UPS shipment volumes and projections. See section IV.G for further detail.

(7) DOE requests comment on commercial and residential price elasticity data for UPS product classes. See section IV.G for further detail.

(8) DOE requests comment or data that may inform historical or forecasted efficiency trends for UPSs. See section IV.H for further detail.

(9) DOE seeks comment on its use of 6.1 percent as a discount rate for UPS manufacturers. See section IV.J.2 for further detail.

(10) DOE seeks comment on its determination that product redesigns necessary to meet the ELs required by the proposed standard would not require investments in equipment and tooling, and on its determination that the majority of product design cycles would either take place before or coincide with the compliance period of the potential standards for UPSs. See section IV.J.2.a for further detail.

(11) DOE seeks comment on its methodology used to calculate product conversion costs, including the assumption of no capital conversion costs or stranded assets for UPS manufacturers at analyzed ELs. See section IV.J.2.a for further detail.

(12) DOE seeks comment on its methodology used to calculate manufacturer markups, its use of different manufacturer markups for each product class, and the specific manufacturer markups DOE estimated for each UPS product class. See section IV.J.2.d for further detail.

(13) DOE seeks comment on its determination that all UPS manufacturing takes place abroad. Additionally, DOE seeks comment on the presence of any domestic UPS manufacturing beyond assembly, R&D, testing, and certification, and if there are any potential negative impacts to domestic employment that could arise due to energy conservation standards on UPSs that are not fully captured by the direct employment impact analysis. See section V.B.2.b for further detail.

(14) DOE seeks comment on any potential UPS component manufacturer capacity constraints caused by the proposed standards in this NOPR. See section V.B.2.c for further detail.

(15) DOE seeks comment on any other manufacturer subgroups that DOE should analyze and/or types of UPS manufacturers for the manufacturer subgroup analysis, including the identification of UPS manufacturer subgroups that should be analyzed separately. See section V.B.2.d for further detail.

(16) DOE seeks comment on the compliance costs that UPS manufacturers must make for any other regulations, especially if compliance with those regulations is required within three years before or after the estimated compliance year of this

proposed standard (2019). See section V.B.2.e for further detail.

(17) DOE seeks comment on its tentative conclusion that the proposed standard will not have a significant impact on a substantial number of small entities. See section VI.B.3 for further detail.

(18) DOE invites comment from the public regarding the competitive impacts that are likely to result from this proposed rule. In addition, stakeholders may also provide comments separately to DOJ regarding these potential impacts. See **ADDRESSES** section for information to send comments to DOJ. See section V.B.5 for further detail.

VIII. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this notice of proposed rulemaking.

List of Subjects in 10 CFR Part 430

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Incorporation by reference, Intergovernmental relations, Small businesses.

Issued in Washington, DC, on July 25, 2016.

David Friedman,

Acting Assistant Secretary, Energy Efficiency and Renewable Energy.

For the reasons set forth in the preamble, DOE proposes to amend part 430 of chapter II, subchapter D, of title 10 of the Code of Federal Regulations, as set forth below:

PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS

■ 1. The authority citation for part 430 continues to read as follows:

Authority: 42 U.S.C. 6291–6309; 28 U.S.C. 2461 note.

■ 2. Section 430.32 is amended by adding paragraph (z)(3) to read as follows:

§ 430.32 Energy and water conservation standards and their effective dates.

* * * * *

(z) * * *

(3) All uninterruptible power supplies (UPS) manufactured on and after [*DATE 2 years after final rule* **Federal Register** *publication*], shall have an average load adjusted efficiency that meets or exceeds the values shown in the table below based on the rated output power (P_{rated}) of the UPS.

Battery Charger Product Class	Rated Output Power	Minimum Efficiency
10a	$0\ W < P_{rated} \leq 300\ W$	-1.09E-06 * P_{rated}^2 + 6.50E-04 * P_{rated} + 0.876
	$300\ W < P_{rated} \leq 700\ W$	-5.63E-08 * P_{rated}^2 + 7.61E-05 * P_{rated} + 0.955
	$P_{rated} > 700\ W$	-6.22E-09 * P_{rated}^2 + 3.91E-06 * P_{rated} + 0.981
10b	$0\ W < P_{rated} \leq 300\ W$	-6.45E-07 * P_{rated}^2 + 3.80E-04 * P_{rated} + 0.929
	$300\ W < P_{rated} \leq 700\ W$	-3.94E-08 * P_{rated}^2 + 4.87E-05 * P_{rated} + 0.974
	$P_{rated} > 700\ W$	-2.28E-09 * P_{rated}^2 – 7.40E-07 * P_{rated} + 0.990
10c	$0\ W < P_{rated} \leq 300\ W$	-3.13E-06 * P_{rated}^2 + 1.96E-03 * P_{rated} + 0.544
	$300\ W < P_{rated} \leq 700\ W$	-2.60E-07 * P_{rated}^2 + 3.65E-04 * P_{rated} + 0.765
	$P_{rated} > 700\ W$	-1.70E-08 * P_{rated}^2 + 3.85E-05 * P_{rated} + 0.877

[FR Doc. 2016–18446 Filed 8–4–16; 8:45 am]

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Part VI

Department of the Interior

Fish and Wildlife Service

50 CFR Parts 32 and 36
Non-Subsistence Take of Wildlife, and Public Participation and Closure Procedures, on National Wildlife Refuges in Alaska; Final Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Parts 32 and 36

[Docket No. FWS–R7–NWRS–2014–0005; FF07R00000 FXRS12610700000 156 Obligation #4500093321]

RIN 1018–BA31

Non-Subsistence Take of Wildlife, and Public Participation and Closure Procedures, on National Wildlife Refuges in Alaska

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service or FWS), are amending regulations for National Wildlife Refuges (NWRs) in Alaska that govern predator control and public participation and closure procedures. The amendments to the regulations are designed to clarify how our existing mandates for the conservation of natural and biological diversity, biological integrity, and environmental health on refuges in Alaska relate to predator control; prohibit several particularly effective methods and means for take of predators; and update our public participation and closure procedures. This rule does not change Federal subsistence regulations or restrict the taking of fish or wildlife for subsistence uses under Federal subsistence regulations.

DATES: This rule is effective September 6, 2016.

FOR FURTHER INFORMATION CONTACT: Stephanie Brady, Chief of Conservation Planning and Policy, or Carol Damberg, Inventory and Monitoring Biologist, National Wildlife Refuge System, Alaska Regional Office, 1011 E. Tudor Rd., Mail Stop 211, Anchorage, AK 99503; telephone (907) 306–7448 or (907) 786–3327. If you use a telecommunications device for the deaf (TDD), call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Background

Proposed Rule and Public Comment Period

On January 8, 2016, we published a proposed rule in the **Federal Register** (81 FR 887) to amend our regulations for refuges in Alaska to clarify how our existing mandates for the conservation of natural and biological diversity, biological integrity, and environmental health on refuges in Alaska relate to predator control; to prohibit several particularly effective methods and means for take of predators; and to update our public participation and closure procedures. The proposed rule was initially open for public comment for 60 days, ending March 8, 2016. On February 26, 2016, we extended the comment period by 30 days, which resulted in a 90-day comment period on the proposed rule ending on April 7, 2016 (see 81 FR 9799). We invited comments through the U.S. mail or hand delivery, through the Federal eRulemaking Portal at *http://www.regulations.gov,* and at scheduled public hearings (see our announcement of the public hearings at 81 FR 886; January 8, 2016).

During the comment period, we held nine public hearings on the proposed rule (January 26, 2016, in Kotzebue, AK; February 8, 2016, in Bethel, AK; February 10, 2016, in Fairbanks, AK; February 11, 2016, in Tok, AK; February 16, 2016, in Soldotna, AK; February 18, 2016, in Anchorage, AK; March 1, 2016, in Dillingham, AK; March 2, 2016, in Kodiak, AK; and March 3, 2016, in Galena, AK). Approximately 218 individuals attended these hearings, and 104 participants provided testimony during the public hearings. We also offered to consult in person with Tribes and Alaska Native Claims Settlement Act, 43 U.S.C. 1601 *et seq.* (ANCSA or Native), corporations and attended numerous Regional Advisory Council (RAC) meetings. Correspondence was received from 28 tribal entities (Native nonprofits, Tribal Governments, RACs) and from four ANCSA corporations. We met with eight Tribes and one ANCSA corporation that requested consultation in person or via conference call: Allakaket Council, Alatna Council, Doyon Corporation, Gwichyaa Zhee Tribal Council, Kaktovik Tribal Council, Nulato Tribe, Togiak Tribal Council, Native Village of Venetie Tribal Council, and Venetie Village Council.

We received approximately 3,643 pieces of correspondence on the proposed rule during the public comment period, and from the correspondence, we derived over 80 comment statements (a comment statement is a portion of the text within a correspondence that addresses a single subject). Correspondence included unique comment letters and form letters. Approximately 2,530 correspondence documents were form letters. Approximately 409 pieces of correspondence received provided substantive comments. Some commenters sent comments by multiple methods. We attempted to match such duplicates and count them as one comment. Additionally, many comments were signed by more than one person. We counted a letter as a single comment, regardless of the number of signatories. A summary of comments and FWS responses is provided below in the section entitled Summary of and Response to Public Comments. After considering the public comments and conducting additional review, FWS made some changes in this final rule from that proposed. These changes are summarized below in the table entitled, Summary of primary differences between our proposed rule and this final rule.

Federal and State Mandates for Managing Wildlife

FWS and the State of Alaska work together to manage fish and wildlife in the National Wildlife Refuge System (NWR System). State fish and wildlife authority remains the comprehensive management backdrop in the absence of specific, overriding Federal law which exists for specific statutory purposes. As explained below, FWS has ultimate management authority over resources in the Federal NWR System pursuant to a variety of statutes. However, effective stewardship of fish and wildlife resources, various statutory provisions, and Department of the Interior policy require close cooperation with the State. Indeed, as a general rule, State regulations governing hunting and fishing on refuges in Alaska are adopted with exceptions tailored to the purpose of each refuge and the relevant Federal authority.

1. Federal Authorities

FWS has various mandates it must adhere to in managing the National Wildlife Refuge System (NWR System). There are three statutes in particular that provide direction and authority specific to NWRs in Alaska: The 1980 Alaska National Interest Lands Conservation Act (ANILCA; 16 U.S.C. 3111–3126); the National Wildlife Administration Act of 1966 (Administration Act) as amended by the National Wildlife Refuge System Improvement Act of 1997 (Improvement Act) (16 U.S.C. 668dd-ee); and the 1964 Wilderness Act (16 U.S.C. 1131-1136).

The Improvement Act provides that ANILCA controls if there is a conflict between the two. ANILCA added approximately 54 million acres of land to the NWR System in Alaska, by establishing new NWRs or expanding and redesignating existing NWRs. ANILCA also designated 18.7 million acres in 13 wilderness areas on refuges in Alaska as units of the National Wilderness Preservation System.

Under ANILCA, each refuge in Alaska has a list of purposes for which it was established, including the first-listed purpose to ''conserve fish and wildlife populations and habitats in their natural diversity'' followed by a list of representative species particular to each refuge. Kenai NWR has an additional statutory purpose to provide opportunities for fish and wildlife-oriented recreation in a manner compatible with these purposes. The other purposes established by ANILCA for Alaska refuges (except international treaty obligations) must be managed consistent with the purpose to conserve fish and wildlife populations and habitats in their natural diversity. Legislative history for ANILCA provides important guidance on the intent and meaning of the term ''natural diversity.'' The 1979 Senate Report on H.R. 39 (ANILCA) states that refuges represent, ''the opportunity to manage these areas on a planned ecosystem-wide basis with all of their pristine ecological processes intact'' (S. Rep. No. 96–413 at 174 (1979), *reprinted in* the 1980 United States Code Congressional and Administrative News (U.S.C.C.A.N.) 5118). During consideration of the concurrent resolution to correct the enrollment of H.R. 39 (ANILCA), Alaska's U.S. Senator Ted Stevens submitted statements explaining H.R. 39 that included the following regarding ''natural diversity'' (126 Cong. Rec. S15131 (Dec. 1, 1980)): ''Sections 302 and 303 of title III designate as a major purpose of each new or expanding refuge the conservation of fish and wildlife populations and habitats 'in their natural diversity.' The phrase 'in their natural diversity' was included in each subsection of those two sections to emphasize the importance of maintaining the flora and fauna within each refuge in a healthy condition. The term is not intended to, in any way, restrict the authority of the Fish and Wildlife Service to manipulate habitat for the benefit of fish or wildlife populations within a refuge or for the benefit of the use of such populations by man as part of the balanced management program mandated by the Alaska National Interest Lands Conservation Act and other applicable law. The term also is not intended to preclude predator control on refuge lands in appropriate instances.'' Senator Stevens goes on to state, ''Section 815(1) recognizes this difference by providing that the level of subsistence uses within a National Park or National Park Monument may not be inconsistent with the conservation of 'natural and healthy' fish and wildlife populations within the park or monument, while within National Wildlife Refuges the level of subsistence uses of such populations may not be inconsistent with the conservation of 'healthy' populations.''

Nine days after ANILCA was signed into law on December 2, 1980, Congressman Morris Udall, Chairman of the Committee on Interior and Insular Affairs and Floor Manager for H.R. 39, during a speech on the floor of the House of Representatives described the source of the term ''natural diversity.'' He stated that the conservation of natural diversity refers to ''protecting and managing all fish and wildlife populations within a particular wildlife refuge system unit in the natural 'mix,' not to emphasize management activities favoring one species to the detriment of another'' (126 Cong. Rec. H12, 352–53 (daily ed. Dec. 11, 1980) (statement of Rep. Udall)). During this floor speech, Congressman Udall also stated that in managing for natural diversity it was the intent of Congress, ''to direct the U.S. Fish and Wildlife Service to the best of its ability, . . . to manage wildlife refuges to assure that habitat diversity is maintained through natural means, avoiding artificial developments and habitat manipulation programs. . .; to assure that wildlife refuge management fully considers the fact that humans reside permanently within the boundaries of some areas and are dependent, . . . on wildlife refuge subsistence resources; and to allow management flexibility in developing new and innovative management programs different from lower 48 standards, but in the context of maintaining natural diversity of fish and wildlife populations and their dependent habitats for the long term benefit of all citizens'' (126 Cong. Rec. H12, 352–53 (daily ed. Dec. 11, 1980) (statement of Rep. Udall)).

Although the above congressional testimonies provide slightly differing views about what is encompassed by managing for natural diversity, there is a common theme to protect and maintain the flora and fauna within each refuge while providing opportunities for subsistence under Title VIII of ANILCA. This legislative history, other ANILCA background documentation, and FWS laws, mandates, and policies serve to guide refuge management to meet the natural diversity purpose language of ANILCA and were used to develop the definition of natural diversity contained in this rule.

In its ANILCA Title VIII statement of policy, Congress also stated, ''nonwasteful subsistence uses of fish and wildlife and other renewable resources [by rural residents] shall be the priority consumptive uses of all such resources on the public lands of Alaska when it is necessary to restrict taking in order to assure the continued viability of a fish or wildlife population or the continuation of subsistence uses of such population, the taking of such population for nonwasteful subsistence uses shall be given preference on the public land over other consumptive uses'' (16 U.S.C. 3112(2)). This subsistence priority applies within all National Wildlife Refuges in Alaska.

All refuges in Alaska (except Kenai National Wildlife Refuge) have among their stated statutory purposes the requirement to provide the opportunity for continued subsistence use by local rural residents in a manner consistent with the conservation of fish and wildlife populations and habitats in their natural diversity and fulfilling the international treaty obligations of the United States with respect to fish and wildlife and their habitats. In a further statement of ANILCA Title VIII policy, Congress stated that ''consistent with sound management principles, and the conservation of healthy populations of fish and wildlife, the utilization of the public lands in Alaska is to cause the least adverse impact possible on rural residents who depend upon subsistence uses of the resources of such lands; consistent with management of fish and wildlife in accordance with recognized scientific principles and the purposes for each unit established . . . the purpose of this title [Title VIII] is to provide the opportunity for rural residents engaged in a subsistence way of life to do so'' (16 U.S.C. 3112(1)). The Senate Committee on Energy and Natural Resources in its report on H.R. 39 stated that ''the phrase 'the conservation of healthy populations of fish and wildlife' is to mean the maintenance of fish and wildlife resources in their habitats in a condition which assures stable and continuing natural populations and species mix of plants and animals in relation to their ecosystems, including recognition that local rural residents engaged in subsistence uses may be a natural part of that ecosystem . . .'' (S. Rep. No. 96–413 at 233, *reprinted in* 1980 U.S.C.C.A.N. 5177). Furthermore, Congress also expressly stated that nothing in Title VIII shall be construed as ''modifying or repealing the provisions of any Federal law governing the conservation or protection of fish and wildlife, including the National Wildlife Refuge System Administration Act of 1966 . . .'' (16 U.S.C. 3125(4)).

FWS recognizes the importance of the fish, wildlife, and other natural

resources in the lives and cultures of Alaska Native people(s) and rural residents, and in the lives of all Alaskans, and we continue to recognize subsistence uses of fish and wildlife and other renewable resources as the priority consumptive use on Federal lands in Alaska, which includes all NWRs in Alaska. This rule does not change the existing Federal subsistence regulations (title 36 of the Code of Federal Regulations (CFR) at part 242 (36 CFR part 242) and 50 CFR part 100) or restrict the taking of fish or wildlife for subsistence uses under the Federal subsistence regulations.

The Improvement Act states that refuges must be managed to fulfill the mission of the NWR System and purposes of the individual refuge. The Improvement Act established the mission of the NWR System, to ''administer a national network of lands and waters for the conservation, management, and where appropriate, restoration of fish, wildlife, and plant resources and their habitats within the United States for the benefit of present and future generations of Americans.'' Section 4(a)(4)(B) of the Improvement Act states that ''In administering the System, the Secretary shall . . . ensure that the biological integrity, diversity, and environmental health [BIDEH] of the System are maintained for the benefit of present and future generations of Americans . . .'' (16 U.S.C. 668dd(a)(4)(B)). The FWS BIDEH policy (601 FW 3), which provides guidance for implementation of this aspect of the Improvement Act, defines biological integrity as ''biotic composition, structure, and functioning at genetic, organism, and community levels comparable with historic conditions, including the natural biological processes that shape genomes, organisms, and communities.'' In that policy, biological diversity is defined as ''the variety of life and its processes, including the variety of living organisms, the genetic differences among them, and communities and ecosystems in which they occur.'' The policy defines environmental health as the ''composition, structure, and functioning of soil, water, air, and other abiotic features comparable with historic conditions, including the natural abiotic processes that shape the environment.'' Abiotic features are nonliving chemical and physical features of the environment (*e.g.,* soil, air, water, temperature, etc.). The policy also defines ''historic conditions'' as the ''composition, structure, and functioning of ecosystems resulting from natural processes that we believe, based on sound professional judgment, were present prior to substantial human related changes to the landscape.'' In implementing this policy on refuges, we favor ''management that restores or mimics natural ecosystem processes or functions to achieve refuge purposes(s).'' Additionally, under this policy, we ''formulate refuge goals and objectives for population management by considering natural densities, social structures, and population dynamics at the refuge level'' and manage populations for ''natural densities and levels of variation.''

Based on the above discussion, we conclude that management in accordance with the BIDEH policy mandated by the Improvement Act is essentially the same as managing for natural diversity as mandated by ANILCA. Each mandate requires us to manage for natural diversity using minimum manipulation where possible, but also recognizes that active management may be required relative to other mandates, altered landscapes, and changing human influences. Each mandate allows appropriate management tools to remain available as needed for future refuge management. The terms biological integrity, diversity, and environmental health are defined in the BIDEH policy, which directs FWS to maintain the variety of life and its processes; to maintain biotic and abiotic compositions, structure, and functioning; and to manage populations for natural densities and levels of variation throughout the NWR System.

The Wilderness Act (16 U.S.C. 1131–1136) states that wilderness ''is hereby recognized as an area where the earth and its community of life are untrammeled by man . . . which is protected and managed so as to preserve its natural conditions.'' Our wilderness stewardship policy (610 FW 1) interprets ''untrammeled'' to be ''the freedom of a landscape from the human intent to permanently intervene, alter, control, or manipulate natural conditions or processes.'' The second chapter of the wilderness stewardship policy, which outlines administration and resource stewardship (610 FW 2), directs that FWS will not manipulate ecosystem processes, specifically including predator/prey fluctuations, in wilderness areas unless ''necessary to accomplish the purposes of the refuge, including Wilderness Act purposes, or in cases where these processes become unnatural'' (*i.e.,* disrupted predator/prey relationships, spread of invasive species, and so forth). Additionally, nothing in this rule applies to or is inconsistent with our policy that outlines special provisions for Alaska wilderness (610 FW 5).

The overarching goal of our wildlife-dependent recreation policy is to enhance opportunities and access to quality visitor experiences on refuges and to manage the refuge to conserve fish, wildlife, plants, and their habitats (605 FW 1.6). We recognize hunting as one of many priority uses of the NWR System (when and where compatible with refuge purposes) that is a healthy, traditional outdoor pastime, deeply rooted in the American heritage (605 FW 2). As stated at 50 CFR part 36, the taking of fish and wildlife through public recreational activities, including sport hunting, is authorized on refuges in Alaska ''as long as such activities are conducted in manner compatible with the purposes for which the areas were established'' (50 CFR 36.31(a)).

2. Applicability of State Authority

In 1970, the Secretary of the Interior developed a policy statement on intergovernmental cooperation in the preservation, use, and management of fish and wildlife resources. The purpose of the policy (36 FR 21034, November 3, 1971; 43 CFR part 24) was to strengthen and support the missions of the several States and the Department of the Interior respecting fish and wildlife. Federal authority exists for specified purposes while State authority regarding fish and resident wildlife remains the comprehensive backdrop applicable in the absence of specific, overriding Federal law.

In general, the States possess broad trustee and police powers over fish and wildlife within their borders, including fish and wildlife found on Federal lands within a State. Under the Property Clause of the Constitution, Congress is given the power to ''make all needful Rules and Regulations respecting the Territory or other Property belonging to the United States.'' In the exercise of power under the Property Clause, Congress may choose to preempt State management of fish and wildlife on Federal lands and, in circumstances where the exercise of power under the Commerce Clause is available, Congress may choose to establish restrictions on the taking of fish and wildlife whether or not the activity occurs on Federal lands, as well as to establish restrictions on possessing, transporting, importing, or exporting fish and wildlife.

Units of the National Wildlife Refuge System constitute federally owned or controlled areas set aside primarily as conservation areas for migratory waterfowl and other species of fish or wildlife. In contrast to multiple use public lands, the conservation,

enhancement, and perpetuation of fish and wildlife is almost invariably the principal reason for the establishment of a unit of the National Wildlife Refuge System. In consequence, Federal activity respecting management of migratory waterfowl and other wildlife residing on units of the National Wildlife Refuge System involves a Federal function specifically authorized by Congress. Units of the National Wildlife Refuge System, therefore, shall be managed, to the extent practicable and compatible with the purposes for which they were established, in accordance with State laws and regulations, comprehensive plans for fish and wildlife developed by the States, and Regional Resource Plans developed by the Fish and Wildlife Service in cooperation with the States.

In Alaska, as such, sport hunting and trapping on refuges are generally regulated by the States, unless further restricted by Federal law (see 50 CFR 32.2(d)) or closures to Federal public land, such as under Federal subsistence regulations (36 CFR 242.26 or 50 CFR 100.26). In Alaska, sport hunting is commonly referred to as general hunting and trapping and includes State subsistence hunts and general permits open to both Alaska residents and nonresidents (see definition of ''sport hunting'' under the Regulation Promulgation section, below). These activities remain subject to Federal law, including mandates under ANILCA; the Improvement Act; and, where applicable, the Wilderness Act. Applicable directives and guidance can also be found in policies in the Service Manual at 601 FW 3 (Biological Integrity, Diversity, and Environmental Health), 605 FW 2 (Hunting), 610 FW 2 (Wilderness Administration and Resource Stewardship), and 610 FW 5 (Special Provisions for Alaska Wilderness). Additionally, the regulations at 50 CFR 36.32(a) state that the Refuge Manager ''may designate areas where, and establish periods when, no taking of a particular population of fish or wildlife shall be permitted.''

The State of Alaska's (State) legal framework for managing wildlife is based on a different principle than the legal framework applicable to management of the NWR system; it is based on the principle of sustained yield, which is defined by statute to mean ''the achievement and maintenance in perpetuity of the ability to support a high level of human harvest of game, subject to preferences among beneficial uses, on an annual or periodic basis'' (Alaska Statute (AS) 16.05.255(j)(5)). Since 1994, Alaska State law (AS 16.05.255) has prioritized human consumptive use of ungulates—specifically moose, caribou, and deer. Known as the Intensive Management (IM) statute, the law requires the Alaska Board of Game (BOG) to designate populations of ungulates for which human consumptive use is the highest priority use and to set population and harvest objectives for those populations. To that end, the BOG must ''adopt regulations to provide for intensive management programs to restore the abundance or productivity of identified big game prey populations as necessary to achieve human consumptive use goals'' (AS 16.05.255(e)). Once designated as an IM population, if either populations or harvests fail to meet management objectives, nonresident hunting must first be eliminated, followed by reductions or eliminations of resident harvest opportunities. However, under the IM statute, the BOG may not significantly reduce the harvest opportunities of an identified IM ungulate population unless it has adopted or is considering the adoption of regulations ''to restore the abundance or productivity of the ungulate population through habitat enhancement, predation control, or other means'' (AS 16.05.255(e)–(g) and (j)).

The BOG has adopted regulations under the IM statute that require targeted reductions of wolf, black bear, brown bear, or a combination of these in designated ''predation control areas'' within game management units. These State regulations are implemented through IM plans (5 Alaska Administrative Code (AAC) 92.106–5 AAC 92.127) that authorize activities including aerial shooting of wolves or bears or both by State agency personnel, trapping of wolves by paid contractors, allowance under permit for same-day airborne hunting of wolves and bears by the public, and allowance under permit for the take of any black or brown bear through baiting or snaring by the public (5 AAC 92).

Thirteen of the 16 refuges in Alaska contain lands within game management units officially designated for IM. While predator control activities occurring under the authority of an IM plan have not been permitted by FWS on any refuge in Alaska, some predator control programs and activities are being implemented in predation control areas immediately adjacent to refuges. Given the large home ranges of many species affected by IM actions, these control programs have the potential to impact wildlife resources, natural systems, and ecological processes, as well as conservation and management of these species on adjacent refuges.

In recent years, concurrent with its adoption and implementation of IM plans for predation control areas, the BOG has also authorized measures under its general hunting and trapping regulations that potentially increase the take of predators to a degree that disrupts natural processes and wildlife interactions. Examples of these recently adopted measures, which apply beyond areas officially designated for IM, including many refuges in Alaska, are:

- Harvesting brown bears over bait at registered black bear bait stations;
- Taking wolves and coyotes (including pups) during the denning season;
- Expanding season lengths and increasing bag limits;
- Classifying black bears as both furbearers and big game species (which could allow for trapping and snaring of bears and sale of their hides and skulls); and
- Authorizing same-day airborne take of bears at registered bait stations (5 AAC 85).

Many of the recent actions by the BOG to liberalize the State's regulatory frameworks for general hunting and trapping of wolves, bears, and coyotes reverse long-standing prohibitions and restrictions on take of these wildlife species under State law. Unlike the recent practice of taking brown bears over bait, black bear baiting has been an authorized practice in Alaska since 1982, including on refuges. Black bear baiting is authorized by the State pursuant to a permit and, in some instances, a special use permit (Service Form 3–1383–G) issued by refuges. Taking of brown bears at black bear baiting stations was recently authorized under State regulations in certain game management units within the State (several of which are within refuges) and is subject to the same restrictions as black bear baiting. The State regulations prohibit setting up a bait station within 1 mile of a home or other dwelling, business, or campground, or within ¼ mile of a road or trail (5 AAC 85).

3. The Interplay of Federal and State Regulations at Refuges in Alaska

Implementation of IM actions under the IM statute and many of the recent liberalizations of the general hunting and trapping regulations have direct implications for the management of refuges in Alaska. The different purposes of State and Federal laws and the increased focus on predator control by the State have resulted in the need for FWS to deviate, in certain respects, from applying State regulations within

refuges. This is because predator-prey interactions represent a dynamic and foundational ecological process in Alaska's arctic and subarctic ecosystems, and are a major driver of ecosystem function. State regulations allowing activities on refuges in Alaska that are inconsistent with the conservation of fish and wildlife populations and their habitats in their natural diversity, or the maintenance of biological integrity, diversity, and environmental health, are in direct conflict with our legal mandates for administering refuges in Alaska under ANILCA, the Improvement Act, and the Wilderness Act, as well as with applicable agency policies (601 FW 3, 610 FW 2, and 605 FW 2).

In managing for natural diversity, FWS conserves, protects, and manages all fish and wildlife populations within a particular wildlife refuge system unit in the natural 'mix,' not to emphasize management activities favoring one species to the detriment of another. FWS assures that habitat diversity is maintained through natural means on refuges in Alaska, avoiding artificial developments and habitat manipulation programs, whenever possible. FWS fully recognizes and considers that rural residents use, and are often dependent on, refuge resources for subsistence purposes, and FWS manages for this use consistent with the conservation of species and habitats in their natural diversity.

This rule does not change Federal subsistence regulations (36 CFR part 242 and 50 CFR part 100) or otherwise restrict the taking of fish or wildlife for subsistence by federally qualified users under those regulations. The rule does not apply to take in defense of life and property as defined under State regulations (see 5 AAC 92.410). Hunting and trapping are priority uses of refuges in Alaska. The rule will not affect implementation of State hunting and trapping regulations that are consistent with Federal law and FWS policies on refuges, nor will it restrict hunting or trapping activities outside FWS-managed refuge lands and waters.

This Final Rule

Summary of Final Rule

We developed the changes to existing refuge regulations included in our January 8, 2016, proposed rule to meet our legal mandates and to ensure consistency with policy, directives, and approved management plans.

This rule makes the following substantive changes to existing NWR regulations:

(1) We define ''natural diversity'' in regulation based on the legislative history from ANILCA. Natural diversity means the existence of all fish, wildlife, and plant populations within a particular wildlife refuge system unit in the natural mix and in a healthy condition for the long-term benefit of current and future generations. Managing for natural diversity includes avoiding emphasis of management activities favoring some species to the detriment of others and assuring that habitat diversity is maintained through natural means, avoiding artificial developments and habitat manipulation programs whenever possible.

(2) We prohibit predator control on refuges in Alaska, unless it is determined necessary to meet refuge purposes; is consistent with Federal laws and policy; and is based on sound science in response to a conservation concern. Demands for more wildlife for human harvest cannot be the sole or primary basis for predator control.

We define predator control as the intention to reduce the population of predators for the benefit of prey species. For clarity, this includes predator reduction practices, such as, but not limited to, those undertaken by government officials or authorized agents, aerial shooting, or same-day airborne take of predators. Other less intrusive predator reduction techniques such as, but not limited to, live trapping and transfer, authorization of particularly effective public harvest methods and means, or utilizing physical or mechanical protections (barriers, fences) are also included with exception for barriers for human life and property safety.

A Refuge Manager will authorize predator control activities on a National Wildlife Refuge in Alaska only if:

(a) Alternatives to predator control have been evaluated as a practical means of achieving management objectives;

(b) Proposed actions have been evaluated in compliance with the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*);

(c) A formal refuge compatibility determination has been completed, as required by law; and

(d) The potential effects of predator control on subsistence uses and needs have been evaluated through an ANILCA section 810 analysis.

This rule ensures that take of wildlife on refuges in Alaska under State regulations and implementation of predator control is consistent with our legal mandates and policies for administration of those refuges.

(3) This rule prohibits the following practices for the taking of wildlife on Alaska National Wildlife refuges (except for subsistence uses by federally qualified subsistence users in accordance with applicable Federal laws and regulations):

- Taking black or brown bear cubs or sows with cubs (exception allowed for resident hunters to take black bear cubs or sows with cubs under customary and traditional use activities at a den site October 15–April 30 in specific game management units in accordance with State law);
- Taking brown bears over bait;
- Taking of bears using traps or snares;
- Taking wolves and coyotes during the denning season (May 1–August 9); and
- Taking bears from an aircraft or on the same day as air travel has occurred. The take of wolves or wolverines from an aircraft or on the same day as air travel has occurred is already prohibited under current refuge regulations.

FWS requested comment on the type of bait allowed to be used for the baiting of black or brown bears. Currently, State regulations, which are adopted on refuges, require the bait used at bear baiting stations to be biodegradable. People use a range of different types of bait for the baiting of bears, including parts of fish and game that are not required to be salvaged when these species are harvested, as well as human and pet food products. We received very few comments expressing opinions on appropriate baits. Based on this, we will continue to adopt State regulations.

(4) We update our regulations to reflect Federal assumption of management of subsistence hunting and fishing under Title VIII of ANILCA by the Federal Government from the State in the 1990s.

(5) As set forth in our January 8, 2016, proposed rule (81 FR 887), we remove a statement at the current 50 CFR 36.32(e) that references compliance with other mandates (such as the Airborne Hunting Act, 16 U.S.C. 742j–1) in order to reduce redundancy. The requirement for compliance with applicable State and Federal laws is set forth at 50 CFR 36.32(a) in this final rule. We also correct the regulations at 50 CFR part 36 by removing a statement set forth at the current 50 CFR 36.32(e) that references sections of subchapter C of title 50 of the CFR (regarding the taking of depredating wildlife) that no longer exist.

(6) We amend 50 CFR 32.2(h) to state that black bear baiting is authorized in accordance with State regulations on NWRs in Alaska. This change ensures

consistency between the provisions of the national hunting regulations at 50 CFR part 32 regarding baiting in Alaska and the Alaska-specific regulations at 50 CFR part 36.

(7) We update procedures for implementing closures or restrictions on refuges, including the taking of fish and wildlife under sport hunting and trapping, to more effectively engage and inform the public and make the notice and durational provisions more consistent with procedures set forth in Federal subsistence closure policy and regulations at 36 CFR 242.19 and 50 CFR 100.19 for emergency special actions on Federal public lands in Alaska. Improved consistency between these Federal regulations and processes will help minimize confusion and make it easier for the public to be involved in the process.

The regulations provide for emergency, temporary, and permanent closures and restrictions. This rule limits emergency closures and restrictions to 60 days, and temporary closures and restrictions are limited to the minimum time necessary, and will not exceed 12 months.

This rule also updates the closures and restrictions notification procedures for refuges in Alaska to reflect the availability of alternative communications technologies and approaches that have emerged or evolved over the last few decades. These changes recognize that the Internet has become one of the primary methods to communicate with the public and is an effective tool for engaging Alaskans and the broader American public and that there are other forms of broadcast media, beyond just the radio, that we may want to use.

The changes to the notification procedures are not intended to limit public involvement or reduce public notice; rather, we intend to engage in ways more likely to encourage public involvement and in a manner that is fiscally responsible. We recognize that in-person public meetings will continue to be the most effective way to engage Alaskans, and we intend to continue that practice. We also recognize that many individuals in rural Alaska do not have access to high speed Internet, and for that reason, we will continue to use other methods of communication, such as regional and local newspapers, posting flyers at local post offices, and radio announcements, where available to provide adequate notice.

TABLE—SUMMARY OF PRIMARY DIFFERENCES BETWEEN OUR PROPOSED RULE AND THIS FINAL RULE

What we proposed in the January 8, 2016, proposed rule (81 CFR 887)	What we are making final in this rule
50 CFR 32.2(h): What are the requirements for hunting on areas of the National Wildlife Refuge System?; Use of bait	
We proposed to revise this provision to add the following statement: ''(Black bear baiting is authorized in accordance with State regulations on national wildlife refuges in Alaska.)''	We are revising this provision to add the following statement: ''(Black bear baiting and use of bait to trap furbearers are authorized in accordance with State regulations on national wildlife refuges in Alaska.)''
50 CFR 36.2: What do these terms mean? (Definitions)	
We proposed to add 13 definitions to the regulations.	Of the 13 definitions proposed, we are defining 8 terms in this final rule. We are not adding definitions for ''biological diversity,'' ''biological integrity,'' ''environmental health,'' ''historic conditions,'' or ''Regional Director'' to the regulations in this final rule. We revised the proposed definition of ''natural diversity'' by removing the following: ''and taking into consideration the fact that humans are dependent on wildlife refuge subsistence resources.'' The definition of ''natural diversity'' we are adopting in this final rule reads: ''Natural diversity means the existence of all fish, wildlife, and plant populations within a particular wildlife refuge system unit in the natural mix and in a healthy condition for the long-term benefit of current and future generations. Managing for natural diversity includes avoiding emphasis of management activities favoring some species to the detriment of others and assuring that habitat diversity is maintained through natural means, avoiding artificial developments and habitat manipulation programs whenever possible.''
50 CFR 36.32(b): Taking of fish and wildlife; predator control prohibition	
We proposed the following language to set forth when predator control is allowed on a refuge: ''Predator control is prohibited on National Wildlife Refuges in Alaska, unless it is determined necessary to meet refuge purposes, Federal laws, or policy; is consistent with our mandates to manage for natural and biological diversity, biological integrity, and environmental health; and is based on sound science in response to a significant conservation concern. Demands for more wildlife for human harvest cannot be the sole or primary basis for predator control. A Refuge Manager will authorize predator control activities on a National Wildlife Refuge in Alaska only if:	We are removing the words ''is consistent with our mandates to manage for natural and biological diversity, biological integrity, and environmental health'' and removing the word ''significant'' before the words ''conservation concern.'' In addition, we removed the words ''attempted'' and ''exhausted'' in the first step of the process to approve predator control activities. The paragraph now reads: ''Predator control is prohibited on National Wildlife Refuges in Alaska, unless it is determined necessary to meet refuge purposes, is consistent with Federal laws and policy, and is based on sound science in response to a conservation concern. Demands for more wildlife for human harvest cannot be the sole or primary basis for predator control. A Refuge Manager will authorize predator control activities on a National Wildlife Refuge in Alaska only if:
(1) Alternatives to predator control have been evaluated, attempted, and exhausted as a practical means of achieving management objectives;	(1) Alternatives to predator control have been evaluated as a practical means of achieving management objectives;

TABLE—SUMMARY OF PRIMARY DIFFERENCES BETWEEN OUR PROPOSED RULE AND THIS FINAL RULE—Continued

What we proposed in the January 8, 2016, proposed rule (81 CFR 887)	What we are making final in this rule
(2) Proposed actions have been evaluated in compliance with the National Environmental Policy Act (42 U.S.C. 4321 et seq.); (3) A formal refuge compatibility determination has been completed, as required by law; and (4) The potential effects of predator control on subsistence uses and needs have been evaluated through an ANILCA section 810 analysis.''	(2) Proposed actions have been evaluated in compliance with the National Environmental Policy Act (42 U.S.C. 4321 et seq.); (3) A formal refuge compatibility determination has been completed, as required by law; and (4) The potential effects of predator control on subsistence uses and needs have been evaluated through an ANILCA section 810 analysis.''.
50 CFR 36.42(b) Public participation and closure procedures; Criteria	
We proposed to add conservation of natural diversity, biological integrity, biological diversity, and environmental health to the list of criteria for closures.	We are not adding conservation of natural diversity, biological integrity, biological diversity, and environmental health to the list of criteria for closures. We are retaining the original closure criteria and regulatory language.
50 CFR 36.42(c)(1), (c)(2), and (c)(3) Emergency closures or restrictions	
We did not propose any changes	In response to a comment, we are adding clarifying language, or making editorial changes, concerning notice of emergency closures or restrictions. Specifically, we are adding reference to 50 CFR 36.42(f), notice procedures, to these paragraphs of the regulations.
50 CFR 36.42(c)(4): Emergency closures or restrictions; time frame	
We proposed that ''Emergency closures or restrictions may not exceed a period of 60 days. Extensions beyond 60 days are subject to nonemergency closure procedures.''	We are adopting the following statement: ''No emergency closure or restriction will exceed 60 days. Closures or restrictions requiring longer than 60 days will follow nonemergency closure procedures (i.e., temporary or permanent; see paragraphs (d) and (e), respectively, of this section).''.
50 CFR 36.42(d)(1), (d)(2), and (d)(3): Temporary closures or restrictions	
We proposed revised language concerning temporary closures or restrictions related to the use of aircraft, snowmachines, motorboats, or nonmotorized surface transportation and to the taking of fish and wildlife and to other temporary closures.	We are adopting our proposed language with additional clarifying language, or editorial changes, concerning notice of temporary closures or restrictions. Specifically, we are adding reference to 50 CFR 36.42(f), notice procedures, to these paragraphs of the regulations.
Proposed 50 CFR 36.42(d)(5) and (d)(6): Temporary closures or restrictions	
We proposed language concerning the time period, evaluation, and removal of temporary closures at proposed 50 CFR 36.42(d)(5). We proposed language concerning a list of closures and restrictions at proposed 50 CFR 36.42(d)(6).	We are not adopting proposed 50 CFR 36.42(d)(5) or (d)(6). Instead, at 50 CFR 36.42(d)(4), we retain historic temporary closure or restriction language to limit temporary closures to a maximum of 12 months; provided, however, a new temporary closure or restriction may be adopted thereafter by following the applicable procedures set forth at 50 CFR 32.42(d)(1), (d)(2), or (d)(3).
50 CFR 36.42(e): Permanent closures or restrictions	
We proposed language for permanent closures or restrictions related to the use of aircraft, snowmachines, motorboats, or nonmotorized surface transportation and to the taking of fish and wildlife that read: ''Permanent closures or restrictions relating to the use of aircraft, snowmachines, motorboats, or nonmotorized surface transportation, or taking of fish and wildlife, will be effective only after allowing for the opportunity for public comment and a public hearing in the vicinity of the area(s) affected and other locations as appropriate, and after publication in the **Federal Register**. Permanent closures or restrictions related to the taking of fish and wildlife would require consultation with the State and affected Tribes and Native Corporations.''	We revised the language to be consistent with 43 CFR 36.11(h)(3). The paragraph now reads: ''Permanent closures or restrictions related to the use of aircraft, snowmachines, motorboats, or nonmotorized surface transportation, or taking of fish and wildlife, will be effective only after notice pursuant to paragraph (f) of this section, and shall be published by rulemaking in the **Federal Register** with a minimum public comment period of 60 days and shall not be effective until after a public hearing(s) is held in the affected vicinity and other locations as appropriate. Permanent closures or restrictions related to the taking of fish and wildlife require consultation with the State and affected Tribes and Native Corporations.''.

(8) We codify definitions for several terms (see the Regulation Promulgation section, below). These terms include ''Bait,'' ''Big game,'' ''Cub bear,'' ''Furbearer,'' ''Natural diversity,'' ''Predator control,'' ''Sport hunting,'' and ''Trapping.'' Most of these definitions, including bait, big game, cub bear, furbearer, and predator control, are based on existing definitions in Federal subsistence regulations or policy.

During our scoping and comment period, and through tribal consultation efforts, we heard that definitions for biological integrity, biological diversity, natural diversity, and environmental health and the origins of these definitions are of significant interest to people. As discussed above, FWS is mandated under the Improvement Act to ''ensure that the biological integrity, diversity, and environmental health [BIDEH] of the System are maintained

for the benefit of present and future generations of Americans. . .'' (16 U.S.C. 668dd(a)(4)(B)). The FWS BIDEH policy (601 FW 3), which provides guidance for implementation of the Improvement Act, provides definitions for each of these terms, as well as the term ''historic conditions.'' As also discussed above, the definition of ''natural diversity'' in this rule is derived from FWS' review of ANILCA's legislative history and FWS' conclusion that the concepts of natural diversity and BIDEH are essentially the same.

Summary of and Response to Public Comments

We reviewed and considered all substantive information we received during the comment period. A summary of substantive comments and FWS responses is provided below. The previous table sets out changes we have made to the provisions of the proposed rule based on the analysis of the comments and other considerations. As comments were often similar or covered multiple topics, we have grouped comments and responses by topic areas, which generally correspond to specific sections of the January 8, 2016, proposed rule.

Guiding Laws and Regulations, Native Americans, and States Rights

(1) Comment: Commenters stated what we proposed is not aligned with ANILCA and gives subsistence a lower priority than other uses.

FWS Response: ANILCA sections 302 and 303 (with the exception of Kenai NWR) established the opportunity for subsistence uses by local residents as one of the main purposes (Refuge purposes) for which NWRs in Alaska (created or expanded by ANILCA) were established and are to be managed. The first two purposes listed for each NWR under ANILCA are: (i) To conserve fish and wildlife populations and habitats in their natural diversity, and (ii) to fulfill the international treaty obligations of the United States with respect to fish and wildlife and their habitats. The third purpose listed is to provide, in a manner consistent with the purposes set forth in (i) and (ii), above, the opportunity for continued subsistence uses by local residents. Although the subsistence purpose carries the same weight as the first two purposes, it is subject to consistency with the first two purposes. ANILCA makes clear that the subsistence purpose (third-listed purpose) is equally important insofar as it is consistent with the preceding purposes ((i) and (ii)). This rule is fully consistent with the purposes and requirements of ANILCA.

(2) Comment: Commenters expressed concerns with FWS' definition of the term ''natural diversity'' and stated the FWS definition derived from the congressional testimony of Congressman Udall was not appropriate and excluded predator control as a management tool.

FWS Response: ANILCA does not include a definition of the term ''natural diversity.'' FWS' definition was developed after carefully considering the statutory language as well as the legislative history of ANILCA. In response to public comments that our proposed discussion and definition did not fully reflect the full legislative history of ANILCA, we added a discussion concerning the portions of Alaska Senator Ted Steven's floor statements that referenced natural diversity. In this final rule, we are defining ''natural diversity'' at 50 CFR 36.2 (see the Regulation Promulgation section, below). As it has since the enactment of ANILCA in 1980, FWS will continue to rely on the statutory provisions of ANILCA, its legislative history, and applicable FWS mandates, laws, and policies to guide NWR management in Alaska. FWS may authorize predator control on Alaska NWRs when it is determined to be in accordance with FWS laws, mandates, and policies. This rule identifies when we will authorize predator control and clarifies how our existing statutory mandates for the conservation of natural and biological diversity, biological integrity, and environmental health on NWRs in Alaska apply to predator control.

(3) Comment: Commenters stated what was proposed violates the intent of ANILCA, and they object to any action that violates the existing Master Memorandum of Understanding (MMOU) between the State and FWS. They feel the State should have primacy in regards to the management of fish and wildlife.

FWS Response: The State of Alaska and FWS have differing missions, goals, and objectives, and authorities are derived through State or Federal statutes, respectively. The purpose of this rule is to exercise FWS' management authority on NWR lands in Alaska to achieve goals of ANILCA's NWR purposes. ANILCA (1980) section 304(a) states, ''Each refuge shall be administered by the Secretary . . . in accordance with the laws governing the administration of units of the NWR System and this Act.'' This rule is consistent with the Administration Act, the Improvement Act, the purposes for which the NWRs were created or expanded as stated in ANILCA sections 302 and 303, and with other provisions of ANILCA. Neither ANILCA nor the MMOU (1982, Recommitment 2006) suggests that the State has or should have primacy in the management of fish and wildlife on NWRs. The MMOU stresses cooperation between FWS and the State, ''to manage fish and resident wildlife populations in their natural diversity on FWS lands.'' FWS prefers to defer to the State on regulations of hunting and trapping on NWRs in Alaska, unless doing so would be inconsistent with Federal laws and policy.

(4) Comment: One commenter expressed concern that the proposed changes are likely not in keeping with what was intended in ANILCA (sections 101, 102). Other commenters suggested that FWS should recognize that wildness is the overarching condition that ANILCA seeks to perpetuate relative to management of NWRs.

FWS Response: FWS manages Alaska NWRs for the purposes expressed in section 101 of ANILCA and consistent with the definitions of terms found in section 102. The term ''wildness'' is not specifically used in the purposes section of ANILCA, sections 101 and 102, but it is alluded to. FWS meets the purposes of ANILCA sections 101 and 102, by managing for natural diversity on all Alaskan refuges.

(5) Comment: Commenters were concerned FWS was not considering the Supreme Court's recent ruling in *Sturgeon* v. *Frost,* 577 U.S. (2016), which ordered the U.S. 9th Circuit of Appeals to reconsider its decision. The Supreme Court opinion stated that ''Alaska is often the exception, not the rule'' when it comes to Federal regulation.

FWS Response: FWS fully recognizes the statutory differences for management of NWRs in Alaska and those in the rest of the United States. Those differences have long been reflected in the Service's regulations and policies. This rule complies with the applicable provisions of ANILCA, is limited in its applicability to activities occurring only on public lands administered by FWS, and is therefore fully consistent with the Supreme Court's decision.

(6) Comment: One commenter expressed concern about whether the changes proposed by FWS are consistent with ANCSA and ANILCA, and suggested FWS engage with rural communities and consult with Alaska Native villages and ANCSA corporations to identify and address any issues pertaining to the proposed regulations.

FWS Response: Our intention in issuing the January 8, 2016, proposed

rule (81 FR 887), as well this final rule, was to ensure consistency with applicable provisions of ANCSA or ANILCA. We took public comments on the proposed rule for 90 days. This final rule modifies certain provisions of the proposed rule based on comments from the public at large, State of Alaska, rural residents, Tribes, and other Alaska Native entities, to reduce the potential effects on federally qualified subsistence users on Alaska NWR lands. This rule does not change Federal subsistence regulations. This rule does not restrict federally qualified subsistence users who are hunting in accordance with Federal subsistence regulations. ANILCA section 304(a) requires that ''Each refuge shall be administered by the Secretary . . . in accordance with the laws governing the administration of units of the NWR System and this Act.'' Further, section 815 of ANILCA is explicit that nothing in Title VIII, the subsistence title, modifies or repeals the provisions of the Administration Act. This rule is consistent with the Administration Act, the Improvement Act, and the purposes for which the NWRs were created or expanded as stated in ANILCA sections 302 and 303.

FWS agrees that consultation with all constituent communities is extremely important and in particular continues to strive for increased cooperation and dialogue with rural Alaskans. We held nine public meetings in urban and rural communities, attended RAC and BOG meetings throughout the State, and contacted Alaska Native Tribes for government-to-government consultation and ANCSA corporations for consultations. We met and communicated with the Tribes and ANCSA corporations that requested formal consultation. Details on the outreach that was conducted with Tribes, the State, and the public are detailed in this rule and the finding of no significant impact (FONSI). FWS remains available to discuss the application of the rule with Tribes and ANCSA corporations at their request.

(7) Comment: Commenters expressed discontent with the BOG management of wildlife on Alaska NWRs. Commenters stated that the public (nationwide) owns the lands within NWRs, and therefore the State should not have sole responsibility for managing these lands and their associated wildlife populations. They also had concerns that the BOG favored management of wildlife for the interests of hunters and trappers and ignored nonconsumptive user groups.

FWS Response: FWS is authorized by ANILCA, the Administration Act, and the Improvement Act to manage wildlife and their habitats within Alaska NWRs. As directed by the Improvement Act, six wildlife-dependent recreational uses are the priority general public uses of the Refuge System. These uses are defined in the Improvement Act to consist of consumptive uses (hunting and fishing) and nonconsumptive uses (wildlife observation, wildlife photography, environmental education, and environmental interpretation).

(8) Comment: Commenters stated FWS does not have the authority to take the proposed action and indicated FWS should resolve issues by working with the State. Commenters were concerned the proposal would affect game on State lands. Commenters stated FWS was preempting the intent of Congress for the State's integral role in fish and wildlife management. Commentators assert that the Improvement Act, 16 U.S.C. 668dd(m), reserves to the States management authority over wildlife on refuge lands.

FWS Response: First, nothing in this rule applies to wildlife when located on other than Refuge-administered lands. At 16 U.S.C. 668dd(l), the Improvement Act states: ''Nothing in this Act shall be construed to authorize the Secretary to control or regulate hunting or fishing of fish and resident wildlife on lands or waters that are not within the System.''

Second, FWS is committed to continuing to work with the State and prefers for the State to manage wildlife populations on refuge lands when consistent with NWR mandates, policies, and laws. However, as explained in more detail above, FWS is required under Federal law to make decisions regarding management of wildlife on refuges to ensure consistency with the purposes for which Congress established those refuges. While State law is the backdrop for fish and wildlife management, pursuant to the Property Clause, Congress enacted certain statutes, including those referenced in the Department's Wildlife Policy statement found at 43 CFR part 24, which obligate FWS to manage Federal refuge lands consistent with their authorized purposes. Cooperation with the States is required in certain respects, but specific laws have provided the Secretary the ultimate authority to make decisions that are required and/or allowed by Federal law. Congress in enacting the Administration Act and the Improvement Act provided FWS with the authority to manage fish and wildlife and their habitats on Federal lands including those within the boundaries of Alaska NWRs. ANILCA section 304(a) directs that ''Each refuge shall be administered by the Secretary . . . in accordance with the laws governing the administration of units of the NWR System and this Act.''

In addition to the authorities discussed above, the Improvement Act (Act) clarifies Federal and State authorities in (16 U.S.C. 668dd(k)): ''Notwithstanding any other provision of this Act, the Secretary may temporarily suspend, allow, or initiate any activity in a refuge in the System if the Secretary determines it is necessary to protect the health and safety of the public or any fish or wildlife populations.''

With respect to the role of the States, one commenter asserted that the Improvement Act actually affords States the authority, to the exclusion of FWS, to make management decisions for fish and wildlife on Federal refuges. At 16 U.S.C. 668dd(m), the Improvement Act states: ''Nothing in this Act shall be construed as affecting the authority, jurisdiction, or responsibility of the several States to manage, control, or regulate fish and resident wildlife under State law or regulations in any area within the System. Regulations permitting hunting or fishing of fish and resident wildlife within the System shall be, to the extent practicable, consistent with State fish and wildlife laws, regulations, and management plans.'' This section establishes a preference for State management and reliance on State regulations where ''practicable,'' but by its very terms contemplates that FWS must make independent determinations to ensure ''practicability,'' which includes compatibility with refuge purposes. The section affirms the responsibility of the State to enforce its fish and wildlife laws and the role of the State in management of fish and wildlife even on Federal refuges, but does not suggest that State authority is exclusive. Furthermore, the reading suggested by the commenter would have the effect of nullifying the many other provisions of the Improvement Act and other laws that impose upon FWS the responsibility to make decisions regarding management of Federal refuges.

Furthermore, this final rule is consistent with the provisions regarding taking of fish and wildlife that are stated in section 1314 of ANILCA. Subsection (a) provides that except for Federal subsistence, nothing in ANILCA ''is intended to enlarge or diminish the responsibility and authority of the State of Alaska for management of fish and wildlife on the public lands''; subsection (b) states that except as specifically provided in ANILCA, ''nothing in this Act is intended to enlarge or diminish the responsibility

and authority of the Secretary over the management of the public lands.''

Prior to initiating this rulemaking process, FWS met with State officials on multiple occasions over the past 10 years to discuss and attempt to resolve the issues that are finally addressed in this rule. Additional meetings with the State occurred during the development of the rule and after we published the proposed rule, but we have been unable to come to common ground. Thus we are proceeding with this rulemaking process in order to ensure that wildlife management on Alaskan NWRs remains consistent with the Service's legal mandates and authorities.

Compliance With Mandates, Laws, and Policies

(9) Comment: Commenters stated the rulemaking violated the intent of the Improvement Act and ANILCA. They also asserted FWS elevated inappropriately through regulations one of the 14 non-hierarchical ''broad responsibilities'' identified in the Improvement Act: ''to ensure that the biological integrity, diversity, and environmental health of the system are maintained for the benefit of present and future generations of Americans.''

FWS Response: This rule codifies regulations that will help FWS meet the mandates of the Improvement Act and that are fully consistent with ANILCA—sections 302, 303, Title VIII, and section 1314, in particular. Under ANILCA, each refuge in Alaska has a list of purposes for which it was established, including to ''conserve fish and wildlife populations and habitats in their natural diversity'' followed by a list of representative species particular to each refuge. The Improvement Act specifically states that in administering the NWR System, the Secretary is authorized to issue regulations to carry out that Act (see 16 U.S.C. 668dd(b)(5)). This rule will specifically help NWRs to comply with the following parts of the Improvement Act: (1) Provide for the conservation of fish, wildlife, and plants, and their habitats within the NWR System (see 16 U.S.C. 668dd(a)(4)(A)); and (2) ensure that the BIDEH of the NWR System is maintained for the benefit of present and future generations of Americans (see 16 U.S.C. 668dd(a)(4)(B)). As identified in the preamble of this rule, FWS management to fulfill management for biological diversity is essentially the same as management for natural diversity as defined in this rulemaking. This rule directly supports the mission of the NWR System as identified in Improvement Act and also supports the 14 directives listed in the Improvement Act, including specifically the directive that states the Secretary shall in administering the system ensure that the BIDEH of the NWR System is maintained for the benefit of present and future generations of Americans (see 16 U.S.C. 668dd(a)(4)(B)). This rule does not elevate or prioritize the importance of this directive over the other directives, but does specifically identify its importance and relevance to the justification for actions specified in the rule.

By law (Improvement Act), regulations (43 CFR part 24), and policy (the Service Manual at 605 FW 1 and 605 FW 2), FWS must, to the extent practicable, ensure that NWR regulations permitting hunting and fishing are consistent with State laws, regulations, and management plans. In recognition of the above, non-conflicting State general hunting and trapping regulations are usually adopted on NWRs. Hunting and trapping, however, remain subject to legal mandates, regulations, and management policies pertinent to the administration and management of NWRs.

(10) Comment: Commenters pointed out that uses allowed on NWRs must be compatible with NWR purposes as per the Improvement Act and also noted that the Improvement Act gives equal priority for priority public uses.

FWS Response: The Service agrees with this comment. Under the Improvement Act, FWS is required to manage NWRs for natural diversity and BIDEH across ecosystems. The Improvement Act also established and reinforced the compatibility standard as the legal backbone for NWRs, defining a ''compatible'' use as one that does not ''materially interfere with or detract from the fulfillment of the National Wildlife Refuge System or the purposes of the national wildlife refuge'' (603 FW 2.6B.). While Alaskan NWRs have historically recognized sport hunting and fishing as priority public uses, the Improvement Act gave equal priority to wildlife viewing, photography, and environmental education and interpretation as priority public uses. The Improvement Act identifies hunting as a permissible use of NWRs, but consumptive recreational uses are not given any higher priority than nonconsumptive uses (such as wildlife watching, hiking, camping, photography, etc.), and protection of wildlife and other natural resources found within NWRs continue to be accorded the highest of priorities (see 16 U.S.C. 668dd). Moreover, the Improvement Act retains and re-emphasizes the Administration Act's compatibility requirements and imposes other standards that require more, not less, biological and ecological evidence to support decisions to open or close NWRs to activities.

(11) Comment: Commenters were concerned that the proposed regulations would be applied to all NWRs nationwide in the future.

FWS Response: In 1981, the Service added a new part 36 to its regulations in title 50 of the CFR to specifically address the requirements of ANILCA. The general National Wildlife Refuge System regulations continue to apply to Alaska refuges, ''except as supplemented or modified by these [part 36] regulations or amended by ANILCA.'' In general, FWS defers to the respective States for management of wildlife on NWRs across the United States. However, it is common for NWRs outside of Alaska to promulgate refuge specific hunting and fishing regulations to ensure refuge management complies with NWR System laws and policies. Public participation and closure procedures for NWRs in the lower 48 States are found at 50 CFR 25.21 and 50 CFR 25.31. The regulations at 50 CFR part 36 are specific to Alaska, and NWRs in other States are subject to their own rulemaking procedures.

Biological Integrity, Diversity, and Environmental Health

(12) Comment: Concern was expressed that our definition of ''natural diversity'' precludes FWS' ability to use predator control as a tool.

FWS Response: ''Natural diversity'' is defined in this rule as the existence of all fish, wildlife, and plant populations within a particular wildlife refuge system unit in the natural mix and in a healthy condition for the long-term benefit of current and future generations. Managing for natural diversity includes avoiding emphasis of management activities favoring some species to the detriment of others and assuring that habitat diversity is maintained through natural means, avoiding artificial developments and habitat manipulation programs whenever possible. In the preamble of this rule, we described statements by Chairman Udall and Senator Stevens, who were floor managers involved in enactment of ANILCA, to provide background on how congressional leaders involved in drafting ANILCA interpreted the words ''natural diversity'' and the term's context relative to future management of NWRs in Alaska. This legislative history provides important context to this rule. This rule does not preclude predator control as a management tool, but instead provides that FWS will only use

predator control on NWRs in Alaska when it is determined necessary to meet refuge purposes, is consistent with Federal laws and policy, and is based on sound science in response to a conservation concern. FWS continues to recognize predator control as an important and valid management tool when appropriate to meet NWR purposes or the NWR System's mission. As explained above, natural diversity is discussed and defined in this rule because it is a statutory purpose of every refuge unit in Alaska, but the term is not defined in ANILCA. The inclusion of a discussion and definition of natural diversity in this rule is to clarify how we interpret this term. The discussions cited from the legislative history on the meaning of natural diversity are an important element considered in our interpretation. Managing to maintain the natural diversity of fish and wildlife and their habitats includes avoiding emphasis of management activities favoring some species to the detriment of others; assuring that habitat diversity is maintained through natural means, avoiding artificial developments and habitat manipulation programs whenever possible.

(13) Comment: The definition of ''natural diversity'' used in the proposed rule was not vetted with the State and Tribes prior to publication of the proposed rule.

FWS Response: The Service did consult with Tribal governments, Native Corporations, and the State before issuing a proposed rule. The Service also engaged in further discussions/consultations after the proposed rule was issued. In the preamble of this rule, we reference ANILCA's legislative history to provide background on how congressional leadership interpreted the term ''natural diversity'' and its context relative to future management of NWRs. This background information provides important context for this rule and how we developed the definition of ''natural diversity'' in this rule.

The context for FWS' interpretation of ''natural diversity'' was included in information shared with the State and the Tribes as early as 2014. Reference to legislative history information that provided specific context for developing FWS' definition of ''natural diversity'' was provided repeatedly to the State and Tribes during the drafting of the rule starting in 2014. Upon repeated requests from the State and Tribes throughout the 2014–2015 rule development, FWS developed the definition of ''natural diversity'' set forth in this rule. We included this definition in the draft of the proposed rule that we shared with the State and Tribes (November 2015) prior to publishing the proposed rule in January 2016. In addition, there was a 90-day comment period to provide a revised or alternate definition. One commenter referenced an alternate definition (see Comment (24), below) that was evaluated and determined inappropriate for this rule. In response to comments, we added additional ANILCA legislation history language from Senator Ted Stevens to the preamble of this rule to provide a broader context for evaluating the interpretation of natural diversity.

(14) Comment: Commenters were concerned the proposal provided FWS Refuge Managers too much latitude for interpreting and making decisions about future management for BIDEH.

FWS Response: The actions Refuge Managers are authorized to take in this rule, and the criteria to be applied when doing so, are consistent with Federal law and are comparable to the actions the managers have long been authorized to take in administering refuges. Refuge Managers are subject matter experts regarding management of refuge units. Refuge Managers are selected to manage operations of a NWR because of their expertise. Refuge Managers receive assistance from their local refuge staff, as well as regional refuge staff as needed or required to make appropriate management decisions. Refuge Managers also seek out scientific information and traditional ecological knowledge from appropriate experts including State biologists and tribal entities. Refuge Managers' decisions are based on a variety of sources, including, but not limited to, laws, regulations, policies, legislative history, and planning documents for which the public has had the opportunity to provide input such as comprehensive conservation plans and step-down management plans. The use of the BIDEH policy guidance by Refuge Managers is incorporated into a diversity of short- and long-term decision-making situations. A few of the examples where BIDEH policy guidance is utilized by a Refuge Manager include development of comprehensive conservation plans, inventory and monitoring plans, and compatibility determinations. A Refuge Manager's decisions to conduct or recommend management actions relative to BIDEH policy are, as appropriate, further evaluated by the respective regional refuge supervisors and refuge chiefs.

(15) Comment: Commenters stated the use of the BIDEH policy is so broad and unspecific that it also allows FWS to justify nearly any action it desires, as long as it is in ''the professional judgment'' of FWS employees.

FWS Response: Section 4(a)(4)(B) of the Improvement Act states that ''In administering the System, the Secretary shall . . . ensure that the biological integrity, diversity, and environmental health [BIDEH] of the System are maintained for the benefit of present and future generations of Americans. . .'' (16 U.S.C. 668dd(a)(4)(B)). The FWS BIDEH policy (601 FW 3) provides guidance for implementation of this aspect of the Improvement Act. The integration of BIDEH policy language in the preamble of this rule and at 50 CFR 36.1 provides clarification of how the rule supports FWS policy mandates and subsequently NWR purposes and the NWR System mission. Refuge Managers will use sound professional judgment when implementing the BIDEH policy primarily during the comprehensive conservation planning process to assess the complex evaluations that are required by the BIDEH policy. Sound professional judgment incorporates field experience, knowledge of refuge resources, the refuge's role within an ecosystem, applicable laws, and best available science including consultation with others both inside and outside FWS. The use of a Refuge Manager's ''professional judgment'' is just one component of decision making and is constrained by the requirement to meet NWR System purposes, mandates, and laws. The BIDEH policy is one of several directives for Refuge Managers to follow while achieving NWR purposes and the NWR System mission. Decisions by Refuge Managers will require professional judgment that can integrate into the decision-making process, a collective understanding and knowledge of the best available science and applicable laws. The BIDEH policy is comprehensive and provides for the consideration and protection of the broad spectrum of fish, wildlife, and habitat resources found on NWRs and associated ecosystems. However, the BIDEH policy also provides Refuge Managers with an effective and purposeful evaluation process to analyze their refuges and recommend the best management direction to prevent further degradation of environmental conditions. Where appropriate, the BIDEH policy, in concert with NWR purposes and NWR System mission, allows a Refuge Manager to pursue the restoration of lost or severely degraded resources.

(16) Comment: Some commenters indicated FWS should not be conducting a formal rulemaking process that encompasses the entire region.

Commenters suggested FWS should instead follow section 3.9(g) of the BIDEH policy that identifies that compatibility reviews and comprehensive conservation plans are the required approach to address NWR specific issues.

FWS Response: FWS adheres to the guidance provided in section 3.9(g) of the BIDEH policy that states, ''Through the Comprehensive Conservation Plan (CCP) process, interim management planning, or compatibility review, determine the appropriate management direction to maintain and, where appropriate, restore BIDEH, while achieving NWR purposes.'' FWS, in evaluating the purpose and need for this rule, determined that it is not a refuge-specific rule and should be applied to all Alaska NWRs. This rule was developed because FWS wanted to establish consistent definitions and guidance for all Alaska NWRs to abide by when evaluating predator control requests on an NWR. It specifically clarifies how our existing mandates for the conservation of natural and biological diversity, biological integrity, and environmental health on NWRs in Alaska relate to predator control (50 CFR 36.32). This rule is fundamental to ensure that Alaska NWRs consistently evaluate predator control requests using standardized criteria and to ensure the public understands the legal authorities associated with predator management decisions.

(17) Comment: Commenters were concerned with FWS definitions for BIDEH and the legality of codifying these terms. They further stated that BIDEH terms require clearer definitions than what we proposed.

FWS Response: We do not include definitions of ''biological diversity,'' ''biological integrity, ''environmental health,'' and ''historic conditions'' in the Regulation Promulgation section of this final rule; these definitions remain in our BIDEH policy (601 FW 3). The NWR System Improvement Act states that, in administering the NWR System, the Secretary shall ''ensure that the biological integrity, diversity, and environmental health of the System are maintained for the benefit of present and future generations of Americans'' (16 U.S.C. 668dd(a)(4)(B)). Refuge Managers are required to comply with the Improvement Act including maintaining BIDEH on NWRs in Alaska. Adequate guidance for Refuge Managers currently exists in policy, including clear definitions of BIDEH. As explained above, the concepts of BIDEH and natural diversity are essentially the same.

(18) Comment: Commenters supported the FWS BIDEH policy because it is consistent with legal requirements for management of NWRs. They stated concerns with State IM program indicating the State did not manage for BIDEH and is not receptive to the nonconsumptive user concerns.

FWS Response: We note these comments.

(19) Comment: Commenters suggest FWS should periodically determine population and genetic status of predator species to establish baseline information to address future criticisms of the use of the BIDEH policy to justify management.

FWS Response: FWS agrees that the collection of population and genetic data for predators is important for informing future management decisions. We recognize the importance of collecting both types of data when funding and resources are available, and of considering the available data to guide our management decisions. We will also seek to continue to partner with the State, other agencies, and appropriate organizations and persons to gather the data that will best inform our current and future management decisions.

(20) Comment: The proposed regulations add a new paragraph (a) to section 36.1, and there was concern the new paragraph fails to accurately and fully reflect Alaska NWR purposes.

FWS Response: The new paragraph at 50 CFR 36.1 clarifies how NWRs in Alaska meet the primary conservation mandates of ANILCA and the Improvement Act. As identified in the preamble section of the rule, the Service finds that the requirements in ANILCA for maintaining the natural diversity of wildlife and their habitats is essentially the same as the BIDEH mandate in the Improvement Act. The added paragraph includes reference to NWR purposes provided in ANILCA (conserving natural diversity) and managing NWRs in accordance with NWR laws, mandates, and policies (Improvement Act, BIDEH policy, etc.). The language does not, nor is intended to, diminish or minimize ANILCA, the Improvement Act, or other purposes for any of the NWRs in Alaska.

(21) Comment: One commenter referenced ''Executive Order 13443'' and interpreted that it prioritizes hunting opportunities above all other wildlife-dependent uses and directs FWS to actively ''foster'' healthy and productive wildlife populations. The commenter indicated FWS does not have the legal option to ignore such a mandate that so clearly expresses its intent.

FWS Response: The purpose of Executive Order 13443, ''Facilitation of Hunting Heritage and Wildlife Conservation,'' is to ''direct Federal agencies that have programs and activities that have a measurable effect on public land management, outdoor recreation, and wildlife management, including the Department of the Interior and the Department of Agriculture, to facilitate the expansion and enhancement of hunting opportunities and the management of game species and their habitat . . . consistent with agency missions.'' There is no directive in that Executive Order (E.O.) for Federal agencies to prioritize hunting over all other uses. Section 2(e) of the E.O. directs Federal agencies to ''Establish short and long term goals, in cooperation with State and tribal governments, and consistent with agency missions, to foster healthy and productive populations of game species and appropriate opportunities for the public to hunt those species.'' FWS manages Alaska NWR lands in compliance with this directive. Alaska NWRs will continue to facilitate hunting opportunities on NWRs in compliance with NWR purposes, the Improvement Act, and the Refuge Recreation Act (16 U.S.C. 460k *et seq.*), in addition to E.O. 13443.

(22) Comment: Concern was expressed that the proposal seeks to limit management tools and preclude manipulation of habitat and/or wildlife populations for the purpose of benefitting hunters, including subsistence users. The commenter quoted from the Senator Stevens Senate Congressional Record of December 1, 1980, S15131, p. 157.

FWS Response: FWS is required to conduct all NWR activities in a manner that complies with law and policy, and we are not attempting to preclude actions that could benefit hunters or subsistence users. To the contrary, FWS has an extensive and lengthy history of management actions for wildlife species that also benefit a variety of user groups including hunters; however, these actions have complied with governing law and policy. This rule responds to the State's IM statute and corresponding recent liberalized methods and means for the take of predators designed for ''the achievement and maintenance in perpetuity of the ability to support a high level of human harvest of game (AS sec. 16.05.255(k)(5)).'' This is not consistent with statutory mandates for NWRs under the Improvement Act or ANILCA purposes for NWRs in Alaska. There is additional language from the Congressional Record associated with ANILCA that adds context to how

NWRs should be managed relative to the term ''natural diversity'' (statements of U.S. Representative Udall and U.S. Senator Stevens, as noted above). The BIDEH policy also does not preclude the manipulation of habitat or populations. Guidance in the BIDEH policy (601 FW 3.7E.) specifically states, ''Management, ranging from preservation to active manipulation of habitats and populations, is necessary to maintain biological integrity, diversity, and environmental health [BIDEH]. We favor management that restores or mimics natural ecosystem processes or functions to achieve refuge purpose(s). Some refuges may differ from the frequency and timing of natural processes in order to meet refuge purpose(s) or address [BIDEH] at larger landscape scales.'' This approach benefits a variety of user groups including hunters and subsistence users. This rule does not change existing Federal subsistence regulations (36 CFR part 242 and 50 CFR part 100) or restrict subsistence uses under Federal subsistence regulations.

(23) Comment: Commentators expressed concern that FWS values BIDEH more than the human environment.

FWS Response: The mission of the NWR System 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. The NWR System exists because people value wildlife. Congress, through its actions, has made the decision to conserve these resources within the NWR System. The Improvement Act makes clear that one of our priority responsibilities is to maintain the natural diversity, ecological processes, and ecological functions of NWRs as expressed by the BIDEH policy. Taking care of these priorities helps us ensure these natural resources will be available for future generations to enjoy, thereby maintaining or improving these areas for people as well. Refuge Managers work to balance the diverse demands of the public with the requirement to meet NWR purposes and the NWR System mission, utilizing the best available science to make decisions.

(24) Comment: One commenter offered a different definition of natural diversity (FWS policy at 701 FW 1) and suggested we consider it as an alternate definition for the rule.

FWS Response: After considering the public comments, we are defining ''natural diversity'' in this final rule as proposed, with the exception that we have removed the phrase ''and taking into consideration the fact that humans are dependent on wildlife refuge subsistence resources'' from the definition. As explained above, in promulgating this definition, we have carefully considered the legislative history of ANILCA, other ANILCA background documentation, and FWS laws, mandates, and policies. The context for the development of the definition of ''natural diversity'' is appropriate because it derives from ANILCA legislation and speaks to the intent of that legislation, which is specific to Alaska. Managing to meet the definition of ''natural diversity'' in this rule is essentially the same as management to achieve the definitions of biological integrity and diversity provided in BIDEH policy, as noted above.

(25) Comment: One commenter provided written quotations from refuge CCPs that identified language that acknowledged our ability to conduct or permit predator control on NWRs and therefore suggested we should not pursue this rulemaking process.

FWS Response: The information about predator control and predator management that was cited from refuge CCPs supports the provisions of this rule. The excerpts from the CCPs indicate that, when appropriate, FWS does conduct predator control on NWRs and that we can allow for the harvest of predators on NWRs, as long as these actions are in compliance with applicable legal and policy mandates. In evaluating the purpose and need for this rule, FWS determined that it is not a refuge-specific rule and should be applied regionally to all Alaska NWRs. This rule was developed to establish consistent definitions and guidance for all Alaska NWRs to follow when evaluating predator control requests and to ensure the public understands the associated legal authorities.

(26) Comment: Concern was expressed that the environmental assessment (EA) and BIDEH policy does not take into consideration fish.

FWS Response: While this rule was developed to address specific predator control proposals for terrestrial species, including specific methods and means for the harvest of bears, wolves, and coyotes, the requirements of natural diversity and the BIDEH policy apply to other species, including fish. Refuge Managers evaluate refuge conditions and future refuge management relative to the BIDEH policy and consider all resources associated with an NWR, including fish. The BIDEH policy is an additional directive for managers to follow while achieving NWR purpose(s) and the NWR System mission. It provides for the consideration and protection of the broad spectrum of fish, wildlife, habitat, and vegetation resources found on NWRs and associated ecosystems.

Economic Impacts

(27) Comment: Commenters expressed concern that depleted predator populations may reduce ecotourism opportunities, like wildlife watching and photography, in the future. Others were concerned the proposal may negatively impact hunting tourism.

FWS Response: Maintaining healthy and sustainable ecosystems on NWRs contributes to the wildlife-based tourism business in Alaska. Although this rule may result in slight changes in refuge visitor experiences, we do not expect this rule to significantly impact visitors engaged in either hunting or nonconsumptive uses like wildlife viewing. In fact, the rule supports the long-term sustainability of both consumptive and nonconsumptive uses on NWRs. FWS recognizes that wildlife-dependent recreational uses (hunting, fishing, wildlife observation and photography, and environmental education and interpretation), when determined to be compatible with NWR purposes, are legitimate and appropriate public uses of the NWR System as mandated by the Improvement Act. As a result of this rule, there may be slight effects to recreational big game hunting on refuges by eliminating a hunter's ability to use a few specific methods and means of take. However, until recent years, many of these methods and means were prohibited Statewide. Due to the historical ban on these methods and means of take of predators, it is estimated that these hunting methods (take of brown bears over bait, take of brown bears using traps or snares, take of wolves and coyotes during the denning season, and same-day airborne take of bears) represent a very small fraction of all big game hunting on NWRs. As a result, opportunities for big game hunting on NWRs will likely change minimally. From 2009 to 2013, big game hunting on NWRs in Alaska averaged about 40,000 days annually and represented 2 percent of wildlife-related recreation on NWRs. Big game hunting on NWRs in Alaska represented only 4 percent of all Statewide big game hunting days (1.2 million days) for the State (U.S. Department of the Interior, U.S. Fish and Wildlife Service, Division of Federal Aid, 2011 National Survey of Fishing, Hunting, and Wildlife Associated Recreation; and U.S. Department of the Interior, U.S. Fish

and Wildlife Service, National Wildlife Refuge System, Refuge Annual Performance Plan 2009–2013. Washington, DC, unpublished). With this final rule and prohibition of certain effective methods and means of take of predators, there may be a small direct positive effect to wildlife watching activities for nonconsumptive users. This rule will not affect the majority of State general hunting regulations or other allowable public uses on NWRs in Alaska. A more naturally functioning ecosystem will better facilitate a diversity of public uses.

Moose

(28) Comment: Commenters expressed concerns about a shortage of moose for subsistence hunters near the Kenai NWR that is likely due to lack of predator management. Other commenters were concerned that moose near Kenai, Alaska, are negatively impacted by trapping lines, disease, habitat loss, and trophy hunting.

FWS Response: Moose populations on the Kenai Peninsula have numbered 5,000 to 6,000 since the mid-1980s and are likely to increase in the near term due to recent and expected wildfires. In the longer term, the effects of a warming climate that include the potential introduction of lethal diseases (*e.g.,* Chronic Wasting Disease) and winter ticks, thermal stress in the spring, and a changing fire regime may negatively impact Kenai moose. In addition, moose-vehicle collisions on the Kenai Peninsula have averaged 244 per year (or about 30 percent of moose killed by humans every year), translating to over 7,100 moose killed by vehicles since 1980. Small numbers of moose may also be killed or maimed by traps, snares, and dogs. Bears and wolves do prey on calves and infirm moose, but their effect on moose population demographics is generally compensatory and not additive unless moose populations are extremely low (U.S. Fish and Wildlife Service. 2015. Draft Environmental Assessment: Non-subsistence Take of Wildlife: Proposed Regulatory Updates to Methods and Means for Predator Harvest on NWRs in Alaska). Overall moose populations within Alaska appear to be healthy and expanding into western portions of the State. Depending on where you are located in Alaska, some populations of moose are at low densities but are stable populations. These populations may be limited in many ways beyond simply predators. In many places, the food availability may actually be the more limiting factor.

Bears

(29) Comment: Comments were received pertaining to allowable bait for bears, as the proposed rule specifically stated FWS was seeking comment on the type of bait that should be allowed for the baiting of black bears. One commenter wrote that the use of carcass remains was ''unethical.'' Three commenters suggested using ''natural'' baits that bears would normally eat (*e.g.,* fish and game remains).

FWS Response: We received few comments regarding they type of bait that should be allowed for baiting bears. As a result of public comments, we have decided to continue to adopt State regulations on allowable baits for black bear hunting. Currently, State regulations, which are adopted on NWRs, require the bait used at bear baiting stations to be biodegradable.

(30) Comment: Commenters opposed same-day aerial shooting of wildlife on NWRs because it benefits trophy hunters, is not in keeping with Refuge tenets, and is not in keeping with the spirit of fair chase.

FWS Response: The allowance for same-day airborne hunting of wolves and bears by the public reverses a long-standing prohibition in the State. It has only recently been allowed by the State in areas where the overall State goal is to reduce predator populations. Same-day airborne take of wildlife is already prohibited on all Alaska NWRs for many species. This rule will add bears to the list of species that cannot be taken by hunters the same day they were airborne. Same-day airborne take of black and brown bears would likely increase harvest pressure and reduce bear populations because it allows the hunter the ability to observe bears from the air, land, and harvest the animal that same day, which provides a large advantage over a person on the ground dealing with limited visibility. Same-day airborne take of black and brown bears is prohibited in this rule because it is a particularly effective means of harvesting predators with the potential to significantly impact predator populations and subsequently impact important ecological process like the predator-prey relationship.

(31) Comment: Certain commenters proposed that the practice of killing bears and cubs in their winter dens should be prohibited, but others expressed support for the harvest method to continue for local residents for cultural reasons only.

FWS Response: In Alaska, State-regulated hunting of sows and cubs has mostly been limited to predator control areas, where the intention is to significantly reduce bear population numbers. There is an allowance under State general hunting regulations for the take of black bears, including sows with cubs and cubs, by resident hunters from a den site from October 15 through April 30 (year-round in Unit 25D, which is within Yukon Flats NWR) for customary and traditional use in interior Alaska. These State regulations open this season to any Alaska resident. These State regulations specify the game management units and seasons during which this method of harvest can occur. This rule prohibits taking black or brown bear cubs or sows with cubs (exception allowed in accordance with State law and regulations for resident hunters to take black bear cubs or sows with cubs under customary and traditional use activities at a den site October 15–April 30 in specific Game Management Units (GMUs)). Allowing cubs, and sows with cubs, to be harvested under general hunting regulations year-round or outside of customary and traditional uses would likely have the consequence of reducing the overall bear population. This would be a high-intensity impact, as the ecological function of a top predator would be reduced and the effects would be considered long term due to life strategies of these species.

(32) Comment: Some commenters were concerned that bait attracts both intended and unintended wildlife species, and the concentrations of wildlife caused by baiting may spread disease. Commentators stated that bear baiting is a serious human safety issue, as bears become habituated and potentially dangerous encounters between bears and humans increase.

FWS Response: We prohibit harvesting brown bears over bait due to the potential to reduce their population by significantly increased harvest rates. Based on basic biological differences in productivity and survival, the recovery time for brown bear populations is much longer than for black bears. At this time, available data do not yet indicate that baiting at current hunter participation levels has resulted in the overharvest of black bears. Brown bears can be attracted to black bear baiting stations in areas where their ranges overlap, and this is an area of concern that FWS will continue to monitor. There is a potential for baited bears to become human-habituated and food-conditioned. While there have been few studies that linked baiting for brown bears to increases in bear attacks on humans, there are studies documenting an increase in negative bear-human encounters when bears become food-conditioned and tolerant of humans.

Previous information on food conditioning and human habituation provides evidence that indirect problems associated with these methods are likely to occur at some level. There is also potential for higher instances of defense of life and property mortalities associated with food- and human-conditioned bears. Brown bear populations in proximity to villages, towns, and cities are often subject to higher rates of mortality from humans related to defense of life and property (U.S. Fish and Wildlife Service. 2015. Draft Environmental Assessment: Non-subsistence Take of Wildlife: Proposed Regulatory Updates to Methods and Means for Predator Harvest on NWRs in Alaska). This source of mortality must be factored into the management of overall human-caused mortality when regulating bear hunting for long-term health and survival of the population. The spread of disease related to bear baiting has not been documented as a problem at this time. Public safety of visitors to NWRs in Alaska is a high priority for FWS. There are inherent risks to visiting remote locations in Alaska, and the provisions of this final rule do not change that. This rule will however, enhance maintenance of more intact ecosystems, and healthier and more resilient populations of animals for both consumptive and nonconsumptive users.

(33) Comment: Commenters expressed concerns regarding the practice of trapping bears and believed it is not humane and not selective relative to bear type, sex, or age.

FWS Response: This rule prohibits the use of traps to harvest bears on NWRs in Alaska. Trapping of bears is a nonselective harvest method that will result in the harvest of cubs or sows with cubs. Harvest of these classes of bears is generally only employed when the goal is to reduce the overall population.

(34) Comment: Concerns were expressed regarding the cultural and biological significance in taking brown bears over bait. Commenters suggested that data have not been collected that indicate that brown bears are harvested on NWRs using bait, and there are no data that indicate brown bear baiting is a particularly effective method of take in certain areas in Alaska.

FWS Response: For federally qualified subsistence users, where the baiting of brown bears is customary and traditional, proposals should be submitted to the Federal Subsistence Board (FSB). For example, the FSB recently allowed the harvest of brown bears over bait in game management units 11, 12, and 25D, an area which includes Tetlin NWR, most of Yukon Flats NWR, and a portion of Arctic NWR. In terms of biological significance, baiting for brown bears has been shown to be a highly effective tool for reducing brown bear populations in some areas. Because of the documented importance of apex predators for maintaining long-term fitness and resilience in their prey populations, and because such predators are part of NWRs' natural diversity, this rule prohibits baiting of brown bears for general sport hunting on all NWRs in Alaska. Even though bear baiting may not be practiced on all refuges, and the effects of bear baiting for population reduction will vary from region to region and from habitat to habitat in Alaska, FWS is legally tasked with maintaining natural diversity and healthy ecosystems. It is not prudent to wait until the practice spreads to new areas or impacts previously unaffected brown bear populations before taking action. Thus, we are proactively precluding the loss of diversity and degradation of ecosystem functions by prohibiting this practice on NWRs Statewide, both where it may have occurred already and where it could be initiated in the future.

(35) Comment: A commenter stated the BOG's management is not scientifically driven and could result in widespread reductions of Alaska's grizzly [1] bear populations. The commenter cited that hunter kill rates on wolves, grizzly bears, and other carnivores has a multiplier effect on total mortality over time that exceeds natural mortality rates and is due to loss of mature reproductive individuals and disruptions of social structures.

FWS Response: FWS proposed regulatory changes specifically to address methods and means employed to reduce predator populations on NWRs in Alaska. Many of these methods this rule prohibits involve the harvest of adult female animals and/or females with dependent young. We concur with the commenter that such approaches have impacts on predator populations beyond just the animals harvested. Predator reduction methods allowed by the State are permitted where the goal is to reduce predator numbers. The elimination or reduction of ungulate predators and predatory forces on wild ungulate populations may seem like the best way to produce more ungulates, but these ecological systems rely on predation and apex predators to maintain long-term fitness and resilience of ungulate populations. It is these ecological processes that must be maintained to provide healthy ungulate populations on NWRs in Alaska for future generations of both consumptive and nonconsumptive users.

(36) Comment: Commenter stated it was inappropriate for FWS to extrapolate the overharvest of brown bears on Kenai NWR, which resulted from State regulations, to a potential scenario of overharvest of brown bears to the rest of the State.

FWS Response: Under its general or sport hunting regulations, the State had a long-standing prohibition on the harvest of brown bears over bait. This was only recently changed in the 2012–2013 regulatory year, when one of the stated goals of the 20E intensive management area, located adjacent to Tetlin NWR, was to significantly reduce brown bear populations to enhance moose populations. That was the reason offered by the State in allowing the harvest of brown bears over bait. While every designed program results in varying amounts of take, the use of bait for brown bears has been and continues to be employed to reduce brown bear population levels. FWS also considered the cumulative impacts from all the various methods and means that have been changed by the State for the purpose of reducing predators. While the level of effectiveness of each method may vary in a given unit or circumstance, the impact of these cumulative changes have had and will have the collective effect of reducing predator populations for the stated goals of increasing ungulate populations for human consumption. Although current human-use patterns that potentially negatively impact brown bear populations on the Kenai may differ relative to the rest of the State today, human-use and access patterns are neither static nor perfectly predictable. In addition, historically remote areas are becoming increasingly accessible. As a result, FWS finds it necessary to adopt these regulatory changes across all NWRs in Alaska. FWS is mandated to preserve the natural diversity of the wildlife and their habitats. Ungulate populations benefit from having apex predators as one of the natural forces driving their populations and maintaining their fitness and resilience. These benefits are lost when predator populations are sharply reduced and maintained at low levels for long periods of time. For these reasons, FWS finds it is necessary to adopt the regulatory changes set forth in this rule for nonsubsistence hunting on NWRs in

[1] According to MacDonald and Cook (2009), brown and grizzly bear are one in the same: *Ursus arctos*. For the purposes of this final rule, brown bear includes grizzly bear but will only be referred to as brown bear.

Alaska. Protection of the ecological processes will provide healthier ungulate populations for all users, both consumptive and nonconsumptive.

(37) Comment: A commenter identified a discrepancy between baiting regulations at 50 CFR 32.2 and at 50 CFR 36.32.

FWS Response: We correct that error in this rule.

Wolves and Coyotes

(38) Comment: Multiple commenters expressed that wolf and coyote season closures should extend through November. Commenters were concerned with the practice currently allowed by the State that allows taking animals while in the denning season. Concerns were expressed about the value of pelts taken in summer.

FWS Response: This rule prohibits the take of wolves and coyotes from May 1 through August 9 for nonsubsistence users. These dates reflect the former longstanding State harvest seasons that provided reasonable harvest opportunities while still maintaining natural diversity with viable and healthy wolf and coyote populations. For the reasons stated herein, this rule maintains this traditional and historically effective management standard that had been used by both State and Federal managers rather than adopting recent State general hunting regulations that lengthened the hunting seasons on both species. FWS understands that some individuals may have uses for wolf pelts that are harvested outside the normal trapping season. This rule, however, protects wolves and coyotes during the denning season when they and their young are vulnerable but allows the opportunity for harvest during the winter months. Should wolf or coyote population levels become a concern with respect to natural diversity in the future, FWS will work with the State and/or the FSB, as applicable, to consider appropriate actions at that time.

(39) Comment: Commenters expressed concerns that predator control measures can eliminate wolf packs and negatively impact wolf pack dynamics, and that hunting can increase levels of cortisol and reproductive hormones that may negate the intent of predator control as intended. Other commenters were concerned about the survival of orphaned pups, and the maintenance of healthy wolf and coyote populations as a whole.

FWS Response: This rule expressly prohibits certain particularly effective harvest methods and means on Alaska NWRs and clarifies when predator control can be authorized. Predator control will not be implemented on a NWR unless it is based on sound science in response to a conservation concern. The rule is intended to reasonably limit, but not eliminate, public hunting opportunities of both wolves and coyotes. The rule shortens hunting seasons for these species to minimize negative impacts to these populations that can occur if species are harvested while raising their pups.

(40) Comment: A commenter opposes restrictions on taking coyotes since they are in conflict with regulations established in other States.

FWS Response: This rule is consistent with the former longstanding State harvest seasons that balance both coyote harvest and coyote conservation. NWRs in other States have a diverse array of coyote hunting seasons ranging from no coyote hunting to seasons lasting several months. Alaska NWRs regulations are developed to meet Alaska NWRs purposes consistent with both ANILCA and the Improvement Act, and these regulations only apply to Alaska NWRs.

(41) Comment: Commenters request reasonable daily bag limits on wolves.

FWS Response: With this rule, FWS intends to address ''particularly effective'' methods of harvest, and does not specifically address daily bag limits for the affected species. Although certain bag limits may have potential to result in a conservation concern in a given area or for a certain species, this rule does not address them. In general, bag limits are more appropriately addressed through the State's regulatory processes and the FSB program in conjunction with harvest information and population data. Should the issue surrounding excessive bag limits become a concern in the future with respect to maintaining natural diversity, FWS will work with the State and the FSB as appropriate.

Sport/General Hunting and State Subsistence Hunting

(42) Comment: Commenters expressed concern the rule would negatively affect subsistence hunting, and if wildlife populations fluctuate to low levels, subsistence users will be required to purchase more food.

FWS Response: ANILCA provides a priority to rural Alaskans for the nonwasteful taking of fish and wildlife for subsistence uses on Federal public lands in Alaska, including on NWRs. Under ANILCA, all NWRs in Alaska are also mandated to provide the opportunity for continued subsistence use by local rural residents, as long as this use is not in conflict with the conservation of fish and wildlife populations and habitats in their natural diversity or with fulfilling the international treaty obligations of the United States. Additionally, Title VIII of ANILCA, section 802, states that ''consistent with sound management principles, and the conservation of healthy populations of fish and wildlife . . . the purpose of this title is to provide the opportunity for rural residents engaged in a subsistence way of life to do so.'' FWS recognizes the importance of the fish, wildlife, and other natural resources in the lives and cultures of Alaska Native peoples and in the lives of all Alaskans, and in accordance with section 804 of ANILCA, we continue to recognize subsistence uses of fish and wildlife and other renewable resources as the priority consumptive use on Alaska NWRs. This rule does not change existing Federal subsistence regulations (36 CFR part 242 and 50 CFR part 100) or restrict the taking of fish or wildlife for subsistence uses under Federal subsistence regulations. FWS is committed to allowing subsistence harvest across a broad taxonomic spectrum of species, specifically so that as some populations decline others remain stable or increase and thus remain readily available for harvest by those who rely on them.

(43) Comment: Commenters expressed concern the rule would negatively affect hunters, as prohibited predator control methods for taking game are important culturally and biologically to hunters.

FWS Response: FWS recognizes that some hunters will be impacted by this rule; however, because this rule maintains methods and means for take of predators that were formerly prohibited by the State, the rule will impact only a small fraction of all big game hunting opportunities on NWRs. This rule restricts certain methods and means of harvest on NWR lands under the State general hunting regulations; it does not prohibit the harvest of predators. In addition, this rule does not affect the current State harvest regulations that are applicable to hunting on non-Federal lands. The Federal subsistence regulations on NWR lands remain unchanged. The Federal subsistence regulations reflect the flexibility that federally qualified subsistence users' desire in seasons and harvest limits.

(44) Comment: Commenters expressed concern about the inappropriate techniques (such as baiting bears, trapping bears, and same-day airborne take of wildlife) used for sport hunting and negative impacts to individual animals and populations.

FWS Response: The specific methods and means for the general or sport

harvesting of predators that are prohibited in this rule conflict with FWS mandates to conserve fish and wildlife populations and habitats in their natural diversity and to maintain BIDEH on NWRs in Alaska. One aspect of the rule is to prohibit certain methods and means for taking predators under State general hunting regulations on NWR lands. While many commenters identified these methods as ''unethical'' or ''inhumane,'' this rulemaking specifically addresses prohibiting those methods and means that have the potential to greatly increase predator harvests and to disrupt natural diversity and the interactions of wildlife.

(45) Comment: Commenters expressed concerns that it is equally important for Alaska residents to be able to hunt on all lands in Alaska. There were also concerns the rule is more about eliminating hunting on refuge lands than predator control management.

FWS Response: This rule does not eliminate subsistence or nonsubsistence hunting on NWR lands for any species. The intent of the rule is to prohibit a small number of specific, highly effective methods and means of predator harvest on NWR lands that have been allowed under the State's general hunting regulations. The Background section, above, discusses the laws and policies that relate to subsistence and nonsubsistence hunting on NWR lands, including the preference/priority for subsistence uses that applies to all Federal lands in Alaska, including NWRs. The Background discussion also states that hunting is recognized as one of several priority uses of the NWR System (605 FW 2), and that taking of fish and wildlife through public recreational activities is authorized on NWRs in Alaska ''as long as such activities are conducted in a manner compatible with the purposes for which the areas were established'' (50 CFR 36.31(a)).

(46) Comment: One commenter indicated that the proposed rule will be unenforceable due to lack of resources.

FWS Response: The methods and means of harvest prohibited by this rule will be enforced by the Service in a similar fashion to other applicable State and Federal harvest regulations. The Service will continue to prioritize its resources to provide for effective enforcement, recognizing that enforcement issues will likely be the greatest near refuge boundaries or in areas with checkerboard land ownerships.

(47) Comment: Commenters expressed concern about the use of drones.

FWS Response: The Alaska State hunting regulations were modified in 2014 to prohibit the use of any device that has been airborne, controlled remotely, and used to spot or locate game with the use of a camera or video device (5 AAC 92.080(7)). 50 CFR 36.32(a) continues to adopt non-conflicting State and Federal laws pertaining to the taking of fish and wildlife. This Alaska law regarding drones is an example of such an adopted regulatory provision, and such use of a drone is also a violation of this rule.

Intensive Management (IM) Programs

(48) Comment: Commenters expressed concern that State IM practices on lands near or adjoining NWRs in Alaska will negatively impact the predator and/or prey populations on NWR lands.

FWS Response: It is possible that IM practices on neighboring lands may have impacts to resources on NWR lands. Each Federal and State agency involved with managing land in Alaska has a different management mandate, and there will be instances where animals that cross boundaries are exposed to different management regimes. This challenge for managers is not new. It is the longstanding practice of FWS that our refuge regulations apply on to the lands and waters that FWS administers.

Fortunately, Alaska NWRs are generally large enough to maintain natural and biological diversity and integrity, despite these challenges. Despite differences in their respective management mandates, Federal and State wildlife managers throughout Alaska strive for as much interagency consistency as possible when developing and implementing wildlife management actions. Such consistency is in the best interests of both our constituents and the wildlife resources they value.

(49) Comment: Commenters stated that enabling legislation for Alaska NWRs does not include directives to conduct IM practices on NWRs. Some commenters believe IM practices are costly and not based on sound science.

FWS Response: IM is a State, not Federal, mandate. The rule will help the agencies and the public better understand differences between the State mandate and Federal laws and policies.

(50) Comment: Some commenters stated that the proposal is politically driven or intended to impede State efforts to manage wildlife on Alaska lands.

FWS Response: The sole purpose of this rule is to ensure that FWS carries out its statutorily mandated responsibilities for Alaska NWRs. The rule establishes definitions and administrative processes that fulfill these responsibilities. This effort is not politically driven, but it is an administrative process to clarify and define the legally mandated management responsibilities of Alaska NWRs, particularly when they are not consistent with those of the State. The regulations clarify FWS' mandate under ANILCA ''to conserve fish and wildlife populations, and habitats in their natural diversity,'' the first-listed management purpose for each Alaska NWR. This effort to clarify and define the natural diversity mandate is intended to provide a better understanding of when predator control is allowed by FWS on Alaska NWRs. Harvest techniques come in many forms, such as lengthening seasons, increasing bag limits, government-funded control, and allowing more effective means of pursuit. These techniques are, however, subject to NWR System laws, regulations, and policies. It is for this reason that we are making the regulatory changes set forth in this rule.

Predator and Prey Species Management

(51) Comment: Commenters expressed support for the proposal and stated the State's current predator management practices do not recognize the importance of apex predators, and many disagreed with BOG predator control measures.

FWS Response: We note this comment.

(52) Comment: Commenters expressed the need to include a prohibition against using Pittman-Robertson funds for predator control.

FWS Response: Addressing the use of Pittman-Robertson (Wildlife Restoration or WR) grant funds is outside the scope of this rulemaking. Regulations for the use of Federal assistance, including WR funds, are uniform and national in scope (see 2 CFR part 200 and 50 CFR part 80). Eligibility of WR funds specific to predator control is not currently addressed in our regulations, but rather in FWS policy (521 FW 1).

(53) Comment: Commenters stated opinions that predator control is effective for providing continued (ungulate) populations for subsistence and nonsubsistence users.

FWS Response: FWS recognizes predator control as a management tool and, as stated above, authorizes the technique when appropriate and consistent with Federal laws and policies.

(54) Comment: Commenters were concerned the rule will negatively

impact hunting and other activities on Alaska's NWRs.

FWS Response: As stated above, the methods and means restrictions do not apply to the take of fish and wildlife under the Federal subsistence regulations. Because this rule follows practices historically used by State wildlife regulators until only recently, there will be minimal incremental impacts to nonsubsistence general hunting through the implementation of the restrictions on certain methods and means of take. The definition of ''predator control'' at 50 CFR 36.2 and the process of allowing predator control on NWRs in Alaska are designed to clearly articulate to Refuge Managers and the public under what circumstances and conditions FWS will consider predator control programs. Not conducting active predator control programs allows predator-prey populations to fluctuate naturally in response to factors that drive these dynamics, including habitat conditions. As a result, healthier populations of both predators and prey will exist but will fluctuate and, at times, may either increase or decrease game hunting opportunities. Predator control programs may temporarily increase prey populations, but can have undesirable impacts such as habitat damage, disease, or declines in herd fitness that also negatively affect opportunities for hunting. This rule complies with ANILCA's legislated purpose that the NWRs were established and shall be managed to conserve fish and wildlife populations and habitats in their natural diversity.

(55) Comment: Some commenters stated restrictions on predator management would impact FWS' ability to maintain healthy predator-prey populations.

FWS Response: The large landscapes within the NWR units in Alaska are still largely intact and fully capable of supporting healthy predator-prey populations without the need for human management actions such as predator control programs. The relationships between predators, prey, and habitat is complicated, subject to large population or habitat condition swings that can be triggered by other factors, including weather, fire, disease, and other wildlife species. When considering predator-prey population dynamics, FWS must also carefully consider human impacts that can affect these relationships, including impacts from hunting (*i.e.,* bag limits and seasons); disturbance, particularly during critical periods such as calving or wintering; potential for introduction of disease; human-caused habitat impacts such as fire or climate change; barriers to movement; and other factors. Successful management of these factors and preserving the natural ecosystem functions of landscapes will enable us to continue to maintain healthy, dynamic prey-predator populations.

(56) Comment: Several commenters are concerned that the term ''predator control'' is vague and could be taken out of context or banned from use.

FWS Response: We have added clarifying language to the preamble of this rule to help readers better understand predator control and its context. The rule defines predator control as ''the intention to reduce the population of predators for the benefit of prey species.'' For clarity, this includes predator reduction practices, such as, but not limited to, those undertaken by government officials or authorized agents, aerial shooting, or same-day airborne take of predators. Other less intrusive predator reduction techniques, such as, but not limited to, live trapping and transfer, and authorization of particularly effective public harvest methods and means, are also included. FWS recognizes predator control as a management tool and uses the technique, when appropriate and consistent with Federal laws and policies governing Alaska NWRs. This rule clarifies, for the public and agencies, how FWS complies with its ANILCA mandate to conserve fish and wildlife populations and habitats in their natural diversity, the first-listed management purpose for Alaska NWRs. This clarification of the ANILCA natural diversity mandate is intended to provide a better understanding of when predator control techniques are allowed on Alaska NWRs.

(57) Comment: Commenters would like more flexibility in working with resource managers in order to decide if and when predator control is necessary.

FWS Response: Any predator control program proposed for NWRs in Alaska must be consistent with Federal laws and policies. A purpose of this rule is to implement a consistent approach for determining when predator control will be conducted and to clarify how Alaska NWRs' natural diversity mandate is linked to predator control management on NWRs. Refuge Managers will continue to discuss refuge management issues with tribal leaders, the State, and other interested parties.

(58) Comment: Commenters expressed that keeping healthy populations of prey species could best be accomplished by maintaining healthy populations of apex predator species.

FWS Response: The Service agrees with this comment.

(59) Comment: Commenters expressed concerns that ungulates are more negatively affected by other factors than by predators.

FWS Response: There are many factors other than predators that affect ungulate populations. Natural phenomena, such as weather and fires, can have significant effects on habitat and wildlife. FWS must also carefully consider human impacts that can affect ungulate populations, including impacts from hunting (*i.e.,* bag limits, methods and seasons); disturbance, particularly during critical periods such as calving or wintering; potential for introduction of disease; human-caused habitat impacts such as fire or introduction of weed species; barriers to movement; and other factors.

(60) Comment: Commenters drew parallels to the wilderness characteristics at stake on Alaska's NWRs compared to what occurred at Yellowstone and other National Parks with the loss of wolves (and subsequent reintroduction), bears, and other predators.

FWS Response: The long-term absence (70 years) of wolves in Yellowstone National Park and their subsequent reintroduction is a classic science-based example of the influence of apex predators in sustaining naturally diverse and healthy ecosystems (*http://www.cof.orst.edu/leopold/papers/RippleBeschtaYellowstone_BioConserv.pdf*). The studies following wolf reintroductions completed in 1995–1996 indicate substantial vegetation, bio-diversity, and hydrologic responses related to reintroducing wolves and their subsequent influence on prey species like elk. Elk density and behavioral changes (primarily foraging) resulting from wolf reintroductions have had cascading positive impacts throughout the Yellowstone ecosystem. ANILCA and the Improvement Act mandate FWS to manage NWRs using a natural diversity approach that maintains healthy ecosystems and where natural biotic and abiotic processes and systems continue to flourish. Maintaining a diverse and healthy population of predators is essential to meeting these mandates, and this rule supports FWS' ability to achieve these mandates while also providing for subsistence and other uses as applicable.

Comment Period

(61) Comment: Commenters expressed concerns that the public comment period was too short to allow for a review of the proposed rule and environmental assessment.

FWS Response: Under the Administrative Procedure Act (see 5 U.S.C. 553), a general notice of proposed rulemaking shall be published in the **Federal Register**, and after that publication, the agency must ordinarily provide the public a reasonable opportunity to submit written data, views, or arguments on the proposed rulemaking for consideration by the agency. Executive Order 12866 establishes 60 days as the standard for a proposed rule's comment period (see section 6(a)(1) of Executive Order 12866).

We published our proposed rule on January 8, 2016 (81 FR 887). The comment period for our proposed rule, as extended (see 81 FR 9799; February 26, 2016), lasted 90 days, ending April 7, 2016. In accordance with the E-Government Act of 2002 (Pub. L. 107–347), FWS provided for submission of comments by electronic means, as well as by hard copy or in person or at public meetings, and made available online the comments and other materials included in the rulemaking docket. We received over 3,600 comments, including substantial comments from the State, BOG, Alaska Native Tribes, ANCSA corporations, RACs, Association of Fish and Wildlife Agencies (AFWA), and numerous other Alaskan constituents, organizations, and businesses. Electronic sites to notify the public about the 30-day extension of the original 60-day comment period (81 FR 9799; February 26, 2016) for the proposed rule were updated immediately on the Alaska NWR System Web site (February 25, 2016) and the Federal eRulemaking Portal (*http://www.regulations.gov*) (February 26, 2016). Both Web sites remained fully functional for the entire comment period. Within the Alaska NWR system Web site, the extended comment period date was highlighted in red text to attract and alert a reviewer to the new comment period deadline. FWS posted phone and email contact information on all social media, electronic Web site, and printed outreach materials to ensure that anyone needing assistance to acquire documents or comment on the proposed rule and EA could contact an FWS representative for assistance. The extensive outreach history conducted prior to and after publication of the proposed rule is well documented in both this rule and the FONSI. FWS is confident, given our comprehensive outreach history and the proposed rule's 90-day comment period, that all interested constituents had a reasonable opportunity to understand and comment on the proposed rule and EA.

(62) Comment: One commenter was concerned there may be last minute language changes or additions to the rule that will not be part of the public commenting process.

FWS Response: The intent of the formal comment period is to obtain feedback and suggested changes on the proposed rule. The notice-and-comment process enables anyone to submit a comment on any part of the proposed rule. At the end of the process, the agency must base its reasoning and conclusions on the rulemaking record, consisting of the comments, scientific data, expert opinions, and facts accumulated during the pre-rule and proposed rule stages. In the case of this rule, FWS has not relied on significant new data or arguments received after the comment period, and we have determined that any modifications to the proposed rule are a logical outgrowth of the information made available to us during the rulemaking period.

Regulations for Closures and Public Participation Procedures

(63) Comment: Commenters expressed agreement with FWS for adding the Internet as a method of notifying affected people and organizations about hearings pertaining to closures or restrictions.

FWS Response: We note this comment.

(64) Comment: Some commenters stated that Internet-based means of soliciting comments might invite people who will never visit Alaska to sway FWS' decision.

FWS Response: The mission of the NWR System is to administer a national network of lands and waters for the conservation, management, and where appropriate, restoration of fish, wildlife, and plant resources and their habitats within the United States for the benefit of present and future generations of Americans. Therefore, when we propose a change to our NWR regulations, we accept all timely comments regardless of their source. Everyone has a right to offer comments on regulations affecting the public lands. FWS is committed to using a wide variety of notification and comment methods to ensure everyone with a vested interest in a given proposal has the opportunity to comment. Utilization of Internet-based communications is in furtherance of, and fully consistent with, the directives of Congress in the E-Government Act of 2002 (see our response to Comment (61)). The eRulemaking Program is a widely utilized method of communication for a wide variety of interested members of the public covering a broad geographic area, including many (not all) parts of Alaska. The public comment process is not like a ballot initiative or an up-or-down vote in a legislature; agencies cannot simply base a final rule on the number of comments in support or against a particular proposal. At the end of the comment process, the agency must base its decision on the record before it which consists of the comments, scientific and other data, expert opinions, laws, policies and facts accumulated during the rulemaking process. A broader range of views and opinions about any agency proposal is critical to FWS in ensuring that the best resource decisions are made for the continuing benefit of the American people. FWS is committed to utilizing a broad range of communication methods to ensure all interested individuals have an opportunity to participate in the process.

(65) Comment: Commenters expressed concern about FWS using the Internet as a method to notify the public because Internet access is limited in rural Alaska. Commenters expressed concerns that the rule removes traditional methods of notification like radio and newspapers.

FWS Response: The rule does not reduce the methods used to conduct public outreach but rather expands the methods that should be used to communicate information to a broadly dispersed and diverse public that includes Alaska and the rest of the United States. FWS is very sensitive to the fact that electronic communication of information may not be appropriate or reliable in rural areas of Alaska, and therefore FWS will continue to use traditional means of communication such as newspapers, postal mail, radio announcements, flyers, and so forth, in addition to providing information via electronic methods like Web sites, list serves, and email. This rule updates our regulations to take advantage of our current options for communication by adding the use of the Internet, broadcast media, or other available methods, in addition to continuing to use the more traditional methods of newspapers, signs, and radio.

(66) Comment: Several commenters indicated that public meetings and hearings are appreciated, but the rule is inconsistent regarding whether or not they are required, in particular as it relates to closures.

FWS Response: We revised applicable paragraphs in the ''Public participation and closure procedures'' section of this rule (50 CFR 36.42 in the Regulation Promulgation section, below) to address

this comment and to clarify when meetings and hearings are required.

(67) Comment: Multiple commenters expressed concern about the closure procedures in the proposed rule. Concerns included increasing the emergency closure period from 30 days to 60 days, which may encompass most or all of an entire hunting season for some species; and fear that temporary closures may extend for years, thus restricting access for subsistence use. Others stated that the proposal for temporary closures eliminates the need for permanent closures.

FWS Response: FWS recognizes that emergency closures may be implemented at any time and may extend up to 60 days, thereby potentially impacting all user groups, including hunters. If an emergency closure is implemented, it is the intent of FWS to resolve the emergency as quickly as possible to reduce impacts to all NWR user groups. Invoking an emergency closure is a serious action that FWS understands may have important consequences and hence will be invoked only when absolutely necessary. FWS clarified language in this rule to indicate that an emergency closure will not exceed 60 days. Closures requiring longer than 60 days will require FWS to comply with temporary or permanent nonemergency closure procedures that require consultation with the State, affected Tribes, and Native Corporations as well as the opportunity for public comment and a public hearing in the vicinity of the area(s) affected. Based on public comments, the time for temporary closures or restrictions related to the taking of fish and wildlife will extend only for as long as necessary to achieve the purpose of the closure or restriction, and may not exceed 12 months. Another temporary closure or restriction may be allowed only after public comment, hearing, and consultation with State, Native Corporations, and Tribes as indicated in 50 CFR 36.42(d)(2). Permanent closures or restrictions related to the taking of fish and wildlife have no time limit associated with the closure period. This is distinctly different from temporary closures, which are implemented with the intent of extending only as long as necessary to achieve a desired purpose for the closure or restriction.

(68) Comment: Some commenters are concerned FWS plans to remove the requirement for FWS to hold a hearing on the emergency closure procedure.

FWS Response: This rule does not change hearing procedures for emergency closures. Emergency closures or restrictions relating to the taking of fish and wildlife will be accompanied by notice pursuant to 50 CFR 36.42(f) with a subsequent hearing.

(69) Comment: Multiple commenters expressed concern about the authority given to the Refuge Manager to initiate closures without input from the public. Commenters suggested that there is consultation with other entities before closures occur.

FWS Response: Only certain emergency closures can be implemented by a Refuge Manager without receiving formal input from the public, State, Tribes, and Native Corporations. For any closure extending beyond 60 days, the manager is required to consult with the State, Tribes, and Native Corporations and provide the opportunity for public comment. To date, there has been a very low level of emergency closures executed on NWRs in Alaska.

Public Process and Involvement

(70) Comment: One commenter was concerned that if FWS received many comments from special interest groups, those comments from ''outsiders'' might outnumber those received from persons directly affected, such as tribal members.

FWS Response: The mission of the NWR System is to ''administer a national network of lands and waters for the conservation, management, and where appropriate, restoration of fish, wildlife, and plant resources and their habitats within the United States for the benefit of present and future generations of Americans.'' Therefore, all Americans have vested interest in the management of NWRs, regardless of where they live. The notice-and-comment process enables anyone to submit a comment on any part of the proposed rule. This process is not like a ballot initiative or an up-or-down vote in a legislature. An agency is not allowed to base its final rule on the number of comments in support of the rule over those in opposition to it. The agency also does not weigh comments based on where the commenter resides. At the end of the process, the agency must base its reasoning and conclusions on the rulemaking record, consisting of the substantive comments, scientific data, expert opinions, and facts accumulated during the pre-rule and proposed rule stages.

(71) Comment: One commenter was concerned that permanent closures for the take of fish and wildlife would not require a public hearing.

FWS Response: Permanent closures or restrictions related to the taking of fish and wildlife will be effective only after allowing for the opportunity for public comment and a public hearing in the vicinity of the area(s) affected and publication in the **Federal Register**. These closures also require consultation with the State and affected Tribes and Native Corporations.

(72) Comment: Commenters expressed discontent with certain ''public process'' experiences, saying they do not believe Alaska residents and other American citizen concerns are being heard.

FWS Response: As a result of public comments during scoping for the proposed rule and EA, and from comments we received during the 90-day public comment period on the proposed rule, FWS made several changes to this rule (see table above titled, Summary of primary differences between our proposed rule and this final rule). These changes are documented in this final rule and the FONSI along with FWS' response to comments. FWS strived to gather input on the proposed rule using a broad array of outreach efforts that included public hearings, open houses, meetings, and communicating the availability of the rule via radio, television, newspapers, Web sites, listservs, emails, posters, flyers, and phone calls. When distributing paper or electronic information, FWS ensured that there was always a phone contact included so that a person could call someone to receive materials or get assistance on how to comment. As a result of this process, we gathered over 3,600 comments, of which 409 were substantive.

(73) Comment: Commenter stated that conserving and enhancing resources for the benefit of the people requires collaborating with the State and enhancing public involvement in decision making.

FWS Response: FWS agrees, and throughout this regulatory process FWS engaged the public, agencies, and nongovernmental organizations in conversations. Public involvement is fundamental to our mission and required by law. Public lands are held in trust for the American people, and they have the right to provide input on how these lands will be managed. Successful management of NWR resources is achieved by working with our conservation partners, like the Alaska Department of Fish and Game (ADFG). FWS prefers to defer to the State on regulations of hunting and trapping on NWRs in Alaska, unless, when doing so, FWS would not be in compliance with Federal laws and FWS policy.

Pubic Uses

(74) Comment: Multiple commenters expressed concern about real or perceived decreased opportunities for wildlife viewing and photography as a result of the State's predator control regulations and IM actions. Commenters were concerned that hunters had higher priority than other public uses and wanted NWRs to have a natural variety of wildlife species.

FWS Response: FWS is mandated by the Improvement Act to permit for a diversity of wildlife-dependent recreational opportunities that includes both consumptive and nonconsumptive opportunities. This rule facilities our ability to manage NWRs for natural diversity and BIDEH, which in turn will facilitate providing a diversity of recreational opportunities from wildlife observation and photography of predators to harvest of predators.

(75) Comment: Commenters expressed concerns that only predators would exist in the future for the public to view due to an unbalanced ecosystem that has resulted from removal of predator control practices.

FWS Response: Maintaining healthy predator-prey relationships is an important part of managing Alaska NWRs. Predators cannot survive without prey. Indeed, predator and prey populations in Alaska co-existed and fluctuated naturally for millennia without intensive predator management.

Scientific Methods

(76) Comment: Commenters expressed concern about the science used to support the proposed rule and were specifically concerned with FWS' use of the terms ''potential'' and ''intent'' relative to proposed management practices and outcomes.

FWS Response: The terms ''intent'' or ''potential'' are used in this rule and the EA to express our interpretation or understanding of information. The use of these terms is appropriate in that we do not necessarily always have specific studies or references for specific Alaska populations or NWRs, but rather we make decisions based on the best available science. In the ideal scenario, we have the data and analysis completed for a specific situation and location that can be directly applied to a decision-making process. Sometimes, however, we are charged with making decisions based on the best scientific information available as well as the professional judgment of our biologists and managers. The justifications for actions identified in this final rule are soundly supported by the best available science and do incorporate analyses of Alaska-specific data where available. FWS' evaluation of the best available science data, along with the professional judgment of our biologists and managers, indicate a strong potential and/or intent that the specific methods and means of take prohibited by this rule will have significant negative impacts to specific populations and the overall conservation of NWR natural ecological processes. It is not the intent of, nor is it appropriate for, FWS to simply wait and document negative impacts of threats that can be avoided. Rather, the prudent conservation approach is to be proactive in our management by curtailing and protecting NWRs from threats that we infer, based on best available science, will have negative consequences (precautionary principal). Throughout the rulemaking process, FWS worked to collect and apply the best available scientific information to evaluate and develop the regulatory changes set forth in this rule. There are substantial references cited in the EA that document our current knowledge of the importance of predator-prey relationships relative to sustaining healthy ecosystems and that clearly outline the justification and rationale for the methods and means prohibitions identified in this rule. This rule is not based on achieving or maintaining any particular wildlife population levels, and therefore did not require comprehensive data documenting those levels. Rather, the rule reflects FWS' responsibility to manage NWRs for natural processes, including predator-prey relationships, and responds to practices that are intended to alter those relationships.

(77) Comment: Commenters expressed support for the proposed rule and agreed with the science and philosophy used by FWS to support regulatory changes and how wildlife is managed on NWRs. Commenters questioned the science behind the purpose and need for the State's current predator management practices, expressing that the State does not recognize the scientific importance of maintaining healthy populations of top predators and does not evaluate other important factors influencing ungulate populations like habitat.

FWS Response: We note this comment.

General or Other Comments

(78) Comment: Commenter expressed concerns over the layout and organization of the proposed rule document and offered suggestions for improvements.

FWS Response: Editorial suggestions from commenters for the rule focused on the layout of the table that summarized the changes proposed to the existing procedures for public participation and closures at 50 CFR 36.42. The suggested edits were evaluated and incorporated as appropriate to clarify rule changes.

(79) Comment: Commenters expressed strong support for the changes proposed by FWS. Many commenters stated they believe the proposed rule does not violate ANILCA and other laws and regulations, will allow for continued subsistence use, and will help secure the BIDEH of the NWR System for the continued benefit of present and future generations.

FWS Response: We note this comment.

(80) Comment: Commenters requested that FWS delete 50 CFR 36.12(d)(3) from the regulations or provide an exception for Unit 23 Selawik NWR. A commenter proposed modifying language to read, ''except for in Unit 23, Selawik NWR, a snowmachine may be used to position a caribou, wolf, or wolverine for harvest provided that the animals are not shot from a moving snowmachine machine.'' Commenters indicated that such use of machines is necessary to pursue and harvest wildlife, especially predators.

FWS Response: This comment cannot be addressed as part of this final rule because it is outside the scope of this rulemaking. We did not include any proposed changes to 50 CFR 36.12 in the proposed rule, and the public was not given notice or a chance to comment on the change. To amend this section of the regulations would require a separate rulemaking.

(81) Comment: Commenters expressed a concern that managing for natural diversity is different in NWRs compared to National Parks.

FWS Response: Alaska NWRs have different management mandates from National Parks and Monuments, as specified by ANILCA and other laws. NWRs are managed differently than National Parks as illustrated in the Senate Congressional Record that states that habitat manipulation and predator control and other management techniques frequently employed on NWR lands are inappropriate within National Parks and NPS Monuments (ANILCA, Senate Record, Dec. 1980). Alaska NWRs may use habitat manipulation, predator control, or other management techniques, as appropriate, when there is a conservation concern and a sound biological justification for the action.

Required Determinations

Plain Language Mandate

This rule, as well as the proposed rule, contains revisions to regulations in order to comply with longstanding Presidential directions to use plain language in regulations. Such revisions do not modify the substance of the previous regulations. These types of changes include using ''you'' to refer to the reader and ''we'' to refer to the NWR System, using the word ''allow'' instead of ''permit'' when we do not require the use of a permit for an activity, and using active voice (*i.e.,* ''We restrict entry into the refuge'' vs. ''Entry into the refuge is restricted'').

Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order (E.O.) 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget will review all significant rules. OIRA has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

Regulatory Flexibility Act

Under the Regulatory Flexibility Act (RFA; 5 U.S.C. 601 *et seq.,* as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996), whenever an agency must publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effects of the rule on small entities (small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of the agency certifies the rule will not have a significant economic impact on a substantial number of small entities. SBREFA amended the RFA to require Federal agencies to provide a statement of the factual basis for certifying that the rule will not have a significant economic impact on a substantial number of small entities. Thus, for a regulatory flexibility analysis to be required, impacts must exceed a threshold for ''significant impact'' and a threshold for a ''substantial number of small entities.'' See 5 U.S.C. 605(b). SBREFA amended the Regulatory Flexibility Act to require Federal agencies to provide a statement of the factual basis for certifying that a rule would have a significant economic impact on a substantial number of small entities.

As described above and in the January 8, 2016, proposed rule (81 FR 887), the changes in this rule will amend regulations for NWRs in Alaska. This rule primarily: (1) Codifies how our existing mandates relate to predator control in Alaska (50 CFR 36.1); (2) prohibits several particularly effective methods and means for take of predators (50 CFR 36.32); and (3) updates our public participation and closure procedures (50 CFR 36.42). Predator control is prohibited on NWRs in Alaska unless it is determined necessary to meet refuge purposes, is consistent with Federal laws and policy, and is based on sound science in response to a conservation concern. Demands for more wildlife to harvest cannot be the sole or primary basis for predator control. This rule does not change Federal subsistence regulations (36 CFR part 242 and 50 CFR part 100) or restrict taking of fish or wildlife for subsistence uses under Federal subsistence regulations. Codifying how our existing mandates relate to predator control in Alaska (50 CFR 36.1) will not result in a significant change of refuge use because these practices were historically prohibited by the State, and thus enforced as a matter of the adoption of non-conflicting provisions of State law. The rule ensures that these prohibitions continue. Codifying previously and currently prohibited sport hunting and trapping practices will not have a significant impact because the few changes that have occurred have been relatively recent, and this rule constitutes a reinstatement of the prior status quo. State general hunting and trapping regulations currently apply to NWRs in Alaska. Therefore, the prohibition of particular methods and means for the take of predators under State regulations on NWRs in Alaska that may affect visitor use on those NWRs include the take of brown bears over bait, take of wolves and coyotes during the denning season, and same-day airborne take of bears. The take of black bear sows with cubs is only allowed under State regulations in specific game management units for customary and traditional use; therefore, it is not currently nor in the past has it been legal for the general public to participate in this activity outside of that framework. As a result, big game hunting may decrease if a hunter's preferred hunting method is prohibited on a NWR and they choose not to hunt elsewhere where such methods are not prohibited. Conversely, wildlife watching activities may well increase if there are increased opportunities to view wildlife, including bears, wolves, and coyotes. From 2009 to 2013, big game hunting on NWRs in Alaska averaged about 40,000 days annually and represented 2 percent of wildlife-related recreation on NWRs. For Statewide hunting, big game hunting on NWRs in Alaska represented only 4 percent of all big game hunting days (1.2 million days). Due to the past ban on these prohibited methods and means for take of predators, we estimate that these hunting methods (take of brown bears over bait, take of wolves and coyotes during the denning season, and same-day airborne take of bears) represent a small fraction of all big game hunting on NWRs. As a result, big game hunting on NWRs is expected to change minimally. This change in opportunity will most likely be offset by other sites (located outside of NWRs) gaining participants. Therefore, there may be a substitute site for these hunting methods, and participation rates will not necessarily change.

Hunters' spending contributes income to the regional economy and benefits local businesses. Due to the unavailability of site-specific expenditure data, we use the Alaska estimate from the 2011 National Survey of Fishing, Hunting, and Wildlife Associated Recreation to identify expenditures for food and lodging, transportation, and other incidental expenses. Using the average trip-related expenditures for big game hunting ($139 per day) yields approximately $5.9 million annually in big game hunting-related expenditures on NWRs in Alaska. Since only a small fraction of big game hunters are likely to choose not to hunt on NWRs because of this rule, the impact will be minimal. The net loss to the local communities should be no more than $5.9 million annually, and most likely considerably less because few hunters use the prohibited methods and those hunters that do will likely choose a substitute site.

Small businesses within the retail trade industry (such as hotels, gas stations, taxidermy shops, etc.) may be impacted from some decreased refuge visitation. A large percentage of these retail trade establishments in local communities around NWRs qualify as small businesses. We expect that the incremental recreational changes will be scattered, and so we do not expect that the rule will have a significant economic effect on a substantial number of small entities in Alaska.

With the small change in overall spending anticipated from this rule, it is unlikely that a substantial number of small entities will have more than a small impact from the spending change near the affected NWRs. Therefore, we certify that this rule will not have a significant economic effect on a substantial number of small entities as defined under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). A regulatory flexibility analysis is not required. Accordingly, a small entity compliance guide is not required.

Small Business Regulatory Enforcement Fairness Act (SBREFA)

This rule is not a major rule under 5 U.S.C. 804(2), the SBREFA. This rule:

a. Will not have an annual effect on the economy of $100 million or more.

b. Will not cause a major increase in costs or prices for consumers; individual industries; Federal, State, or local government agencies; or geographic regions.

c. Will not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S. based enterprises to compete with foreign-based enterprises.

Unfunded Mandates Reform Act

As this rule applies to uses on federally owned and managed NWRs, it will not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than $100 million per year. The rule will not have a significant or unique effect on State, local, or tribal governments or the private sector. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

Takings (E.O. 12630)

This rule does not effect a taking of private property or otherwise have taking implications under E.O. 12630. This rule affects only the public use and management of Federal lands managed by FWS in Alaska. A takings implication assessment is not required.

Federalism (E.O. 13132)

As discussed in the *Regulatory Planning and Review* and *Unfunded Mandates Reform Act* sections, above, this rule will not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement under E.O. 13132. The rule's effect is limited to Federal NWR lands managed by FWS in Alaska, and the rule will not have a substantial direct effect on State and local governments in Alaska. In preparing this rule, we worked with State governments. A federalism summary impact statement is not required.

Civil Justice Reform (E.O. 12988)

This rule complies with the requirements of E.O. 12988. Specifically, this rule:

a. Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and

b. Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

Consultation With Indian Tribes (E.O. 13175 and Department Policy) and Alaska Native Claims Settlement Act Native Corporations

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951 (May 4, 1994)), Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments; 65 FR 67249 (November 9, 2000)), and the Department of the Interior Manual, 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis, and we did seek the Tribes' input in evaluating the proposed rule. In addition, we evaluated the proposed rule in accordance with 512 DM 4 under Department of the Interior Policy on Consultation with Alaska Native Claims Settlement Act (ANCSA) Corporations, August 10, 2012.

Prior to the development of the proposed rule, we sought feedback from interested parties, including Tribal governments, ANCSA corporations, the State of Alaska, and the Federal Subsistence RACs. We contacted 146 Tribal governments, 12 regional and 106 village ANCSA corporations, and 13 Native nonprofits, all within proximity to NWRs in Alaska. In response to what we heard, we significantly narrowed the scope and complexity of what we proposed (*e.g.,* reducing the number of proposed prohibited methods and means of take from 16 to 5; not opening collection of natural resources (berries, mushrooms, downed timber); and shortening the temporary closure from a maximum of 5 years to maximum of 3 years and providing additional clarification, where possible).

We sent out an initial invitation consultation to Tribal governments, ANCSA corporations, and Native nonprofit organizations in Alaska, and the Alaska Federation of Natives, on September 24, 2014. We then sent a follow-up letter to the same contacts in the first week of February 2015, and another in mid-May 2015. In December 2015, several weeks prior to publication of the proposed rule and EA, we sent out a fourth letter notifying the Tribal governments and ANCSA corporations of the impending publication and scheduled hearings, and we provided an overview of the proposed rule, as well as another invitation to consult with us on the proposed rule. In early March 2016, we sent letters and/or emails to all Tribal governments, ANCSA corporations, and Native nonprofit organizations to notify them that we extended the comment period on the proposed rule for another 30 days, ending April 7, 2016.

FWS conducted three Statewide Tribal consultation teleconferences that included opportunity to dialogue with the Regional Director and the Chief of NWRs for Alaska. These teleconferences were held in November 2014 and February 2015. We also reached out to Tribal governments, ANCSA corporations, and Native nonprofit organizations through phone calls, emails, and meetings to notify them of our availability for consultation and to encourage comment on the proposed rule. Specific consultations requested during the comment period occurred with the following: Allakaket Council and Alatna Council on March 1, 2016; Doyon Corporation on March 7, 2016; Gwichyaa Zhee Tribal Council on February 24, 2016; Kaktovik Tribal Council on February 16, 2016; Native Village of Venetie Tribal Council and the Venetie Village Council on February 25, 2016; Nulato Tribe on February 3, 2016; and Togiak Tribal Council on April 1, 2016.

We provided information on the proposed rule at conferences and meetings including the Alaska Federation of Natives (October 2014 and 2015), Bureau of Indian Affairs Service Providers Conference (December 2014 and 2015), and the Federal Subsistence RACs meetings (September–October

2014, February–March 2015, October–November 2015, and March 2016).

The Department of the Interior strives to strengthen its government-to-government relationship with Indian Tribes through a commitment to consultation with Indian Tribes and recognition of their right to self-governance and tribal sovereignty. We evaluated this rule under the criteria in E.O. 13175 and under the Department's tribal consultation and ANCSA corporation policies and determined that tribal consultation is not required because the rule will have no substantial direct effect on federally recognized Indian Tribes. While FWS has determined the rule will have no substantial direct effect on federally recognized Indian Tribes or ANCSA corporation lands, water areas, or resources, FWS has consulted with Alaska Native Tribes and ANCSA corporations on the proposed rule as indicated above.

Paperwork Reduction Act of 1995 (PRA)

This rule does not contain any new collections of information that require approval by the Office of Management and Budget (OMB) under the PRA (44 U.S.C. 3501 *et seq.*). The application (FWS Form 3–1383–G) for the special use permit mentioned in this rule is already approved by OMB under OMB control number 1018–0102, which expires on June 30, 2017. We 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.

National Environmental Policy Act

FWS has analyzed this rule in accordance with the criteria of the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and the Department of the Interior's manual at 516 DM. An environmental assessment (EA) entitled ''Non-Subsistence Take of Wildlife: Proposed Regulatory Updates to Methods and Means for Predator Harvest on National Wildlife Refuges in Alaska Draft Environmental Assessment, December 23, 2015'' was prepared to determine whether this rule will have a significant impact on the quality of the human environment. The draft EA was adopted without changes. This rule does not constitute a major Federal action significantly affecting the quality of the human environment, and an environmental impact statement is not required because we reached a finding of no significant impact (FONSI). The EA and FONSI are available online at *http://www.regulations.gov* under Docket No. FWS–R7–NWRS–2014–0005.

Energy Supply, Distribution, or Use (E.O. 13211)

Executive Order 13211 requires agencies to prepare Statements of Energy Effects when undertaking actions that significantly affect energy supply, distribution, or use. This rule is not a significant regulatory action under E.O. 12866, and we do not expect it to significantly affect energy supplies, distribution, or use. Therefore, this action is not a significant energy action, and no Statement of Energy Effects is required.

Authors

The primary authors of this rule are Heather Abbey Tonneson, Stephanie Brady, and Carol Damberg of the U.S. Fish and Wildlife Service, Alaska Regional Office, with considerable review and input from other Service Alaska refuge and Office of Subsistence Management managerial and biological staff.

List of Subjects

50 CFR Part 32

Fishing, Hunting, Reporting and recordkeeping requirements, Wildlife, Wildlife refuges.

50 CFR Part 36

Alaska, Recreation and recreation areas, Reporting and recordkeeping requirements, Wildlife refuges.

Regulation Promulgation

For the reasons set forth in the preamble, the Service amends title 50, chapter I, subchapter C, of the Code of Federal Regulations as follows:

PART 32—HUNTING AND FISHING

■ 1. The authority citation for part 32 continues to read as follows:

Authority: 5 U.S.C. 301; 16 U.S.C. 460k, 664, 668dd–668ee, and 715i.

§ 32.2 [Amended]

■ 2. Amend § 32.2(h) by removing the words, ''(Baiting is authorized in accordance with State regulations on national wildlife refuges in Alaska)'' and adding in their place the words, ''(Black bear baiting and use of bait to trap furbearers are authorized in accordance with State regulations on national wildlife refuges in Alaska.)''.

PART 36—ALASKA NATIONAL WILDLIFE REFUGES

■ 3. The authority citation for part 36 continues to read as follows:

Authority: 16 U.S.C. 460(k) *et seq.*, 668dd–668ee, 3101 *et seq.*

Subpart A—Introduction and General Provisions

■ 4. Amend § 36.1 by:

■ a. Redesignating paragraphs (a), (b), and (c) as paragraphs (b), (c), and (d), respectively; and

■ b. Adding a new paragraph (a) to read as follows:

§ 36.1 How do the regulations in this part apply to me and what do they cover?

(a) National Wildlife Refuges in Alaska are maintained to conserve species and habitats in their natural diversity and to ensure biological integrity, diversity, and environmental health of these refuges are maintained for the continuing benefit of present and future generations.

* * * * *

■ 5. Amend § 36.2 by adding, in alphabetical order, definitions for ''Bait'', ''Big game'', ''Cub bear'', ''Furbearer'', ''Natural diversity'', ''Predator control'', ''Sport hunting'', and ''Trapping'' to read as follows:

§ 36.2 What do these terms mean?

* * * * *

Bait means any material excluding a scent lure that is placed to attract an animal by its sense of smell or taste; however, those parts of legally taken animals that are not required to be salvaged and which are left at the kill site are not considered bait.

Big game means black bear, brown bear, bison, caribou, Sitka black-tailed deer, elk, mountain goat, moose, muskox, Dall sheep, wolf, and wolverine.

Cub bear means a brown (grizzly) bear in its first or second year of life, or a black bear (including the cinnamon and blue phases) in its first year of life.

* * * * *

Furbearer means a beaver, coyote, arctic fox, red fox, lynx, marten, mink, least weasel, short-tailed weasel, muskrat, river (land) otter, flying squirrel, ground squirrel, red squirrel, Alaskan marmot, hoary marmot, woodchuck, wolf, or wolverine.

Natural diversity means the existence of all fish, wildlife, and plant populations within a particular wildlife refuge system unit in the natural mix and in a healthy condition for the long-term benefit of current and future generations. Managing for natural diversity includes avoiding emphasis of management activities favoring some species to the detriment of others and assuring that habitat diversity is maintained through natural means, avoiding artificial developments and

habitat manipulation programs whenever possible.

* * * * *

Predator control is the intention to reduce the population of predators for the benefit of prey species.

* * * * *

Sport hunting means the taking of or attempting to take wildlife under State hunting or trapping regulations. In Alaska, this is commonly referred to as general hunting and trapping and includes State subsistence hunts and general permits open to both Alaska residents and nonresidents.

* * * * *

Trapping means taking furbearers under a trapping license.

Subpart B—Subsistence Uses

§ 36.11 [Amended]

■ 6. Amend § 36.11 by removing paragraph (d) and by redesignating paragraph (e) as paragraph (d).

■ 7. Revise § 36.13 to read as follows:

§ 36.13 Subsistence fishing.

Fish may be taken by federally qualified subsistence users, as defined at 50 CFR 100.5, for subsistence uses on Alaska National Wildlife Refuges where subsistence uses are allowed in compliance with this subpart and 50 CFR part 100.

■ 8. Revise § 36.14 to read as follows:

§ 36.14 Subsistence hunting and trapping.

Federally qualified subsistence users, as defined at 50 CFR 100.5, may hunt and trap wildlife for subsistence uses on Alaska National Wildlife Refuges where subsistence uses are allowed in compliance with this subpart and 50 CFR part 100.

Subpart D—Non-Subsistence Uses

■ 9. Revise the heading of subpart D to read as set forth above.

■ 10. Revise § 36.32 to read as follows:

§ 36.32 Taking of fish and wildlife.

(a) The taking of fish and wildlife for sport hunting and trapping and for sport fishing is authorized in accordance with applicable State and Federal law, and such laws are hereby adopted and made a part of these regulations, except as set forth in this section and provided however, that the Refuge Manager, pursuant to § 36.42, may designate areas where, and establish periods when, no taking of a particular population of fish or wildlife will be allowed.

(b) Predator control is prohibited on National Wildlife Refuges in Alaska, unless it is determined necessary to meet refuge purposes, is consistent with Federal laws and policy, and is based on sound science in response to a conservation concern. Demands for more wildlife for human harvest cannot be the sole or primary basis for predator control. A Refuge Manager will authorize predator control activities on a National Wildlife Refuge in Alaska only if:

(1) Alternatives to predator control have been evaluated as a practical means of achieving management objectives;

(2) Proposed actions have been evaluated in compliance with the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*);

(3) A formal refuge compatibility determination has been completed, as required by law; and

(4) The potential effects of predator control on subsistence uses and needs have been evaluated through an ANILCA section 810 analysis.

(c) The exercise of valid commercial fishing rights or privileges obtained pursuant to existing law, including any use of refuge areas for campsites, cabins, motorized vehicles, and aircraft landing directly incident to the exercise of such rights or privileges, is authorized; *Provided, however,* that the Refuge Manager may restrict or prohibit the exercise of these rights or privileges or uses of federally owned lands directly incident to such exercise if the Refuge Manager determines, after conducting a public hearing in the affected locality, that they are inconsistent with the purposes of the refuge and that they constitute a significant expansion of commercial fishing activities within such refuge beyond the level of such activities in 1979.

(d) The following provisions apply to any person while engaged in the taking of fish and wildlife within an Alaska National Wildlife Refuge:

(1) *Trapping and sport hunting.* (i) Each person must secure and possess all required State licenses and must comply with the applicable provisions of State law unless further restricted by Federal law.

(ii) Each person must comply with the applicable provisions of Federal law.

(iii) In addition to the requirements of paragraphs (a) and (c) of this section, each person must continue to secure a trapping permit from the appropriate Refuge Manager prior to trapping on the Kenai, Izembek, and Kodiak Refuges and the Aleutian Islands Unit of the Alaska Maritime Refuge.

(iv) It is unlawful for a person having been airborne to use a firearm or any other weapon to take or assist in taking any species of bear, wolf, or wolverine until after 3 a.m. on the day following the day in which the flying occurred, except that a trapper may use a firearm or any other weapon to dispatch a legally caught wolf or wolverine in a trap or snare on the same day in which the flying occurred. This prohibition does not apply to flights on regularly scheduled commercial airlines between regularly maintained public airports.

(v) The following methods and means for take of wildlife are prohibited:

Prohibited acts	Exceptions
(A) Using snares, nets, or traps to take any species of bear	None.
(B) Using bait	(*1*) Bait may be used to trap furbearers. (*2*) Bait may be used to hunt black bears.
(C) Taking wolves and coyotes from May 1 through August 9 ...	None.
(D) Taking bear cubs or sows with cubs	In accordance with Alaska State law and regulation, resident hunters may take black bear cubs or sows with cubs under customary and traditional use activities at a den site October 15–April 30 in game management units 19A, 19D, 21B, 21C, 21D, 24, and 25D.

(2) *Sport and commercial fishing.* (i) Each person must secure and possess all required State licenses and must comply with the applicable provisions of State law unless further restricted by Federal law.

(ii) Each person must comply with the applicable provisions of Federal law.

(e) Persons transporting fish or wildlife through Alaska National Wildlife Refuges must carry an Alaska State hunting or fishing license, or in cases where a person is transporting game for another person, they are required to carry an Alaska State ''Transfer of Possession Form'' on their person and make these available when

requested by law enforcement personnel.

(f) Nothing in this section applies to or restricts the taking or transporting of fish and wildlife by federally qualified subsistence users under Federal subsistence regulations.

(g) Animal control programs will only be conducted in accordance with a special use permit issued by the Refuge Manager.

■ 11. Amend § 36.42 by revising paragraphs (a), (c), (d), (e), (f), (g), and (h) to read as follows:

§ 36.42 Public participation and closure procedures.

(a) *Applicability and authority.* The Refuge Manager may close an area or restrict an activity in an Alaska National Wildlife Refuge on an emergency, temporary, or permanent basis in accordance with this section.

(b) * * *

(c) *Emergency closures or restrictions.* (1) Emergency closures or restrictions relating to the use of aircraft, snowmachines, motorboats, or nonmotorized surface transportation will be made after notice pursuant to paragraph (f) of this section and hearing;

(2) Emergency closures or restrictions relating to the taking of fish and wildlife will be accompanied by notice pursuant to paragraph (f) of this section with a subsequent hearing;

(3) Other emergency closures or restrictions will become effective upon notice as prescribed in paragraph (f) of this section; and

(4) No emergency closure or restriction will exceed 60 days. Closures or restrictions requiring longer than 60 days will follow nonemergency closure procedures (*i.e.,* temporary or permanent; see paragraphs (d) and (e), respectively, of this section).

(d) *Temporary closures or restrictions.* (1) Temporary closures or restrictions relating to the use of aircraft, snowmachines, motorboats, or nonmotorized surface transportation will be effective only after notice pursuant to paragraph (f) of this section and hearing in the vicinity of the area(s) affected by such closures or restriction, and other locations as appropriate.

(2) Temporary closures or restrictions related to the taking of fish and wildlife will be effective only after notice pursuant to paragraph (f) of this section and after allowing for the opportunity for public comment and a public hearing in the vicinity of the area(s) affected, and other locations as appropriate. Temporary closures or restrictions related to the taking of fish and wildlife also require consultation with the State and affected Tribes and Native Corporations.

(3) Other temporary closures will be effective upon notice as set forth at paragraph (f) of this section.

(4) Temporary closures or restrictions will extend only for as long as necessary to achieve the purpose of the closure or restriction, and may not exceed 12 months; *Provided, however,* a new temporary closure or restriction may be adopted thereafter by following the applicable procedures set forth at paragraph (d)(1), (d)(2), or (d)(3) of this section.

(e) *Permanent closures or restrictions.* Permanent closures or restrictions related to the use of aircraft, snowmachines, motorboats, or nonmotorized surface transportation, or taking of fish and wildlife, will be effective only after notice pursuant to paragraph (f) of this section, and shall be published by rulemaking in the **Federal Register** with a minimum public comment period of 60 days and shall not be effective until after a public hearing(s) is held in the affected vicinity and other locations as appropriate. Permanent closures or restrictions related to the taking of fish and wildlife require consultation with the State and affected Tribes and Native Corporations.

(f) *Notice.* Emergency, temporary, or permanent closures or restrictions will be published on the U.S. Fish and Wildlife Service's Web site at *http://www.fws.gov/alaska/nwr/ak_sp_hunt_regs.htm.* Additional means of notice reasonably likely to inform residents in the affected vicinity will also be provided where available, such as:

(1) Publication in a newspaper of general circulation in the State and in local newspapers;

(2) Use of electronic media, such as the Internet and email lists;

(3) Broadcast media (radio, television, etc.); or

(4) Posting of signs in the local vicinity or at the Refuge Manager's office.

(g) *Openings.* In determining whether to open an area to public use or activity otherwise prohibited, the Refuge Manager will provide notice in the **Federal Register** and will, upon request, hold a public meeting in the affected vicinity and other locations, as appropriate, prior to making a final determination.

(h) Except as otherwise specifically allowed under the provisions of this part, entry into closed areas or failure to abide by restrictions established under this section is prohibited.

Dated: July 22, 2016.

Michael J. Bean,

Principal Deputy Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2016–18117 Filed 8–4–16; 8:45 am]

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Part VII

Department of the Interior

Fish and Wildlife Service

50 CFR Part 18

Marine Mammals; Incidental Take During Specified Activities; Final Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 18

[Docket No. FWS–R7–ES–2016–0060; FF07CAMM00FXFR133707REG01167]

RIN 1018–BA99

Marine Mammals; Incidental Take During Specified Activities

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: In accordance with the Marine Mammal Protection Act of 1972, as amended, and its implementing regulations, we, the U.S. Fish and Wildlife Service, finalize incidental take regulations (ITR) that authorize the nonlethal, incidental, unintentional take of small numbers of Pacific walruses and polar bears during oil and gas industry activities in the Beaufort Sea and adjacent northern coast of Alaska. Industry operations include similar types of activities covered by the previous 5-year Beaufort Sea ITRs effective from August 3, 2011, through August 3, 2016. This rule is also effective for 5 years from the date of issuance.

DATES: This rule is effective August 5, 2016, and remains effective through August 5, 2021.

ADDRESSES: You may view this rule, the associated environmental assessment, biological opinion, comments received, and other supporting material at *http://www.regulations.gov* under Docket No. FWS–R7–ES–2016–0060.

FOR FURTHER INFORMATION CONTACT: Christopher Putnam, Marine Mammals Management Office, U.S. Fish and Wildlife Service, 1011 East Tudor Road, MS–341, Anchorage, AK 99503, Telephone 907–786–3844, or Email: *christopher_putnam@fws.gov*. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, 24 hours a day, 7 days a week.

SUPPLEMENTARY INFORMATION:

Executive Summary

In accordance with the Marine Mammal Protection Act of 1972, as amended (MMPA), and its implementing regulations, we, the U.S. Fish and Wildlife Service (Service or we), finalize incidental take regulations (ITR) that authorize the nonlethal, incidental, unintentional take of small numbers of Pacific walruses (*Odobenus rosmarus divergens*) and polar bears (*Ursus maritimus*) during oil and gas industry (Industry) activities in the Beaufort Sea and adjacent northern coast of Alaska. Industry operations include similar types of activities covered by the previous 5-year Beaufort Sea ITRs effective from August 3, 2011, through August 3, 2016, and found in title 50 of the Code of Federal Regulations (CFR) in part 18, subpart J. This rule will be effective for 5 years from the date of issuance.

This rule sets forth permissible methods of incidental nonlethal taking, mitigation measures designed to ensure the least practicable adverse impacts upon these species and their habitats, and requirements for monitoring and reporting. This rule is based on our findings that the total takings of Pacific walruses (walruses) and polar bears during Industry activities will impact only small numbers of animals, will have a negligible impact on these species, and will not have an unmitigable adverse impact on the availability of these species for subsistence use by Alaska Natives. We base our findings on data from monitoring the encounters and interactions between these species and Industry; research on these species; oil spill risk assessments; potential and documented Industry effects on these species; information regarding the natural history and conservation status of walruses and polar bears; and data reported from Alaska Native subsistence hunters. Compliance with the rule is not expected to result in additional costs to Industry that it has not already been subjected to during all previous ITRs for this area. These costs are minimal in comparison to those related to actual Industry operations. We also prepared an environmental assessment (EA) in accordance with NEPA requirements for this rulemaking and made a finding of no significant impact (FONSI).

Effective Date

In accordance with 5 U.S.C. 553(d)(3), we find that we have good cause to make this rule effective less than 30 days after publication (see **DATES**). Making this rule effective immediately upon publication will ensure that Industry implements mitigation measures and monitoring programs in the geographic region that reduce the risk of lethal and nonlethal effects to polar bears and Pacific walruses by Industry activities.

Summary of Changes From the Proposed Rule

In preparing these final regulations for the Pacific walrus and polar bear, we reviewed and considered comments and information from the public on our proposed rule published in the **Federal Register** on June 7, 2016 (81 FR 36664). We also reviewed and considered comments and information from the public for our EA. Based on those considerations we are finalizing these regulations with the following changes from our proposed rule:

In this final rule, we have:

1. Revised text throughout the document referring to Industry activity as ''proposed'' or ''lawful'' to simply state Industry activity.

2. Revised text in the ''Background'' section clarifying the meaning of the term ''least practicable adverse impacts.''

3. Revised text clarifying when a Plan of Cooperation will be required in the ''Description of Plans of Cooperation (POCs)'' section.

4. Revised text clarifying Caelus Energy Alaska, LLC's Oooguruk production activities, Nuna development activities, and Tulimaniq exploration activities in the ''Description of Activities'' section.

5. Revised text citing recent scientific findings in the ''Climate Change'' section.

6. Revised text in the ''Take Estimates for Pacific Walruses and Polar Bears'' section clarifying how we addressed the least practicable adverse impacts requirement by adding a subsection titled ''*Least Practicable Adverse Impacts Determination*.''

7. Revised text in the ''Findings'' section clarifying how we addressed the least practicable adverse impacts requirement by adding a subsection titled ''*Least Practicable Adverse Impacts*.''

8. Revised text clarifying the meaning of the term ''small numbers'' in section 18.121 of the regulation.

9. Revised text in section 18.128(c)(4) clarifying that the mitigation measure described is relevant for vessels transiting through the Chukchi Sea bound for the Beaufort Sea.

Background

Section 101(a)(5)(A) of the MMPA (16 U.S.C. 1371(a)(5)(A)) gives the Secretary of the Interior (Secretary) the authority to allow the incidental, but not intentional, taking of small numbers of marine mammals, in response to requests by U.S. citizens (as defined in 50 CFR 18.27(c)) engaged in a specified activity (other than commercial fishing) in a specified geographic region. The Secretary has delegated authority for implementation of the MMPA to the U.S. Fish and Wildlife Service (Service). According to the MMPA, the Service

shall allow this incidental taking if we make findings that the total of such taking for the 5-year regulatory period:

(1) Will affect only small numbers of individuals of these species;

(2) will have no more than a negligible impact on these species;

(3) will not have an unmitigable adverse impact on the availability of these species for taking for subsistence use by Alaska Natives; and

(4) we issue regulations that set forth:

(a) Permissible methods of taking,

(b) means of effecting the least practicable adverse impact on the species, their habitat, and the availability of the species for subsistence uses, and

(c) requirements for monitoring and reporting.

If regulations allowing such incidental taking are issued, we may then subsequently issue Letters of Authorization (LOAs), upon request, to authorize incidental take during the specified activities.

The term ''take,'' as defined by the MMPA, means to harass, hunt, capture, or kill, or attempt to harass, hunt, capture, or kill any marine mammal. Harassment, as defined by the MMPA, for activities other than military readiness activities or scientific research conducted by or on behalf of the Federal Government, means ''any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild'' (the MMPA calls this Level A harassment); or ''(ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering'' (the MMPA calls this Level B harassment).

The terms ''negligible impact'' and ''unmitigable adverse impact'' are defined in 50 CFR 18.27 (*i.e.,* regulations governing small takes of marine mammals incidental to specified activities) as follows. ''Negligible impact'' is an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival. ''Unmitigable adverse impact'' means an impact resulting from the specified activity: (1) That is likely to reduce the availability of the species to a level insufficient for a harvest to meet subsistence needs by (i) causing the marine mammals to abandon or avoid hunting areas, (ii) directly displacing subsistence users, or (iii) placing physical barriers between the marine mammals and the subsistence hunters; and (2) that cannot be sufficiently mitigated by other measures to increase the availability of marine mammals to allow subsistence needs to be met.

Also defined in 50 CFR 18.27 is the term ''small numbers,'' however, we do not rely on that definition here as it conflates ''small numbers'' with ''negligible impacts.'' We recognize ''small numbers'' and ''negligible impacts'' as two separate and distinct requirements for promulgating ITRs under the MMPA. Instead, for our small numbers determination, we estimate the likely number of takes of marine mammals, and evaluate if that take is small relative to the size of the population or stock.

The term ''least practicable adverse impact'' is not defined in the MMPA or its enacting regulations. For these ITRs, we ensure the least practicable adverse impact by requiring mitigation measures that are effective in reducing the impact of Industry activities, but are not so restrictive as to make Industry activities unduly burdensome or impossible to undertake and complete.

In these ITRs, the term ''Industry'' includes individuals, companies, and organizations involved in exploration, development, production, extraction, processing, transportation, marketing, research, monitoring, and support services of petroleum products, and other substantially similar activities. Industry activities may result in the taking of walruses and polar bears. The MMPA does not require that Industry must obtain incidental take authorization; however, any taking that occurs without authorization is a violation of the MMPA. Since 1993, the oil and gas industry operating in the Beaufort Sea and the adjacent northern coast of Alaska has requested, and we have issued, ITRs for the incidental take of walruses and polar bears in specified areas during specified activities. For a detailed history of our recent Beaufort Sea ITRs, refer to the **Federal Register** at, 76 FR 47010, August 3, 2011; 71 FR 43926, August 2, 2006; and 68 FR 66744, November 28, 2003. These regulations are at 50 CFR part 18, subpart J (§§ 18.121 to 18.129).

Summary of Current Request

On May 5, 2014, the Service received a petition from the Alaska Oil and Gas Association (AOGA) on behalf of its members and other participating companies to promulgate regulations for nonlethal incidental take of small numbers of walruses and polar bears in the Beaufort Sea and adjacent northern coast of Alaska for a period of 5 years (2016–2021). The anticipated incidental takes would be limited to Level B harassment. We received an amendment to the petition on July 1, 2015. The petition and previous regulations are available at: *http://www.fws.gov/alaska/fisheries/mmm/itr_beaufort.htm.* The petition is also available at *www.regulations.gov* at Docket No. FWS–R7–ES–2016–0060.

The AOGA application requests regulations that will be applicable to any company conducting oil and gas exploration, development, and production activities as described within the application. This includes AOGA members and other non-member companies planning to conduct oil and gas operations in the specified geographic region. Members of AOGA represented in the petition include Alyeska Pipeline Service Company, Apache Corporation, BP Exploration (Alaska) Inc. (BPXA), Caelus Energy Alaska, LLC, Chevron USA, Inc., Eni Petroleum; ExxonMobil Production Company, Flint Hills Resources, Inc., Hilcorp Alaska, LLC, Petro Star Inc., Repsol, Shell Exploration & Production Company (Shell), Statoil, Tesoro Alaska Company, and XTO Energy, Inc.

Non-AOGA companies include ConocoPhillips Alaska, Inc. (CPAI), Brooks Range Petroleum Corporation (BRPC), and Arctic Slope Regional Corporation (ASRC) Energy Services. The activities and geographic region specified in AOGA's request, and considered in these regulations, are described in the following sections titled Description of Activities and Description of Geographic Region.

In response to this request, prior to issuing regulations at 50 CFR part 18 subpart J, we have evaluated the level of Industry activities, their associated potential effects upon walruses and polar bears, and their effects on the availability of these species for subsistence use. The information provided by the petitioners indicates that projected oil and gas activities over this period will encompass onshore and offshore exploration, development, and production activities. The Service analyzed the impacts that Industry activities will have on walruses and polar bears. In addition, we evaluated the potential for oil spills and associated impacts on walruses and polar bears.

Description of the Regulations

These regulations do not authorize, or ''permit,'' Industry activities. Rather, they authorize the nonlethal incidental, unintentional take of small numbers of walruses and polar bears associated with those activities based on standards set forth in the MMPA. The Bureau of

Ocean Energy Management (BOEM), the Bureau of Safety and Environmental Enforcement (BSEE), the U.S. Army Corps of Engineers, and the Bureau of Land Management (BLM) are responsible for permitting activities associated with Industry activities in Federal waters and on Federal lands. The State of Alaska is responsible for permitting Industry activities on State lands and in State waters. The regulations include:

- Permissible methods of nonlethal taking;
- Measures designed to ensure the least practicable adverse impact on walruses and polar bears and the availability of these species for subsistence uses; and
- Requirements for monitoring and reporting.

Description of LOAs

Under these ITRs, companies, groups, or individuals conducting an Industry, or other substantially similar, activity within the specified geographic region may request an LOA for the authorized nonlethal, incidental, Level B take of walruses and polar bears. We must receive requests for LOAs in writing at least 90 days before the activity is to begin. Requests must include an operations plan for the activity, a walrus and polar bear interaction plan, and a site-specific marine mammal monitoring and mitigation plan that specifies the procedures to monitor and mitigate the effects of the activities on walruses and polar bears. We will evaluate each request for an LOA, including plans of operation and interaction plans, based on the activity and location. We will condition each LOA depending on specific circumstances for the activity and location to ensure the activity and level of take are consistent with our findings in these ITRs. We will issue an LOA if the activity and the level of take caused by the activity are consistent with the findings of these ITRs. We must receive an after action report on the monitoring and mitigation activities within 90 days after the LOA expires.

The monitoring and mitigation measures included in each LOA will be designed to ensure that the effects of Industry activity are both negligible and effect the least practicable adverse impacts from Industry activities. For example, conditions include, but are not limited to: (1) A reminder that LOAs do not authorize intentional taking of walruses or polar bears, nor lethal incidental take; (2) measures to protect pregnant polar bears during denning activities (*e.g.,* den selection, birthing, nurturing of cubs, and departing the den site); and (3) the requirement of a site-specific plan of operation and a site-specific interaction plan. For more information on requesting and receiving an LOA, refer to 50 CFR 18.27.

Description of Plans of Cooperation (POCs)

A POC is a documented plan with potentially affected subsistence hunting communities that describes measures to mitigate potential conflicts between Industry activities and subsistence hunting. To ensure that Industry activities do not adversely impact subsistence hunting opportunities, applicants requesting an LOA must provide the Service documentation of communication and coordination with potentially affected Alaska Native communities potentially affected by the Industry activity and, as appropriate, with representative subsistence hunting and co-management organizations, such as the North Slope Borough (NSB) and Eskimo Walrus Commission (EWC), among others. A POC is not always needed, and in many cases communication and coordination is sufficient to document community concerns and mitigate conflicts whether voluntarily by Industry or through mitigation measures in an LOA. We will require a POC in cases where Alaska Native communities or representative subsistence hunting organizations express a desire for a more formal process and commitment from Industry. We may also require a POC in other cases if we are not satisfied with an LOA applicant's communication and coordination process, responsiveness to community concerns, or subsistence hunting conflict mitigation measures. As part of the POC process, Industry representatives engage with Native communities to provide information and respond to questions and concerns. Industry representatives inquire whether their activities will adversely affect the availability of walruses and polar bears for subsistence use. If community concerns suggest that Industry activities may have an impact on the subsistence uses of these species, the POC must document the procedures for how Industry will cooperate with the affected subsistence communities and what actions Industry will take to mitigate adverse impacts on the availability of walruses and polar bears for subsistence uses. We will review these plans and provide guidance to ensure compliance with the MMPA. We will not accept POCs if they fail to provide adequate measures to ensure that Industry activities will not have an unmitigable adverse impact on the availability of walruses and polar bears for subsistence uses.

Description of Geographic Region

The geographic region covered by the requested ITRs (Beaufort Sea ITR region (Figure 1)) encompasses all Beaufort Sea waters east of a north-south line through Point Barrow, Alaska (71°23′29″ N., −156°28′30″ W., BGN 1944), and extending approximately 322 kilometers (km) (~200 miles (mi)) north, including all Alaska State waters and Outer Continental Shelf (OCS) waters, and east of that line to the Canadian border. The offshore boundary of the Beaufort Sea ITR region matches the boundary of the BOEM Beaufort Sea Planning area, approximately 322 km (~200 mi) offshore. The onshore region is the same north/south line through Point Barrow, extending 40.2 km (25 mi) inland and east to the Canning River. The Arctic National Wildlife Refuge (ANWR) is not included in the Beaufort Sea ITR region. The geographical extent of the Beaufort Sea ITR region (approximately 29.8 million hectares (ha) (~73.6 million acres (ac))) is similar to the region covered in previous regulations (approximately 29.9 million ha (~68.9 million ac)) (76 FR 47010, August 3, 2011). An increase in the geographic area of the Beaufort Sea ITR region versus the region set forth in previous ITRs (approximately 1.9 million ha (~4.7 million ac)) is the result of matching the offshore boundary with that of the BOEM Beaufort Sea Planning area boundary.

Description of Activities

This section summarizes the type and scale of Industry activities in the Beaufort Sea ITR region from 2016 to 2021. Year-round onshore and offshore Industry activities are anticipated. Planned and potential activities considered in our analysis include activities described by the petitioners (AES Alaska 2015) and other potential activities identified by the Service and deemed substantially similar to the activities requested in the petition. During the 5 years that the ITRs will be in place, Industry activities are expected to be generally similar in type, timing, and effect to activities that have been evaluated under the prior ITRs. Due to the large number of variables affecting Industry activities, prediction of exact dates and locations of activities is not possible. However, operators must provide specific dates and locations of activities in their application for an LOA. Requests for LOAs for activities and impacts that exceed the scope of analysis and determinations for these ITRs will not be issued. Additional information is available in the AOGA petition for ITRs at: *http://www.fws.gov/*

alaska/fisheries/mmm/Beaufort_Sea/Beaufort%20Sea%20ITR%20Petition_2015.pdf and at *www.regulations.gov* in Docket No. FWS–R7–ES–2016–0060.

Exploration Activities

In the Beaufort Sea ITR region, oil and gas exploration occurs onshore, in coastal areas, and in the offshore environment. Exploration activities may include geological and geophysical surveys consisting of: Geotechnical site investigations, reflective seismic exploration, vibratory seismic data collection, airgun and water gun seismic data collection, explosive seismic data collection, vertical seismic profiling, and subsea sediment sampling. Exploratory drilling involves construction and use of drilling structures such as caisson-retained islands, ice islands, bottom-supported or bottom-founded structures such as the steel drilling caisson, or floating drill vessels. Exploratory drilling and associated support activities and features may include: Transportation to site; setup and relocation of lodging camps and support facilities (such as lights, generators, snow removal, water plants, wastewater plants, dining halls, sleeping quarters, mechanical shops, fuel storage, landing strips, aircraft support, health and safety facilities, data recording facilities, and communication equipment); building gravel pads; building gravel islands with sandbag and concrete block protection; construction of ice islands, pads, and ice roads; gravel hauling; gravel mining; road building; road maintenance; operating heavy equipment; digging trenches; burying and covering pipelines; security operations; dredging; moving floating drill units; helicopter support; and conducting ice, water, and flood management. Support facilities include pipelines, electrical lines, water lines, buildings and facilities, sea lifts, and large and small vessels. Exploration activities could also include the development of staging facilities; oil spill prevention, response, and cleanup activities; and site restoration and remediation. The level of exploration activities is similar to levels during past regulatory periods, although exploration projects may shift to different locations, particularly to the National Petroleum Reserve—Alaska (NPR–A). During the 5-year regulatory period, exploration activities are anticipated to occur in the offshore environment and to continue in the existing oilfield units.

BOEM Outer Continental Shelf Lease Sales

BOEM manages oil and gas leases in the Alaska OCS region, which encompasses 242 million ha (600 million ac). Of that acreage, approximately 26 million ha (~65 million ac) are within the Beaufort Sea Planning Area and within the scope of the ITRs. Ten lease sales have been held in this area since 1979, resulting in 147 active leases, where 32 exploratory wells were drilled. Production has occurred on one joint Federal/State unit, with Federal oil production accounting for more than 28.7 million barrels (bbl) (1 bbl = 42 U.S. gallons or 159 liters) of oil since 2001 (BOEM 2015). Details regarding availability of future leases, locations, and acreages are not yet available, but exploration of the OCS is expected to continue. Lease Sale 242 previously planned in the Beaufort Sea during 2017 (BOEM 2012) was cancelled in 2015. A Draft Programmatic Environmental Impact Statement (EIS) for the 2017–2022 OCS Oil and Gas Leasing Program is planned for public comment in 2016 and is expected to propose Beaufort Sea Lease Sale 255 for the year 2020 (BOEM 2015).

Shell Exploration and Production Company (Shell) is the majority lease holder of BOEM Alaska OCS leases. In 2015 Shell announced that it would cease exploration activities on its BOEM Alaska OCS leases for the foreseeable future. Nevertheless, it is possible that Shell may pursue some sort of exploration activities on its Beaufort Sea BOEM Alaska OCS leases or State of Alaska offshore leases during the 5-year period of these ITRs. Shell may conduct exploration and/or delineation drilling during the open-water Arctic drilling season from a floating drilling vessel along with attendant ice management and oil spill response (OSR) equipment. For the winter drilling season, Shell may conduct drilling from an ice island or bottom-founded structure, along with attendant OSR equipment. Shell will provide a detailed exploration plan prior to conducting any activities in the Beaufort Sea BOEM Alaska lease area.

National Petroleum Reserve—Alaska

The BLM manages the 9.2-million-ha (22.8-million-ac) NPR–A of which 1.3 million ha (3.2 million ac) occur within the Beaufort Sea ITR region. Within this area, the BLM has offered approximately 4.7 million ha (~11.8 million ac) for oil and gas leasing (BLM 2013a). Between 1999 and 2014, 2.1 million ha (5.1-million ac) were sold in 10 lease sales. As of January 2015, there were 205 leases amounting to over 0.6 million ha (1.7 million ac) leased (BLM 2015). From 2000 to 2013, Industry drilled 29 wells in federally managed portions of the NPR–A and 3 in adjacent Native lands (BLM 2013b). ConocoPhillips Alaska, Inc. (CPAI) currently holds a majority of the leased acreage and is expected to continue exploratory efforts, especially seismic work and exploratory drilling, within the Greater Mooses Tooth and Bear Tooth Units of the NPR–A. Other operators, including Anadarko E&P Onshore LLC and NORDAQ Energy, Inc. also hold leases in the NPR–A. Caelus Energy Alaska, LLC (Caelus) has recently announced acquisition of leases and intentions to pursue exploratory drilling and possible development near Smith Bay in the Tulimaniq prospect. This exploration phase of the Tulimaniq project would include construction of ice pads, ice roads, temporary camps, and a temporary ice airstrip. The development phase would include construction of ice roads, gravel roads, gravel pads, and camps.

Area-Wide Lease Sales

The State of Alaska Department of Natural Resources (ADNR), Oil and Gas Division, holds annual lease sales of State lands available for oil and gas development. Lease sales are organized by planning area. The approximately 0.8 million ha (~2 million ac) Beaufort Sea planning area occurs in coastal land and shallow waters along the shoreline of the North Slope between the NPR–A and the ANWR (State of Alaska 2015a). It is entirely within the boundary of the Beaufort Sea ITR region. The North Slope planning area includes tracts located to the south and inland from the Beaufort Sea planning area. Of the approximately 2.1 million ha (~5.1 million ac), 0.8 million ha (2 million ac) occur within the Beaufort Sea ITR region. As of August 2015, there were 1,253 active leases on the North Slope, encompassing 1.1 million ha (2.8 million ac), and 261 active leases in the State waters of the Beaufort Sea, encompassing 284,677 ha (703,452 ac; State of Alaska 2015b). The number of acres leased has increased by 25 percent on the North Slope and 14 percent in the Beaufort Sea planning areas since 2013. Although most of the existing oil and gas development in the Southern Beaufort ITR region is concentrated in these State planning areas, the increase in leased acreage suggests that exploration on State lands and waters will continue during the 2016–2021 ITR period.

Development Activities

Industry operations during oil and gas development may include construction of roads, pipelines, waterlines, gravel pads, work camps (personnel, dining, lodging, and maintenance facilities), water production and wastewater

treatment facilities, runways, and other support infrastructure. Activities associated with the development phase include transportation activities (automobile, airplane, and helicopter); installation of electronic equipment; well drilling; drill rig transport; personnel support; and demobilization, restoration, and remediation work. Industry development activities are often planned or coordinated by unit. A unit is composed of a group of leases covering all or part of an accumulation of oil or gas. Alaska's North Slope oil and gas field primary units include Prudhoe Bay, Kuparuk River, Greater Point McIntyre, Milne Point, Endicott, Badami, the Alpine oilfields of the Colville River Unit, Greater Mooses Tooth (GMT), Northstar, Oooguruk, Nikaitchuq, Liberty, Beechey Point and Point Thomson. In addition, some of these fields are associated with satellite oilfields: Tarn, Palm, Tabasco, West Sak, Meltwater, West Beach, North Prudhoe Bay, Niakuk, Western Niakuk, Kuparuk, Schrader Bluff, Sag River, Eider, Sag Delta North, Qannik, and others.

Alpine Satellites and Greater Mooses Tooth Units

Continued expansion of the existing Alpine oilfield within the Colville River Unit is planned for the 2016–2021 ITR period. Three new drill sites, Colville Delta drill site 5 (CD5, also known as Alpine West), GMT–1 (Lookout prospect, formerly CD6), and GMT–2 (Rendezvous prospect, formerly CD7) are located in the Northeast NPR–A. The GMT–1 project would facilitate the first production of oil from Federal lands in the NPR–A (although within NPR–A, CD5 is not on Federal land). These facilities will connect to existing infrastructure at Alpine via a gravel road and four bridges over the Colville River (BLM 2014). Development of CD5 is currently under way, and commercial oil production began in October 2015. The GMT–1 project has received permits, and road, pad, pipeline, and facilities construction is anticipated for 2017–2018, but due to permitting delays and low oil prices, CPAI has slowed construction plans that would have begun production by late 2017 (CPAI 2015). Permitting for GMT–2 has not yet been completed, but construction and first production is tentatively scheduled for 2019 and 2020. In addition to new drill site development in the NPR–A, expansion of existing drill sites in the Colville River Unit are also being considered. Additional development infrastructure in the area is planned with construction of the Nuiqsut spur road. Although the road is not specifically for Industry purposes, it will provide access to Alpine workers living in Nuiqsut.

The Colville-Kuparuk Fairway Units

The region between the Alpine field and the Kuparuk Unit has been called the Colville-Kuparuk Fairway (NSB 2014). Within this region, Brooks Range Petroleum Corporation (BRPC) has proposed development of 3 drill sites by 2020 as part of the 13-well Mustang development. An independent processing center is proposed at the hub of the Mustang Development, but production pipelines will tie into the Kuparuk facilities. Approximately 32.2 km (~20 mi) of gravel road and pipeline will need to be constructed to tie in the drill sites back to the Mustang development and provide year-round access. First production of oil is planned for 2016. BRPC has also proposed development within the Tofkat Unit southeast of the Alpine oilfield for the years 2020–2021. If constructed, the Tofkat gravel pad will cover approximately 6.07 ha (~15 ac) and will connect to Alpine infrastructure via an 8-km (5-mi) gravel road and pipeline.

Caelus has begun development of the Nuna prospect within the fairway. This project is located at the northeast end, within the Oooguruk Unit. Development activities include seismic surveys, continued exploratory drilling, drilling production wells, and construction of drill pads, roads, and pipeline connections to Kuparuk infrastructure.

Kuparuk River Unit

Spanish oil company, Repsol, has submitted plans for development of five potential well locations with a three-well exploration program just northwest of the Alpine field. If deemed commercial, a spine-and-spur road system expanded from these drill sites to existing Kuparuk facilities is easily envisaged, along with multiple new drill sites, a centralized processing facility, and a network of flow lines tied into the Alpine Pipeline System.

CPAI has pursued ongoing infield and peripheral development at the existing Kuparuk River Unit over the past decade and is likely to do so into the foreseeable future. Efforts have focused on improving technologies, expanding current production, and developing new drill sites. Technological advancements have included hydraulic fracturing, enhanced oil recovery, coil-tube drilling, and 4–D seismic surveys. Two new drill rigs are being brought online in 2016. As of 2015, a new drill site ''2S'' in the southwest ''Shark Tooth'' portion of the unit is under construction. It will require approximately 3.2 km (2 mi) of additional gravel road, pipelines, and power lines. Oil production from this well is planned for later in 2016. The ''Northeast West Sak'' expansion of the existing ''1H'' drill site is also under way. The 3.8-ha (9.3-ac) project will accommodate additional wells and is planned to be complete in 2017. Oil from these facilities would be routed through the Kuparuk facilities to the Trans-Alaska pipeline. Other pad expansions and two additional drill sites in the eastern portion of the Kuparuk Unit may be developed later this decade to access additional oil resources.

Prudhoe Bay Unit

New development within the Prudhoe Bay Unit is planned to help offset declining production from older wells. The newer wells employ horizontal and multilateral drilling, improved water and miscible gas injection techniques, multi-stage fracturing, and other technologies to access oil from sediments with low permeability at the periphery of the main oilfield. The BPXA has discussed the possibility of development of as many as 200 new wells within the Greater Prudhoe Bay Unit area during the upcoming decade. Much of this expansion is planned to occur as part of the ''West End Development Program.'' Proposed activities in this program include drilling 16 new wells, improving capacity of existing facilities, adding 25 additional miles of pipeline, construction of the first new pad in more than a decade, adding 2 drill rigs to the fleet, and expanding 2 additional pads within the unit. This program of development has been under way since 2013 and is expected to be completed in 2017 or later.

Beechey Point/East Shore Units

The Beechey Point Unit lies immediately north of the Prudhoe Bay Unit near the shore of Gwydyr Bay. The unit operator, BRPC, is planning to produce oil from several small hydrocarbon accumulations in and near this unit as part of the East Shore Development Project. Existing Prudhoe Bay infrastructure will be incorporated with new development to access the estimated 26 million bbl of recoverable reserves in the Central North Slope region. The East Shore pad will cover approximately 6.07 ha (~15 ac). An 8.9-km (5.5-mi) gravel road will be constructed to provide year-round access to production facilities. Oil will be transported via a 1.6-km (1-mi) pipeline from the East Shore pad to

existing pipelines. Gravel construction is expected to begin in 2018 with first oil planned for 2020.

Liberty Unit

Hilcorp Alaska, LLC (Hilcorp) recently assumed operation of the Liberty Unit, located in nearshore Federal waters in Foggy Island Bay about 17 km (11 mi) west of the Prudhoe Bay Unit. Initial development of the Liberty Unit began in early 2009 but was suspended following changes in production strategy. The current project concept involves production from a gravel island over the reservoir with full on-island processing capacity. Support infrastructure would include a 12.9-km (8-mi) subsea pipeline connecting to the existing Badami pipeline. Pending permit approvals, first oil production is expected by 2020 or later. This project concept supersedes the cancelled Liberty ultraextended-reach drilling project.

Point Thomson Unit

The Point Thomson Unit is located approximately 25 km (~20 mi) east of the Liberty Unit and 97 km (60 mi) east of Prudhoe Bay. The reservoir straddles the coastline of the Beaufort Sea. It consists of a gas condensate reservoir containing up to 8 trillion cubic feet (ft^3) of gas and hundreds of millions of bbl of gas liquids and oil. This amount is an estimated 25 percent of the North Slope's natural gas reserves and is critical to any major gas commercialization project. Operator ExxonMobil is actively pursuing development of a processing facility capable of handling 10,000 bbl per day, a pipeline with a design capacity of 70,000 bbl per day, a camp, an airstrip, and other ancillary facilities. Production began in 2016. All proposed wells and supporting infrastructure are located onshore. No permanent roads connecting with Prudhoe Bay are currently proposed, but gravel roads will connect the infield facilities. Ice roads and barges are used seasonally to provide equipment and supplies. Potential full field development may include two satellite drill sites, additional liquids production, and sale of gas. The timing and nature of additional expansion will depend upon initial field performance and potential construction of a gas pipeline to export gas from the North Slope.

Natural Gas Pipeline

Two proposals currently exist for construction of a natural gas pipeline to transport natural gas from the Point Thomson and Prudhoe Bay production fields. The Alaska Liquefied Natural Gas (LNG) project is an Industry-sponsored partnership whose members include BP Alaska LNG LLC; ConocoPhillips Alaska LNG Company; and ExxonMobil Alaska LNG LLC. The Alaska LNG project proposes to build a large-diameter (45–106 centimeters (cm), 18–42 inch (in)) natural gas pipeline from the North Slope to Southcentral Alaska. In 2014, the State of Alaska joined in the project as a 25 percent co-investor. Since then, the project has begun the preliminary front end engineering and design phase, which has extended into 2016 with gross spending of more than $500 million. The routing of the Alaska LNG project pipeline is from Prudhoe Bay, generally paralleling the Dalton Highway corridor from the North Slope to Fairbanks. An approximately 56.3-km (~35-mi) lateral pipeline will take off from the main pipeline and end at Fairbanks. The main pipeline would continue south, terminating at a natural gas liquefaction plant near Nikiski. There the remaining hydrocarbons will be condensed for export to national and international markets.

The second partnership, the Alaska Stand Alone Gas Pipeline (ASAP) project, was originally planned as a 24-in diameter natural gas pipeline with a natural gas flow rate of 500 million ft^3 per day at peak capacity, and is currently considered by many as a backup plan for the larger Alaska LNG project. The Alaska Gasline Development Corporation in partnership with TransCanada Corp. has led the planning effort for ASAP. Production from this pipeline would emphasize in-State distribution, although surplus gas would also likely be condensed and exported.

Either project would include an underground pipeline with elevated bridge stream crossings, compressor stations, possible fault crossings, pigging facilities, and off-take valve locations. Both pipelines would be designed to transport a highly conditioned natural gas product, and would follow the same general route. As currently proposed, approximately 40 km (~25 mi) of pipeline would occur within the Beaufort ITR region. A gas conditioning facility would need to be constructed near Prudhoe Bay and will likely require one or more large equipment modules to be off-loaded at the West Dock loading facility. The West Dock facility is a gravel causeway stretching 4 km (2.5 mi) into Prudhoe Bay. Shipments to West Dock will likely require improvements to the dock facilities including installing breasting dolphins to facilitate berthing and mooring of vessels, and raising the height of the existing dockhead to accept the large shipments. Dredging will be needed to deepen the navigational channel to the dockhead. Continued preconstruction project engineering and design work involving site evaluations and environmental surveys on the North Slope is likely to occur in the 2016–2021 period. Additional early-phase construction work could occur during this time but would likely be limited to expansion of West Dock beginning in 2020, gravel extraction and placement for pads and roads near Prudhoe Bay beginning in 2019, and ice-road construction in 2018–2021.

Production Activities

North Slope production facilities occur between the oilfields of the Alpine Unit in the west to Badami and Point Thomson in the east. Production activities include building operations, oil production, oil transport, facilities maintenance and upgrades, restoration, and remediation. Production activities are permanent, year-round activities, whereas exploration and development activities are usually temporary and seasonal. Alpine and Badami are not connected to the road system and must be accessed by airstrips, barges, and seasonal ice roads. Transportation on the North Slope is by automobile, airplanes, helicopters, boats, rolligons, tracked vehicles, and snowmobiles. Aircraft, both fixed wing and helicopters, are used for movement of personnel, mail, rush-cargo, and perishable items. Most equipment and materials are transported to the North Slope by truck or barge. Much of the barge traffic during the open water season unloads from West Dock. Maintenance dredging of up to 220,000 cubic yards per year of material is performed at West Dock to ensure continued operation.

Oil pipelines extend from each developed oilfield to the Trans-Alaska Pipeline System (TAPS). The 122-cm (48-in) diameter TAPS pipeline extends 1,287 km (800 mi) from the Prudhoe Bay oilfield to the Valdez Marine Terminal. Alyeska Pipeline Service Company conducts pipeline operations and maintenance. Access to the pipeline is primarily from established roads, such as the Spine Road and the Dalton Highway, or along the pipeline right-of-way.

Colville River Unit

The Alpine oilfield within the Colville River Unit was discovered in 1994 and began production in 2000. CPAI maintains a majority interest and is the primary operator. Alpine is currently the westernmost production

oilfield on the North Slope, located 50 km (31 mi) west of the Kuparuk oilfield and 14 km (9 mi) northeast of the village of Nuiqsut. Facilities include a combined production pad/drill site and 3 additional drill sites with a total of approximately 180 wells. Pads, gravel roads, an airstrip, and processing facilities cover a total surface area of 66.8 ha (165 ac). Crude oil from Alpine is transported 34 mi through a 14-in pipeline to the Trans-Alaska Pipeline System. An ice road is constructed annually between Alpine and the Kuparuk oilfield to support major resupply activities. Small aircraft are used year-round to provide supplies and crew changeovers; camp facilities can support up to approximately 630 personnel.

Oooguruk Unit

The Oooguruk Unit, operated by Caelus, is located at the north end of the Colville-Kuparuk fairway, adjacent to the Kuparuk Unit in shallow waters of Harrison Bay. The Oooguruk drillsite is located on a 6 acre artificial island in the shallow waters of Harrison Bay. A 9.2 kilometer (5.7 mile) system of subsea flowlines, power cables, and communications cables connects the island to onshore support facilities. Production began in 2008. Expansion of the drill site in the future would increase the working surface area from 2.4 hectare (6 acres) to 3.8 hectare (9.5 acres). Drilling of additional production wells are planned and new injection well technology will be employed. Cumulative production was estimated to be 9.8 million bbl as of 2011 (AOGCC 2013).

Kuparuk River Unit

The Kuparuk oilfield, operated by CPAI, is Alaska's second-largest producing oilfield behind Prudhoe Bay. The gross volume of the oilfield has been estimated to be 6 billion bbl; more than 2.5 billion bbl have been produced as of 2014 (CPAI 2014). Nearly 900 wells have been drilled in the Greater Kuparuk Area, which includes the satellite oilfields of Tarn, Palm, Tabasco, West Sak, and Meltwater. The total development area in the Greater Kuparuk Area is approximately 603 ha (~1,508 ac), including 167 km (104 mi) of gravel roads, 231 km (144 mi) of pipelines, 6 gravel mine sites, and over 50 gravel pads. The Kuparuk operations center and construction camp can accommodate up to 1,200 personnel.

Nikaitchuq Unit

The Nikaitchuq Unit, operated by Eni, is north of the Kuparuk River Unit. The offshore portion of Nikaitchuq, the Spy Island Development, is located south of the barrier islands of the Jones Island group and 6.4 km (4 mi) north of Oliktok Point. In 2007, Eni became the operator in the area and subsequently constructed an offshore gravel pad and onshore production facilities at Spy Island and Oliktok Point. The offshore pad is located in shallow water (*i.e.,* 3 meters (m) (10 feet (ft) deep)). A subsea flowline was constructed to transfer produced fluids from shore. The wells require an electrical submersible pump to produce oil because they are not capable of unassisted flow. The flow can be stopped by turning off the pump. Production began in 2011 at Oliktok Point and in 2012 at Spy Island. Cumulative production at the end of 2011 was approximately 2 million bbl. A program to expand production began in 2015 and is still underway, including drilling of 20 or more new wells to recover oil from the nearby Schrader Bluff reservoirs.

Milne Point Unit

The Milne Point Unit, operated by Hilcorp, is located approximately 56 km (~35 mi) northwest of Prudhoe Bay and immediately east of the Nikaitchuq Unit. This field consists of more than 220 wells drilled from 12 gravel pads. Milne Point produces oil from three main fields: Kuparuk, Schrader Bluff, and Sag River. Cumulative oil production as of the end of 2012 was 308 million barrrels of oil equivalent (BOE, the amount of hydrocarbon product containing the energy equivalent of a barrel of oil). Average daily production rate in 2012 was 17,539 BOE with 114 production wells online. The total gravel footprint of Milne Point and its satellites is 182 ha (450 ac). The Milne Point Operations Center has accommodations for up to 180 people. An expansion program is under way for the Milne Point Unit. It is likely to improve technology of existing wells and may also include building a new drill pad, roads, and associated wells.

Prudhoe Bay Unit

The Prudhoe Bay Unit, operated by BPXA, is one of the largest oilfields by production in North America and ranks among the 20 largest oilfields worldwide. Over 12 billion bbl have been produced from a field originally estimated to have 25 billion bbl of oil in place. The Prudhoe Bay oilfield also contains an estimated 26 trillion ft^3 of recoverable natural gas. More than 1,100 wells are currently in operation in the Prudhoe Bay oilfields, approximately 830 of which are producing oil (others are for gas or water injection). Average daily production in 2012 was around 255,500 BOE.

The Prudhoe Bay Unit encompasses several oilfields, including the Point McIntyre, Lisburne, Niakuk, Western Niakuk, West Beach, North Prudhoe Bay, Borealis, Midnight Sun, Polaris, Aurora, and Orion reservoirs. Of these, the largest field by production is the Point McIntyre oilfield, which lies about 11 km (7 mi) north of Prudhoe Bay. Cumulative oil production between 1993 and 2011 was 436 million bbl (AOGCC 2013). In 2014, production at Point McIntyre averaged about 18,700 bbl of oil per day. The Lisburne field is largest by area. It covers about 80,000 ac just northwest of the main Prudhoe Bay field. Production was reported as 7,070 bbl per day in 2011, and cumulative production was approximately 182 million BOE as of 2014. The Niakuk fields have also reached high cumulative yields among the Greater Prudhoe Bay area oilfields. Between 1994 and 2011, these fields produced about 157 million bbl. In 2014, the combined Niakuk fields yielded about 1,200 bbl per day. Orion, Aurora, Polaris, Borealis and Midnight Sun are considered satellite fields and were producing more than 22,500 bbl per day combined in 2014 (BPXA 2015). In total, Prudhoe Bay satellite fields have produced more than 184 million BOE.

The total development area in the Prudhoe Bay Unit is approximately 2,785 ha (~6,883 ac) within an area of about 86,418 ha (213,543 ac). On the east side of the field the main construction camp can accommodate up to 625 people, the Prudhoe Bay operations center houses up to 449 people, and the Tarmac Camp houses 244 people. The base operations center on the western side of the Prudhoe Bay oilfield can accommodate 474 people. Additional personnel are housed at facilities in nearby Deadhorse industrial center or in temporary camps placed on existing gravel pads. Activities in the Prudhoe Bay Unit are likely to emphasize greater production of natural gas if a gas pipeline is approved during the 2016–2021 ITR period.

Northstar Unit

The Northstar oilfield, currently operated by Hilcorp, is located 6 km (4 mi) northwest of the Point McIntyre and 10 km (6 mi) north of the Prudhoe Bay Unit in approximately 10 m (~33 ft) of water. It was developed by BPXA in 1995, and began producing oil in 2001. The 15,360 ha (38,400 ac) reservoir lies offshore in waters up to 40 ft deep. A 2-ha (5-ac) artificial island supports 24 operating wells and all support facilities for this field. A subsea pipeline

connects facilities to the Prudhoe Bay oilfield. As of 2013, production had surpassed 158.26 million bbl. The onsite base operations center houses 50 people. Access to Northstar is via helicopter, hovercraft, boat, and seasonal ice road. Of the existing offshore facilities Northstar is located the farthest from shore.

Duck Island Unit

The Endicott oilfield, operated by Hilcorp, is located in the Duck Island Unit approximately 16 km (~10 mi) northeast of Prudhoe Bay. In 1986 it became the first continuously producing offshore field in the U.S. Arctic. The Endicott oilfield was developed from two man-made gravel islands connected to the mainland by a gravel causeway. The operations center and processing facilities are located on the 24-ha (58-ac) main production island approximately 4.8 km (~3 mi) offshore. As of August 2013, 501 million BOE have been produced from Endicott. Production is from the Endicott reservoir in the Kekiktuk formation and two satellite fields (Eider and Sag Delta North) in the Ivishak formation. All wells were drilled from Endicott's main production island. The total area of development is 210 ha (522 ac) of land (including the Liberty satellite drilling island) with 24 km (15 mi) of roads, 43 km (24 mi) of pipelines, and 1 gravel mine site. Approximately 85 people can be housed at Endicott's Liberty camp.

Badami and Point Thomson Units

The Badami and Point Thomson units are located in the eastern portion of the North Slope and Beaufort Sea planning areas. Production from the Badami oilfield began in 1998 and from Point Thomson in 1983, but has not been continuous from either unit. The Badami field is located approximately 56 km (~35 mi) east of Prudhoe Bay and is the most easterly oilfield currently in production on the North Slope. Point Thomson, located 4 km (2.5 mi) east of Badami, was not in production as of 2016. The Badami development area is approximately 34 ha (~85 ac) of tundra including 7 km (4.5 mi) of gravel roads, 56 km (35 mi) of pipeline, 1 gravel mine site, and 2 gravel pads with a total of eight wells. As of 2011, cumulative production had reached 5.7 million bbl. There is no permanent road connection from Badami to Prudhoe Bay. A pipeline connecting the Badami oilfield to the common carrier pipeline system at Endicott was built from an ice road.

Other Activities

Gas Hydrate Exploration and Research

Growing interest in the North Slope's methane gas hydrate resources is expected to continue in the upcoming 5 years. The U.S. Geological Survey (USGS) has estimated the volume of technically recoverable undiscovered methane gas hydrate on the North Slope is approximately 85 trillion ft^3 (with a range of 25–158 trillion ft^3 (USGS 2013)). Recent gas hydrate test wells drilled on the North Slope have confirmed the presence of viable reservoirs and buoyed interest in long-term testing. International and Gulf of Mexico test well simulations have generated production-level gas yields. Gas hydrate research on the North Slope is supported by Federal funding and State initiatives. In 2013, the State of Alaska temporarily set aside 11 tracts of unleased State lands on the North Slope for methane hydrate research. This support is expected to result in a continued interest in gas hydrate research and exploration, but development of this nonconventional hydrocarbon resource is yet unproven and uncertainties regarding economic feasibility, safety, and environmental impact remain unresolved. For these reasons, a relatively low, but increasing level of gas hydrate exploration and research is expected during the regulatory period.

Barrow Gas Fields

The NSB operates the Barrow Gas Fields located south and east of the city of Barrow. The Barrow Gas Fields include the Walakpa, South, and East Gas Fields; of these, the Walakpa Gas Field and a portion of the South Gas Field are located within the boundaries of the Chukchi Sea geographical region and, therefore, not discussed here. The East Field and part of the South Field are included in the Beaufort Sea ITR region.

The Barrow Gas Fields provide a source of heat and electricity for the Barrow community. Drilling and testing of the East Barrow Field began in 1974, and regular gas production from the pool began in December 1981. Production peaked at about 2.75 million ft^3 of gas per day in 1983, and then began to decline. In 2011 and 2012, NSB increased production by drilling five new wells, upgrading pipelines, and installing modern wellhead housings. In the winter of 2013, production was about 350 million ft^3 per day. Cumulatively, the field produced more than 8.8 billion ft^3 through July 2013, surpassing the original estimate of 6.2 billion ft^3 of gas in place.

Although activities within the Barrow Gas Fields were not specifically identified by the Applicants, the petition did include this area as part of the request for ITRs. Additionally, a portion of the Barrow Gas Fields are similarly described in ITRs for the Chukchi Sea (78 FR 35364, June 12, 2013), while the remainder is located in the Beaufort Sea geographic region. Therefore, as part of this analysis, we have included the Barrow Gas Fields in the event that LOAs for activities on the Beaufort Sea side of the field are requested. Gas production is expected to continue at its current rate during the next 5 years, and will be accompanied by maintenance and support activities, including possible access by air or over land, ice road construction, survey work, or on-pad construction.

Evaluation of the Nature and Level of Activities

Based on the Industry request, we assume that the activities will increase the area of the industrial footprint with the addition of new facilities, such as drill pads, pipelines, and support facilities at a rate consistent with prior 5-year regulatory periods. However, oil production volume is expected to continue a long-term decline during this 5-year regulatory period despite new development. This prediction is due to declining production from currently producing fields. During the period covered by the regulations, we assume the annual level of activity at existing production facilities, as well as levels of new annual exploration and development activities, will be similar to that which occurred under the previous regulations, although exploration and development may shift to new locations and new production facilities will add to the overall Industry footprint. Additional onshore and offshore facilities are being considered within the timeframe of these regulations, potentially adding to the total permanent activities in the area. The rate of progress is similar to prior production schedules, but there is a potential increase in the accumulation of the industrial footprint, with an increase mainly in onshore facilities.

Biological Information

Pacific Walrus

Pacific walruses constitute a single panmictic population inhabiting the shallow continental shelf waters of the Bering and Chukchi seas (Lingqvist *et al.* 2009, Berta and Churchill 2012). The distribution of walruses is largely influenced by the extent of the seasonal pack ice and prey densities. From April

to June, most of the walrus population migrates from the Bering Sea through the Bering Strait and into the Chukchi Sea. Walruses tend to migrate into the Chukchi Sea along lead systems that develop in the sea-ice. Walruses are closely associated with the edge of the seasonal pack ice during the open-water season. By July, thousands of animals can be found along the edge of the pack ice from Russian waters to areas west of Point Barrow, Alaska. The pack-ice usually advances rapidly southward in late fall, and most walruses return to the Bering Sea by mid- to late-November. During the winter breeding season walruses are found in three concentration areas of the Bering Sea where open leads, polynyas, or thin ice occur (Fay *et al.* 1984, Garlich-Miller *et al.* 2011a). While the specific location of these groups varies annually and seasonally depending upon the extent of the sea-ice, generally one group occurs near the Gulf of Anadyr, another south of St. Lawrence Island, and a third in the southeastern Bering Sea south of Nunivak Island into northwestern Bristol Bay.

Although most walruses remain in the Chukchi Sea throughout the summer months, a few occasionally range into the Beaufort Sea in late summer. Industry monitoring reports have observed no more than 35 walruses in the area of these ITRs between 1995 and 2016, with only a few instances of disturbance to those walruses (AES Alaska 2015, Kalxdorff and Bridges 2003, USFWS unpubl. data). Beginning in 2008, the USGS, and since 2013 the Alaska Department of Fish and Game (ADF&G), have fitted about 30–60 walruses with satellite transmitters each year during spring and summer. In 2014, a female tagged by ADF&G spent about 3 weeks in Harrison Bay (ADF&G 2014). The USGS tracking data indicates that at least one instrumented walrus ventured into the Beaufort Sea for brief periods in all years except 2011. Most of these movements extend northeast of Barrow to the continental shelf edge north of Smith Bay (USGS 2015). All available information indicates that few walruses enter the Beaufort Sea and those that do spend little time there. The Service and USGS are conducting multiyear studies on the walrus population to investigate movements and habitat use patterns. It is possible that as sea-ice diminishes in the Chukchi Sea beyond the 5-year period of this rule, walrus distribution and habitat use may change.

Walruses are generally found in waters of 100 m (328 ft) or less although they are capable of diving to greater depths. They use sea-ice as a resting platform over feeding areas, as well as for giving birth, nursing, passive transportation and avoiding predators (Fay 1982, Ray *et al.* 2006). They feed almost exclusively on benthic invertebrates. Native hunters have also reported incidences of walruses preying on seals, and other items such as fish and birds are occasionally taken (Sheffield and Grebmeier 2009, Seymour *et al.* 2014). Foraging trips may last for several days with walruses diving to the bottom nearly continuously. Most foraging dives last between 5 and 10 minutes, with a 1–2-minute surface interval. The activity of foraging walruses disturbs the sea floor releasing nutrients into the water column providing food for scavenger organisms, contributes to the diversity of the benthic community, and is thought to have a significant influence on the ecology of the Bering and Chukchi seas (Ray *et al.* 2006).

Walruses are social and gregarious animals. They travel and haul-out onto ice or land in groups. Walruses spend approximately 20–30 percent of their time out of the water. Hauled-out walruses tend to be in close physical contact. Young animals often lie on top of adults. The size of the hauled out groups can range from a few animals up to several thousand individuals. The largest aggregations occur at land haulouts. In recent years, the barrier islands north of Point Lay, Alaska, have held large aggregations of walruses (20,000–40,000) in late summer and fall (Monson *et al.* 2013).

The size of the walrus population has never been known with certainty. Based on large sustained harvests in the 18th and 19th centuries, Fay (1957) speculated that the pre-exploitation population was represented by a minimum of 200,000 animals. Since that time, population size following European contact is believed to have fluctuated markedly in response to varying levels of human exploitation. Large-scale commercial harvests are believed to have reduced the population to 50,000–100,000 animals in the mid-1950s (Fay *et al.* 1989). The population increased rapidly in size during the 1960s and 1970s in response to harvest regulations that limited the take of females. The population likely reached or exceeded the food-based carrying capacity (K) of the region by 1980 (Fay *et al.* 1989, Fay *et al.* 1997, Garlich-Miller *et al.* 2006, MacCracken *et al.* 2014).

Between 1975 and 1990, aerial surveys conducted jointly by the United States and Russia at 5-year intervals produced population estimates ranging from about 200,000 to 255,000 individuals, with large confidence intervals. Efforts to survey the walrus population were suspended by both countries after 1990 because problems with survey methods produced population estimates with unknown bias and unknown variances that severely limited their utility. In 2006, the United States and Russia conducted another joint aerial survey in the pack ice of the Bering Sea using thermal imaging systems to more accurately count walruses hauled out on sea-ice and apply satellite transmitters to account for walruses in the water. The number of walruses within the surveyed area was estimated at 129,000 with 95 percent confidence limits of 55,000 to 507,000 individuals. This estimate should be considered a minimum, as weather conditions forced termination of the survey before large areas of the Bering Sea were surveyed (Speckman *et al.* 2011).

Taylor and Udevitz (2015) used both the aerial survey population estimates described above and ship-based age and sex composition counts that occurred in 1981–1984, 1998, and 1999 (Citta *et al.* 2014) in a Bayesian integrated population model to estimate population trend and vital rates from 1975–2006. They recalculated the 1975–1990 aerial survey estimates based on a lognormal distribution for inclusion in their model. Their results generally agreed with the large-scale population trends identified by the previous efforts, but with slightly different population estimates in some years along with more precise confidence intervals. They were careful to note that all of the demographic rates in their model were estimated based on age structure data from 1981 to 1999, when the population was in decline, and that projections outside those years are extrapolations of demographic functions that may not accurately reflect dynamics for different population trends. Ultimately, they concluded (i) that though their model provides improved clarity on past walrus population trends and vital rates, it cannot overcome the large uncertainties in the available population size data, and (ii) that the absolute size of the Pacific walrus population will continue to be speculative until accurate empirical estimation of the population size becomes feasible.

A detailed description of the Pacific walrus stock can be found in the Pacific Walrus (*Odobenus rosmarus divergens*) Stock Assessment Report (announced at 79 FR 22154, April 21, 2014). A digital copy of the Stock Assessment Report is available at: *http://www.fws.gov/alaska/fisheries/mmm/stock/Revised_April_2014_Pacific_Walrus_SAR.pdf*.

Polar bears are known to prey on walruses, particularly calves, and killer whales *(Orcinus orca)* have been known to take all age classes of walruses (Frost *et al.* 1992, Melnikov and Zagrebin 2005). Predation rates are unknown but are thought to be highest near terrestrial haulout sites where large aggregations of walruses can be found. However, few observations exist of predation upon walruses farther offshore.

Walruses have been hunted by coastal Natives in Alaska and Chukotka for thousands of years. Exploitation of the walrus population by Europeans has also occurred in varying degrees since beginning with the arrival of exploratory expeditions. Commercial harvest of walruses ceased in the United States in 1941 and sport hunting ceased in 1972 with the passage of the MMPA. Commercial harvest of walruses in Russia ceased in 1990. Presently, walrus hunting in Alaska and Chukotka is restricted to subsistence use by aboriginal peoples. Harvest mortality from 2000–2014 for both the United States and Russian Federation averaged 3,207 (SE = 194) walruses per year. This mortality estimate includes corrections for under-reported harvest (U.S. only) and struck and lost animals. Harvests have been declining by about 3 percent per year since 2000 and were exceptionally low in the United States in 2012–2014. Resource managers in Russia have concluded that the population has declined and reduced harvest quotas in recent years accordingly (Kochnev 2004; Kochnev 2005; Kochnev 2010; pers. comm.; Litovka 2015, pers. comm.), based in part on the lower abundance estimate generated from the 2006 survey. However, Russian hunters have never reached the quota (Litovka 2015, pers. comm.).

Intra-specific trauma at coastal haulouts is also a known source of injury and mortality (USFWS 2015). Disturbance events can cause walruses to stampede into the water and have been known to result in injuries and mortalities. The risk of stampede-related injuries increases with the number of animals hauled out. Calves and young animals are particularly vulnerable to trampling injuries and mortality. Management and protection programs in both the United States and Russian Federation have been successful in reducing disturbances and large mortality events at coastal haulouts (USFWS 2015).

The Service announced a 12-month petition finding to list the Pacific walrus as endangered or threatened and to designate critical habitat on February 10, 2011 (76 FR 7634). The listing of walruses was found to be warranted, but precluded due to higher priority listing actions, and the Pacific walrus was added to the list of candidate species under the Endangered Species Act (ESA; 16 U.S.C. 1533 *et seq.*). We will make a determination whether Pacific walruses shall be listed under the ESA by September 2017. If we determine that walruses should be listed under the ESA, we will publish a proposed listing in the **Federal Register** and solicit public comments. If walruses are listed under the ESA, then designation of critical habitat is required unless it is imprudent or indeterminable.

Polar Bear

Polar bears are found throughout the ice-covered seas and adjacent coasts of the Arctic with a current population estimate of approximately 26,000 individuals (95 percent Confidence Interval (CI) = 22,000–31,000) (Wiig *et al.* 2015). Polar bears live up to 30 years, have no natural predators, though cannibalism is known to occur, and they do not often die from diseases or parasites. Polar bears typically occur at low densities throughout their circumpolar range (DeMaster and Stirling 1981). They are generally found in areas where the sea is ice-covered for much of the year; however, polar bears are not evenly distributed throughout their range. They are typically most abundant on sea-ice, near the ice edges or openings in the ice, over relatively shallow continental shelf waters with high marine productivity (Durner *et al.* 2004). Their primary prey is ringed *(Pusa hispida)* and bearded *(Erignathus barbatus)* seals, although diet varies regionally with prey availability (Thiemann *et al.* 2008, Cherry *et al.* 2011). Polar bears use the sea-ice as a platform to hunt seals. Over most of their range, polar bears remain on the sea-ice year-round or spend only short periods on land. They may, however, be observed throughout the year in the onshore and nearshore environments, where they will opportunistically scavenge on beached marine mammal carcasses (Kalxdorff and Fischbach 1998). Their distribution in coastal habitats is often influenced by the movement of seasonal sea-ice.

Females can initiate breeding at 5 to 6 years of age. Females without dependent cubs breed in the spring. Pregnant females enter maternity dens by late November, and the young are usually born in late December or early January. Only pregnant females den for an extended period during the winter; other polar bears may excavate temporary dens to escape harsh winter winds. On average two cubs are born per reproductive event, and, therefore, reproductive potential (intrinsic rate of increase) is low. The average reproductive interval for a polar bear is 3 to 4 years, and a female polar bear can produce 8–10 cubs in her lifetime, in healthy populations, and 50–60 percent of the cubs will survive.

In late March or early April, the female and cubs emerge from the den. If the mother moves young cubs from the den before they can walk or withstand the cold, mortality to the cubs increases. Therefore, it is thought that successful denning, birthing, and rearing activities require a relatively undisturbed environment. Radio and satellite telemetry studies elsewhere indicate that denning can occur in multiyear pack ice and on land. In the Southern Beaufort Sea (SBS) population the proportion of dens on pack ice declined from approximately 60 percent from 1985 through 1994 to 40 percent from 1998 through 2004 (Fischbach *et al.* 2007). This change is likely in response to reductions in stable old ice, increases in unconsolidated ice, and lengthening of the melt season (Fischbach *et al.* 2007). If sea-ice extent in the Arctic continues to decrease and the amount of unstable ice increases, a greater proportion of polar bears may seek to den on land (Durner *et al.* 2006, Fischbach *et al.* 2007).

In Alaska, maternal polar bear dens appear to be less densely concentrated than those in Canada and Russia. In Alaska, certain areas, such as barrier islands (linear features of low-elevation land adjacent to the main coastline that are separated from the mainland by bodies of water), river bank drainages, much of the North Slope coastal plain, and coastal bluffs that occur at the interface of mainland and marine habitat, receive proportionally greater use for denning than other areas. Maternal denning occurs on tundra-bearing barrier islands along the Beaufort Sea and also in the large river deltas, such as those associated with the Colville and Canning rivers.

During the late summer/fall period (August through October), polar bears are most likely to be encountered along the coast and barrier islands. They use these areas as travel corridors and hunting areas. Based on Industry observations, encounter rates are higher during the fall (August to October) than any other time period. The duration of time the bears spend in these coastal habitats depends on a variety of factors including storms, ice conditions, and the availability of food. In recent years, polar bears have been observed in larger numbers than previously recorded during the fall period. The remains of

subsistence-harvested bowhead whales at Cross and Barter islands provide a readily available food source for bears in these areas and appear to play a role in this increase (Schliebe *et al.* 2006). Based on Industry observations and coastal survey data acquired by the Service, up to 125 polar bears have been observed annually during the fall period between Barrow and the Alaska-Canada border.

In 2008, the Service listed polar bears as threatened under the ESA due to the loss of sea-ice habitat caused by climate change (73 FR 28212, May 15, 2008). The Service later published a final rule under section 4(d) of the ESA for the polar bear, which was vacated then reinstated when procedural requirements were satisfied (78 FR 11766, February 20, 2013). This special rule provides for measures that are necessary and advisable for the conservation of polar bears. Specifically, the 4(d) rule: (a) Adopts the conservation regulatory requirements of the MMPA and the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) for the polar bear as the appropriate regulatory provisions, in most instances; (b) provides that incidental, nonlethal take of polar bears resulting from activities outside the bear's current range is not prohibited under the ESA; (c) clarifies that the special rule does not alter the Section 7 consultation requirements of the ESA; and (d) applies the standard ESA protections for threatened species when an activity is not covered by an MMPA or CITES authorization or exemption.

The Service designated critical habitat for polar bear populations in the United States effective January 6, 2011 (75 FR 76086, December 7, 2010). On January 13, 2013, the U.S. District Court for the District of Alaska issued an order that vacated and remanded the polar bear critical habitat final rule to the Service (*Alaska Oil and Gas Association and American Petroleum Institute* v. *Salazar, Case No. 3:11–cv–0025–RRB*). On February 29, 2016, the United States Court of Appeals for the 9th Circuit reversed that order and remanded it back to the U.S. District Court for the District of Alaska for entry of judgment in favor of FWS (*Alaska Oil and Gas Association* v. *Jewell, Case No. 13–35619*).

Critical habitat identifies geographic areas that contain features that are essential for the conservation of a threatened or endangered species and that may require special management or protection. Under section 7 of the ESA, if there is a Federal action, we will analyze the potential impacts of the action upon polar bear critical habitat. Polar bear critical habitat units include: Barrier island habitat, sea-ice habitat (both described in geographic terms), and terrestrial denning habitat (a functional determination). Barrier island habitat includes coastal barrier islands and spits along Alaska's coast; it is used for denning, refuge from human disturbance, access to maternal dens and feeding habitat, and travel along the coast. Sea-ice habitat is located over the continental shelf, and includes water 300 m (~984 ft) or less in depth. Terrestrial denning habitat includes lands within 32 km (~20 mi) of the northern coast of Alaska between the Canadian border and the Kavik River and within 8 km (~5 mi) between the Kavik River and Barrow. The total area designated covers approximately 484,734 km^2 (~187,157 mi^2), and is entirely within the lands and waters of the United States. Polar bear critical habitat is described in detail in the final rule that designated polar bear critical habitat (75 FR 76086, December 7, 2010). A digital copy of the final critical habitat rule is available at: *http://alaska.fws.gov/fisheries/mmm/polarbear/pdf/federal_register_notice.pdf.*

Management and conservation concerns for the SBS and Chukchi/Bering Seas (CS) polar bear populations include sea-ice loss due to climate change, bear-human conflict, oil and gas industry activity, oil spills and contaminants, increased marine shipping, increased disease, and the potential for overharvest. Research has linked declines in sea-ice to reduced physical condition, growth, and survival of polar bears (Bromaghin *et al.* 2015). Projections indicate continued climate warming at least through the end of this century (IPCC 2013). The associated reduction of summer Arctic sea-ice is expected to be a primary threat to polar bear populations (Amstrup *et al.* 2008, Stirling and Derocher 2012).

Stock Definition, Range, and Status

Polar bears are distributed throughout the circumpolar Arctic region. In Alaska, polar bears have historically been observed as far south in the Bering Sea as St. Matthew Island and the Pribilof Islands (Ray 1971). A detailed description of the SBS and CS polar bear stocks can be found in the Polar Bear *(Ursus maritimus)* Stock Assessment Reports (announced at 74 FR 69139, December 30, 2009). Digital copies of the Stock Assessment Reports are available at: *http://www.fws.gov/alaska/fisheries/mmm/stock/final_sbs_polar_bear_sar.pdf* and *http://www.fws.gov/alaska/fisheries/mmm/;stock/final_cbs_polar_bear_sar.pdf.* A summary of the Alaska polar bear stocks are described below.

Southern Beaufort Sea

The SBS polar bear population is shared between Canada and Alaska. Radio-telemetry data, combined with eartag returns from harvested bears, suggest that the SBS population occupies a region with a western boundary near Icy Cape, Alaska, and an eastern boundary near Pearce Point, Northwest Territories, Canada (USFWS 2010).

Early estimates from the mid-1980s suggested the size of the SBS population was approximately 1,800 polar bears, although uneven sampling was known to compromise the accuracy of that estimate. A population analysis of the SBS stock was completed in June 2006 through joint research coordinated between the United States and Canada. That analysis indicated the population of the region between Icy Cape and Pearce Point was approximately 1,500 polar bears (95 percent confidence intervals approximately 1,000–2,000). Although the confidence intervals of the 2006 population estimate overlapped the previous population estimate of 1,800, other statistical and ecological evidence (*e.g.,* high recapture rates encountered in the field) suggest that the current population is actually smaller than has been estimated for this area in the past. The most recent population estimate for the SBS population was produced by the USGS in 2015. Bromaghin *et al.* (2015) developed mark-recapture models to investigate the population dynamics of polar bears in the SBS from 2001 to 2010. They estimated that in 2010 there were approximately 900 polar bears (90 percent CI 606–1212) in the SBS population (Bromaghin *et al.* 2015). That study showed a 25 to 50 percent decline in abundance of SBS bears due to low survival from 2004 through 2006. Though survival of adults and cubs began to improve in 2007, and abundance was comparatively stable from 2008 to 2010, survival of subadult bears declined throughout the entire period.

Chukchi/Bering Seas

The CS polar bear population is shared between Russia and Alaska. The CS stock is widely distributed on the pack-ice in the Chukchi Sea, northern Bering Sea, and adjacent coastal areas in Alaska and Chukotka, Russia. Radio-telemetry data indicate that the northeastern boundary of the CS population is near the Colville Delta in the central Beaufort Sea and the western boundary is near the Kolyma River in

northeastern Siberia (Garner *et al.*1990; Amstrup 1995; Amstrup *et al.* 2005). The population's southern boundary is determined by the extent of annual sea-ice in the Bering Sea. There is an extensive area of overlap between the SBS and CS populations roughly between Icy Cape, Alaska, and the Colville Delta (Garner *et al.* 1990; Garner *et al.* 1994; Amstrup *et al.* 2000; Amstrup *et al.* 2004; Obbard *et al.* 2010; Wiig *et al.* 2015).

It has been difficult to obtain a reliable population estimate for this stock due to the vast and inaccessible nature of the habitat, movement of bears across international boundaries, logistical constraints of conducting studies in the Russian Federation, and budget limitations (Amstrup and DeMaster 1988; Garner *et al.* 1992; Garner *et al.* 1998; Evans *et al.* 2003).

Estimates of the stock have been derived from observations of dens and aerial surveys (Chelintsev 1977; Stishov 1991a; Stishov 1991b; Stishov *et al.* 1991); however, those estimates have wide confidence intervals and are outdated. The most recent estimate of the CS stock was approximately 2,000 animals, based on extrapolation of aerial den surveys (Lunn *et al.* 2002; USFWS 2010; Wiig *et al.* 2015). However, accurate estimates of the size and trend of the CS stock are difficult to obtain and not currently available. Ongoing and planned research studies for the period 2016–2018 will result in improved information, although the wide distribution of polar bears on sea ice, the vast size of the region, and the lack of infrastructure to support research studies will continue to make it difficult to obtain up-to-date and accurate estimates of vital rates and population size. More information about polar bears can be found at: *http://www.fws.gov/alaska/fisheries/mmm/polarbear/pbmain.htm.*

Climate Change

As atmospheric greenhouse gas concentrations increase so will global temperatures (Pierrehumbert 2011). The Arctic has warmed at twice the global rate (IPCC 2007), and long-term data sets show that substantial reductions in both the extent and thickness of Arctic sea-ice cover have occurred over the past 40 years (Meier *et al.* 2014, Frey *et al.* 2015). Stroeve *et al.* (2012) estimated that, since 1979, the minimum area of fall Arctic sea-ice declined by over 12 percent per decade through 2010. Record minimum areas of fall Arctic sea-ice extent were recorded in 2002, 2005, 2007, and 2012 (lowest on record). The overall trend of continued decline of Arctic sea-ice is expected to continue for the foreseeable future (Stroeve *et al.* 2007, Amstrup *et al.* 2008, Hunter *et al.* 2010, Overland and Wang 2013, 73 FR 28212, May 15, 2008).

For walruses, climate-driven trends in the Chukchi Sea have resulted in seasonal fall sea-ice retreat beyond the continental shelf over deep Arctic Ocean waters. Reasonably foreseeable impacts to walruses as a result of diminishing sea-ice cover include potential shifts in range, habitat use, local abundance, increased frequency and duration at coastal haulouts, increased vulnerability to predation and disturbance, and localized declines in prey. It is unknown if walruses will utilize the Beaufort Sea more in the future due to climate change effects. Currently, and for the next 5 years, it appears that walruses will remain uncommon in the Beaufort Sea.

For polar bears, sea-ice habitat loss due to climate change has been identified as the primary cause of conservation concern. Amstrup *et al.* (2007) projected a 42 percent loss of optimal summer polar bear habitat by 2050. They concluded that, if current Arctic sea-ice declines continue, polar bears may eventually be excluded from onshore denning habitat in the Polar Basin Divergent Ecoregion, where ice is formed and then drawn away from near-shore areas, especially during the summer minimum ice season. The SBS and CS polar bear populations inhabit this ecoregion, and Amstrup *et al.* (2008) projected that these populations may be extirpated within the next 45–75 years if sea-ice declines continue at current rates.

Climate change is likely to have serious consequences for the worldwide population of polar bears and their prey (Amstrup *et al.* 2007, Amstrup *et al.* 2008, Hunter *et al.* 2010). Climate change is expected to impact polar bears in a variety of ways including increased movements, changes in bear distributions, changes to the access and allocation of denning areas, increased energy expenditure from open-water swimming, and possible decreased fitness. The timing of ice formation and breakup will impact seal distributions and abundance and, consequently, how efficiently polar bears can hunt seals. Reductions in sea-ice are expected to require polar bears to use more physiological energy, as moving through fragmented sea-ice and open water requires more energy than walking across consolidated sea-ice (Cherry *et al.* 2009, Pagano *et al.* 2012, Rode *et al.* 2014).

Decreased sea-ice extent may impact the reproductive success of denning polar bears. In the 1990s, approximately 50 percent of the maternal dens of the SBS polar bear population occurred annually on the pack-ice in contrast to terrestrial sites (Amstrup and Gardner 1994). The proportion of dens on sea-ice declined from 62 percent in 1985–1994 to 37 percent in 1998–2004 (Fischbach *et al.* 2007) causing a corresponding increase in terrestrial dens. This trend in terrestrial denning appears to have continued. Polar bears require a stable substrate for denning. As sea-ice conditions deteriorate and become less stable, coastal dens become vulnerable to erosion from storm surges. Polar bear dens on land, especially on the North Slope of Alaska, are also at greater risk of conflict with human activities.

Atwood *et al.* (2016) recently discussed how sea ice decline in the southern Beaufort Sea is related to the increased polar bear use of Beaufort Sea coastal areas of Alaska during the fall open-water period (June through October). They found that the percentage of radio-collared adult females from the SBS stock utilizing terrestrial habitats has tripled over 15 years. They also found an overall trend of SBS polar bears seasonally arriving onshore earlier, staying longer, and leaving for the sea ice later. The Service anticipates that polar bear use of the Beaufort Sea coast will continue to increase during the open-water season. This change in polar bear distribution has been correlated with diminished sea ice and the distance of the pack-ice from the coast during the open water period (*i.e.,* the less sea ice and the farther from shore the leading edge of the pack-ice, the more bears observed onshore) (Schliebe *et al.* 2006; Atwood *et al.* 2016). The current trend for sea-ice in the region will result in increased distances between the ice edge and land, likely resulting in more bears coming ashore during the open-water period. More polar bears on land for a longer period of time may increase the exposure of polar bears to human activities and may lead to increased human-bear interactions during this time period.

Potential Effects of Oil and Gas Industry Activities on Subsistence Uses of Pacific Walruses and Polar Bears

Pacific Walrus

Few walruses are harvested in the Beaufort Sea along the northern coast of Alaska since their primary range is in the Bering and Chukchi seas. Walruses constitute a small portion of the total marine mammal harvest for the village of Barrow. Hunters from Barrow harvested 451 walruses in the past 20 years with 78 harvested since 2009.

Walrus harvest from Nuiqsut and Kaktovik is opportunistic. They have reported taking four walruses since 1993. Less than 1.5 percent of the total walrus harvest for Barrow, Nuiqsut, and Kaktovik from 2009 to 2014 has occurred within the geographic range of the incidental take regulations.

Polar Bear

Based on subsistence harvest reports, polar bear hunting is less prevalent in communities on the north coast of Alaska than it is in west coast communities. There are no quotas under the MMPA for Alaska Native polar bear harvest in the Southern Beaufort Sea; however, there is a Native-to-Native agreement between the Inuvialuit in Canada and the Inupiat in Alaska, created in 1988. This agreement, referred to as the Inuvialuit-Inupiat Polar Bear Management Agreement, established quotas and recommendations concerning protection of denning females, family groups, and methods of take. In Canada, Native polar bear hunters are subject to provincial regulations consistent with the Agreement, while in Alaska implementation is on a voluntary basis by Native polar bear hunters. Commissioners for the Inuvialuit-Inupiat Agreement set the original quota at 76 bears in 1988, split evenly between the Inuvialuit in Canada and the Inupiat in the United States. In July 2010, the quota was reduced to 70 bears per year.

The Alaska Native subsistence harvest of polar bears from the SBS population has remained relatively consistent since 1980 and averages 36 bears annually. From 2005 through 2009, Alaska Natives harvested 117 bears from the SBS population, an average of approximately 23 bears annually. From 2010 through 2014, Alaska Natives harvested 98 polar bears from the SBS population, an average of approximately 20 bears annually. The reason for the decline of harvested polar bears from the SBS population is unknown. Alaska Native subsistence hunters and harvest reports have not indicated a lack of opportunity to hunt polar bears or disruption by Industry activity.

Evaluation of Effects of Activities on Subsistence Uses of Pacific Walruses and Polar Bears

Barrow and Kaktovik are expected to be affected to a lesser degree by Industry activities than Nuiqsut. Nuiqsut is located within 5 mi of ConocoPhillips' Alpine production field to the north and ConocoPhillips' Alpine Satellite development field to the west. However, Nuiqsut hunters typically harvest polar bears from Cross Island during the annual fall bowhead whaling. Cross Island is approximately 16 km (~10 mi) offshore from the coast of Prudhoe Bay. We have received no evidence or reports that bears are altering their habitat use patterns, avoiding certain areas, or being affected in other ways by the existing level of oil and gas activity near communities or traditional hunting areas that would diminish their availability for subsistence use.

Changes in activity locations may trigger community concerns regarding the effect on subsistence uses. Industry will need to remain proactive to address potential impacts on the subsistence uses by affected communities through consultations, and where warranted, POCs. Open communication through venues such as public meetings, which allow communities to express feedback prior to the initiation of operations, will be required as part of an LOA application. If community subsistence use concerns arise from new activities, appropriate mitigation measures are available and will be applied, such as a cessation of certain activities at certain locations during specified times of the year, *i.e.,* hunting seasons.

No unmitigable concerns from the potentially affected communities regarding the availability of walruses or polar bears for subsistence uses have been identified through Industry consultations with the potentially affected communities of Barrow, Kaktovik, and Nuiqsut. Based on Industry reports, aerial surveys, direct observations, community consultations, and personal communication with hunters, it appears that subsistence hunting opportunities for walruses and polar bears have not been affected by past Industry activities, and we do not anticipate that the activities for these ITRs will have different effects.

Potential Effects of Oil and Gas Industry Activities on Pacific Walruses, Polar Bears, and Prey Species

Individual walruses and polar bears can be affected by Industry activities in numerous ways. These include (1) noise disturbance, (2) physical obstructions, (3) human encounters, and (4) effects on habitat and prey. In order to evaluate effects to walruses and polar bears, we analyzed both documented and potential effects, including those that could have more than negligible impacts. The effects analyzed included the loss or preclusion of habitat, harassment, lethal take, and exposure to oil spills.

Pacific Walrus

Walruses do not utilize the Beaufort Sea frequently and the likelihood of encountering walruses during Industry operations is low. During the time period of these regulations, Industry operations may occasionally encounter small groups of walruses swimming in open water or hauled out onto ice floes or along the coast. Industry monitoring data have reported 35 walruses between 1995 and 2016, with only a few instances of disturbance to those walruses (AES Alaska 2015, USFWS unpublished data). From 2009 through 2014 no interactions between walrus and Industry were reported in the Beaufort Sea ITR region. We have no evidence of any physical effects or impacts to individual walruses due to Industry activity in the Beaufort Sea ITR region. If an interaction did occur, it could potentially result in some level of disturbance. The response of walruses to disturbance stimuli is highly variable. Anecdotal observations by walrus hunters and researchers suggest that males tend to be more tolerant of disturbances than females and individuals tend to be more tolerant than groups. Females with dependent calves are considered least tolerant of disturbances. In the Chukchi Sea, disturbance events are known to cause walrus groups to abandon land or ice haulouts and occasionally result in trampling injuries or cow-calf separations, both of which are potentially fatal. Calves and young animals at terrestrial haulouts are particularly vulnerable to trampling injuries.

Noise Disturbance

Walruses hear sounds both in air and in water. Kastelein *et al.* (1996) tested the in-air hearing of a walrus from 125 hertz (Hz) to 8 kilohertz (kHz) and determined the walrus could hear all frequency ranges tested but the best sensitivity was between 250 Hz and 2 kHz. Kastelein *et al.* (2002) tested underwater hearing and determined that range of hearing was between 1 kHz and 12 kHz with greatest sensitivity at 12 kHz. The small sample size warrants caution; other pinnipeds can hear up to 40 kHz. Many of the noise sources generated by Industry activities, other than the very high frequency seismic profiling, are likely to be audible to walruses.

Seismic operations, pile driving, ice breaking, and various other Industry activities introduce substantial levels of noise into the marine environment. Greene *et al.* (2008) measured underwater and airborne noise from ice road construction, heavy equipment operations, auguring, and pile driving during construction of a gravel island at Northstar. Underwater sound levels

from construction ranged from 103 decibels (dB) at 100 m (328 ft) for auguring to 143 dB at 100 m (328 ft) for pile driving. Most of the energy of these sounds was below 100 Hz. Airborne sound levels from these activities ranged from 65 dB at 100 m (328 ft) for a bulldozer and 81 dB at 100 m (328 ft) for pile driving. Most of the energy for in-air levels was also below 100 Hz. Airborne sound levels and frequencies typically produced by Industry are unlikely to cause hearing damage unless marine mammals are very close to the sound source, but may cause disturbance.

Typical source levels associated with underwater marine 3D and 2D seismic surveys are 230–240 dB. Airgun arrays produce broadband frequencies from 10 Hz to 2 kHz with most of the energy concentrated below 200 Hz. Frequencies used for high-resolution oil and gas exploration surveys are typically 200 Hz–900 kHz. Commercial sonar systems may also generate lower frequencies audible to marine mammals (Deng et al 2012). Some surveys use frequencies as low as 50 Hz or as high as 2 MHz. Broadband source levels for high-resolution surveys can range from 210 to 226 dB at 1 m. Sound attenuates in air more rapidly than in water, and underwater sound levels can be loud enough to cause hearing loss in nearby animals and disturbance of animals at greater distances.

Noise generated by Industry activities, whether stationary or mobile, has the potential to disturb walruses. Marine mammals in general have variable reactions to noise sources, particularly mobile sources such as marine vessels. Reactions depend on the individuals' prior exposure to the disturbance source, their need, or desire to be in the particular habitat or area where they are exposed to the noise, and visual presence of the disturbance source. Walruses are typically more sensitive to disturbance when hauled out on land or ice than when they are in the water. In addition, females and young are generally more sensitive to disturbance than adult males.

Potential impacts of Industry-generated noise include displacement from preferred foraging areas, increased stress, energy expenditure, interference with feeding, and masking of communications. Any impact of Industry noise on walruses is likely to be limited to a few individuals due to their geographic range and seasonal distribution. Walruses typically inhabit the pack-ice of the Bering and Chukchi seas and do not often move into the Beaufort Sea.

In the nearshore areas of the Beaufort Sea, stationary offshore facilities could produce high levels of noise that has the potential to disturb walruses. These include Endicott, BPXA's Saltwater Treatment Plant (located on the West Dock Causeway), Oooguruk, and Northstar facilities. The Liberty project will also have this potential when it commences operations. From 2009 through 2014 there were no reports of walruses hauling out at Industry facilities in the Beaufort Sea ITR region. Previous observations have been reported of walruses hauled out on Northstar Island and swimming near the Saltwater Treatment Plant. In 2007, a female and a subadult walrus were observed hauled-out on the Endicott Causeway. In instances where walruses have been seen near these facilities, they have appeared to be attracted to them, possibly as a resting area or haulout.

In the open waters of the Beaufort Sea, seismic surveys and high-resolution site-clearance surveys will be the primary source of high levels of underwater sound. Such surveys are typically carried out away from the edge of the seasonal pack-ice. This scenario will minimize potential interactions with large concentrations of walruses, which typically favor sea-ice habitats. The most likely response of walruses to acoustic disturbances in open water will be for animals to move away from the source of the disturbance. Displacement from a preferred feeding area may reduce foraging success, increase stress levels, and increase energy expenditures. Potential adverse effects of Industry noise on walruses can be reduced through the implementation of the monitoring and mitigation measures identified in these ITRs.

Potential acoustic injuries from high levels of sound such as those produced during seismic surveys may manifest in the form of temporary or permanent changes in hearing sensitivity. The underwater hearing abilities of the Pacific walrus have not been studied sufficiently to develop species-specific criteria for preventing harmful exposure. Sound pressure level thresholds have been developed for other members of the pinniped taxonomic group, above which exposure is likely to cause behavioral responses and injuries (Finneran 2015). Otariid pinnipeds in particular, as a group, appear to have hearing characteristics most similar to Pacific walruses ((Kastelein et al. 1996; Hemilä et al. 2006; Finneran 2015). Therefore, the Service uses the data available for otariid pinnipeds in conjunction with that for walruses to evaluate acoustic disturbance and develop mitigation measures.

Historically, the National Oceanic and Atmospheric Administration's National Marine Fisheries Service (NOAA Fisheries Service, or NMFS) has used 190 dB_{rms} as a threshold for predicting injury to pinnipeds and 160 dB_{rms} as a threshold for behavioral impacts from exposure to impulse noise (NMFS 1998, HESS 1999). The behavioral response threshold was developed based primarily on observations of marine mammal responses to airgun operations (*e.g.,* Malme *et al.,* 1983a, 1983b; Richardson *et al.,* 1986, 1995). Southall *et al.* 2007 assessed relevant studies, found considerable variability among pinnipeds, and determined that exposures between ~90 and 140 dB generally do not appear to induce strong behavioral responses in pinnipeds in water, but an increasing probability of avoidance and other behavioral effects exists in the 120 to 160 dB range.

The NMFS 190-dB_{rms} injury threshold is an estimate of the sound level likely to cause a permanent shift in hearing threshold (permanent threshold shift or PTS). This value was modelled from temporary threshold shifts (TTS) observed in pinnipeds (NMFS 1998, HESS 1999). More recently, Kastak *et al.* (2005) found exposures resulting in TTS in pinniped test subjects ranging from 152 to 174 dB (183 to 206 dB SEL). Southall *et al.* (2007) reviewed the literature and derived behavior and injury thresholds based on peak sound pressure levels of 212 dB (peak) and 218 dB (peak) respectively. Because onset of TTS can vary in response to duration of exposure, Southall *et al.* (2007) also derived thresholds based on sound exposure levels (SEL). Sound exposure level can be thought of as a composite metric that represents both the magnitude of a sound and its duration. The study proposed threshold SELs weighted at frequencies of greatest sensitivities for pinnipeds of 171 dB (SEL) and 186 dB (SEL) for behavioral impacts and injury respectively (Southall *et al.* 2007). Reichmuth *et al.* (2008) demonstrated a persistent TTS, if not a PTS, after 60 seconds of 184 dB SEL. Kastelein (2012) found small but statistically significant TTSs at approximately 170 dB SEL (136 dB, 60 min) and 178 dB SEL (148 dB, 15 min).

Based on these data, and applying a precautionary approach in the absence of empirical information, we assume it is possible that walruses exposed to 190-dB or greater sound levels from underwater activities (especially seismic surveys) could suffer injury from PTS. Walruses exposed to underwater sound pressure levels greater than 180 dB

could suffer temporary shifts in hearing thresholds. Repeated or continuous exposure to sound levels between 160 and 180 dB may also result in TTS, and exposures above 160 dB are more likely to elicit behavioral responses than lower level exposures. The Service's underwater sound mitigation measures include employing protected species observers (PSOs) to monitor established and acoustically verified 160-dB, 180-dB, and 190-dB isopleth mitigation zones centered on any underwater sound source greater than 160 db. The 160-dB zone must be monitored; walruses in this zone will be assumed to experience Level B take. The 180-dB and 190-dB zones shall be free of marine mammals before the sound-producing activity can begin and must remain free of marine mammals during the activity. The ITRs incorporate slight changes in the mitigation zones when compared to previous ITRs for the region. Previous ITRs have required separate actions for groups of greater than 12 walruses. Industry activities are unlikely to encounter large aggregations of walruses in the Beaufort Sea. This stipulation was originally developed for and is more applicable to mitigation of impacts to walruses in the Chukchi Sea and is not likely to be applicable in the Beaufort Sea.

The acoustic thresholds for marine mammals under NMFS' jurisdiction are currently being revised (NOAA 2015, NOAA 2016). New thresholds will estimate PTS onset levels for impulsive (*e.g.,* airguns, impact pile drivers) and nonimpulsive (*e.g.,* sonar, vibratory pile drivers) sound sources. Thresholds will be specific to marine mammal functional hearing groups; separate thresholds for otariid and phocid pinnipeds will be adopted. Auditory weighting functions will be incorporated into calculation of PTS threshold levels. The updated acoustic thresholds will also account for accumulation of injury due to repeated or ongoing exposure by adopting dual metrics of sound (cumulative sound exposure level and peak sound pressure level). The updated criteria will not provide specification for modeling sound exposures from various activities. They will not update thresholds for preventing behavioral responses, nor will they provide any new information regarding the Pacific walrus.

Once NMFS' new criteria for preventing harm to marine mammals from sound exposure are finalized, the Service will evaluate the new thresholds for applicability to walruses. In many cases, the Service's existing thresholds for Pacific walrus will result in greater separation distances or shorter periods of exposure to Industry sound sources than would NMFS' draft pinniped thresholds. Assuming walrus hearing sensitivities are similar to other otariid pinnipeds, the Service's sound exposure thresholds are, in many situations, likely to be more conservative and therefore provide additional protection against potential injury from PTS and TTS. However, animals may be exposed to multiple stressors beyond acoustics during an activity, with the possibility of additive, cumulative, or synergistic effects (*e.g.,* Crain *et al.* 2008). The Service's mitigation measures are intended to prevent acoustic injury as well as minimize impacts from noise exposures that may cause biologically significant behavioral reactions in walruses.

To reduce the likelihood of Level B harassment, and prevent behavioral responses capable of causing Level A harassment, the Service has established an 805-m (0.5-mile) operational exclusion zone around groups of walruses feeding in water or any walrus observed on land or ice. As mentioned previously, walruses show variable reactions to noise sources. Relatively minor reactions, such as increased vigilance, are not likely to disrupt biologically important behavioral patterns and, therefore, do not reach the level of harassment, as defined by the MMPA. However, more significant reactions have been documented in response to noise. Industry monitoring efforts in the Chukchi Sea suggest that icebreaking activities can displace some walrus groups up to several kilometers away (Brueggeman *et al.* 1990). Approximately 25 percent of walrus groups on pack-ice responded by diving into the water, and most reactions occurred within 1 km (0.6 mi) of the ship (Brueggeman *et al.* 1991). Reactions such as fleeing a haulout or departing a feeding area have the potential to disrupt biologically significant behavioral patterns, including nursing, feeding, and resting, and may result in decreased fitness for the affected animal. These reactions meet the criteria for Level B harassment under the MMPA. Industry activities producing high levels of noise or occurring in close proximity also have the potential to illicit extreme reactions (Level A harassment) including separation of mothers from young or instigation of stampedes. However, most groups of hauled out walruses showed little reaction to icebreaking activities beyond 805 m (0.5 mi; Brueggeman *et al.* 1990).

Because some seismic survey activities are expected to occur in nearshore regions of the Beaufort Sea, impacts associated with support vessels and aircraft are likely to be locally concentrated, but distributed over time and space. Therefore, noise and disturbance from aircraft and vessel traffic associated with seismic surveys are expected to have relatively localized, short-term effects. The mitigation measures stipulated in these ITRs will require seismic survey vessels and associated support vessels to apply acoustic mitigation zones, maintain an 805-m (0.5-mile) distance from Pacific walrus groups, introduce noise gradually by implementing ramp-up procedures, and to maintain a 457-m (1,500-ft) minimum altitude above walruses. These measures are expected to reduce the intensity of disturbance events and to minimize the potential for injuries to animals.

With the low occurrence of walruses in the Beaufort Sea and the adoption of the mitigation measures required by this ITR, the Service concludes that the only anticipated effects from Industry noise in the Beaufort Sea would be short-term behavioral alterations of small numbers of walruses.

Vessel Traffic

Although seismic surveys and offshore drilling operations are expected to occur in areas of open water away from the pack ice, support vessels and aircraft servicing seismic and drill operations may encounter aggregations of walruses hauled out onto sea-ice. The sight, sound, or smell of humans and machines could potentially displace these animals from any ice haulouts. Walruses react variably to noise from vessel traffic; however, it appears that low-frequency diesel engines cause less of a disturbance than high-frequency outboard engines. In addition, walrus densities within their normal distribution are highest along the edge of the pack-ice, and Industry vessel traffic typically avoids these areas. The reaction of walruses to vessel traffic is dependent upon vessel type, distance, speed, and previous exposure to disturbances. Walruses in the water appear to be less readily disturbed by vessels than walruses hauled out on land or ice. Furthermore, barges and vessels associated with Industry activities travel in open water and avoid large ice floes or land where walruses are likely to be found. In addition, walruses can use a vessel as a haul-out platform. In 2009, during Industry activities in the Chukchi Sea, an adult walrus was found hauled out on the stern of a vessel. It eventually left once confronted.

Drilling operations are expected to involve drill ships attended by icebreaking vessels to manage

incursions of sea-ice. Ice management operations are expected to have the greatest potential for disturbances since walruses are more likely to be encountered in sea-ice habitats and ice management operations typically require the vessel to accelerate, reverse direction, and turn rapidly, thereby maximizing propeller cavitation and producing significant noise. Previous monitoring efforts in the Chukchi Sea suggest that icebreaking activities can displace some walrus groups up to several kilometers away; however, most groups of hauled-out walruses showed little reaction beyond 805 m (0.5 mi).

Monitoring programs associated with exploratory drilling operations in the Chukchi Sea since 1990 noted that approximately 25 percent of walrus groups encountered in the pack-ice during icebreaking responded by diving into the water, with most reactions occurring within 1 km (0.6 mi) of the ship. The monitoring report noted that: (1) Walrus distributions were closely linked with pack-ice; (2) pack-ice was near active prospects for relatively short time periods; and (3) ice passing near active prospects contained relatively few animals. The report concluded that effects of the drilling operations on walruses were limited in time, geographical scale, and the proportion of population affected.

When walruses are present, underwater noise from vessel traffic in the Beaufort Sea may ''mask'' ordinary communication between individuals by preventing them from locating one another. It may also prevent walruses from using potential habitats in the Beaufort Sea and may have the potential to impede movement. Vessel traffic will likely increase if offshore Industry expands and may increase if warming waters and seasonally reduced sea-ice cover alter northern shipping lanes.

Because offshore exploration activities are expected to move throughout the Beaufort Sea, impacts associated with support vessels and aircrafts are likely to be distributed in time and space. Therefore, the only effect anticipated would be short-term behavioral alterations impacting small numbers of walruses in the vicinity of active operations. Adoption of mitigation measures that include an 805-m (0.5-mi) exclusion zone for marine vessels around walrus groups observed on ice are expected to reduce the intensity of disturbance events and minimize the potential for injuries to animals.

Aircraft Traffic

Aircraft overflights may disturb walruses. Reactions to aircraft vary with range, aircraft type, and flight pattern, as well as walrus age, sex, and group size. Adult females, calves, and immature walruses tend to be more sensitive to aircraft disturbance. Fixed-winged aircraft are less likely to elicit a response than helicopter overflights. Walruses are particularly sensitive to changes in engine noise and are more likely to stampede when planes turn or fly low overhead. Researchers conducting aerial surveys for walruses in sea-ice habitats have observed little reaction to fixed-winged aircraft above 457 m (1,500 ft) (USFWS unpubl. data). Although the intensity of the reaction to noise is variable, walruses are probably most susceptible to disturbance by fast-moving and low-flying aircraft (100 m (328 ft) above ground level) or aircraft that change or alter speed or direction. In the Chukchi Sea there are recent examples of walruses being disturbed by aircraft flying in the vicinity of haulouts. It appears that walruses are more sensitive to disturbance when hauled out on land versus sea-ice.

Physical Obstructions

Based on known walrus distribution and the very low numbers found in the Beaufort Sea, it is unlikely that walrus movements would be displaced by offshore stationary facilities, such as the Northstar Island or causeway-linked Endicott complex, or by vessel traffic. There is no indication that the few walruses that used Northstar Island as a haulout in the past were displaced from their movements. Vessel traffic could temporarily interrupt the movement of walruses, or displace some animals when vessels pass through an area. This displacement would probably have minimal or no effect on animals and would last no more than a few hours.

Human Encounters

Human encounters with walruses could occur in the course of Industry activities, although such encounters would be rare due to the limited distribution of walruses in the Beaufort Sea. These encounters may occur within certain cohorts of the population, such as calves or animals under stress. In 2004, a suspected orphaned calf hauled-out on the armor of Northstar Island numerous times over a 48-hour period, causing Industry to cease certain activities and alter work patterns before it disappeared in stormy seas. Additionally, a walrus calf was observed for 15 minutes during an exploration program 60 ft from the dock at Cape Simpson in 2006. From 2009 through 2014, Industry reported no similar interactions with walruses.

Effect on Prey Species

Walruses feed primarily on immobile benthic invertebrates. The effect of Industry activities on benthic invertebrates most likely would be from oil discharged into the environment. Oil has the potential to impact walrus prey species in a variety of ways including, but not limited to, mortality due to smothering or toxicity, perturbations in the composition of the benthic community, as well as altered metabolic and growth rates. Relatively few walruses are present in the central Beaufort Sea. It is important to note that, although the status of walrus prey species within the Beaufort Sea are poorly known, it is unclear to what extent, if any, prey abundance plays in limiting the use of the Beaufort Sea by walruses. Further study of the Beaufort Sea benthic community as it relates to walruses is warranted. The low likelihood of an oil spill large enough to affect prey populations (see the section titled Risk Assessment of Potential Effects Upon Polar Bears from a Large Oil Spill in the Beaufort Sea) combined with the fact that walruses are not present in the region during the ice-covered season and occur only infrequently during the open-water season indicates that Industry activities will likely have limited indirect effects on walruses through effects on prey species.

Polar Bear

Noise Disturbance

Noise produced by Industry activities during the open-water and ice-covered seasons could disturb polar bears. The impact of noise disturbances may affect bears differently depending upon their reproductive status (*e.g.,* denning versus non-denning bears). The best available scientific information indicates that female polar bears entering dens, or females in dens with cubs, are more sensitive than other age and sex groups to noises.

Noise disturbance can originate from either stationary or mobile sources. Stationary sources include construction, maintenance, repair and remediation activities, operations at production facilities, gas flaring, and drilling operations from either onshore or offshore facilities. Mobile sources include vessel and aircraft traffic, open-water seismic exploration, winter vibroseis programs, geotechnical surveys, ice road construction, vehicle traffic, tracked vehicles and snowmobiles, drilling, dredging, and ice-breaking vessels.

Noise produced by stationary activities could elicit variable responses

from polar bears. The noise may act as a deterrent to bears entering the area, or the noise could potentially attract bears. Attracting bears to these facilities, especially exploration facilities in the coastal or nearshore environment, could result in human-bear encounters, unintentional harassment, intentional hazing, or lethal take of the bear.

Industry activities may potentially disturb polar bears at maternal den sites. The timing of potential Industry activity compared with the timing of the maternal denning period can have variable impacts on the female bear and her cubs. Disturbance, including noise, may negatively impact bears less during the early stages of denning when the pregnant female has less investment in a den site before giving birth. She may abandon the site in search of another one and still successfully den and give birth. Premature den site abandonment after the birth of cubs may also occur. If den site abandonment occurs before the cubs are able to survive outside of the den, or if the female abandons the cubs, the cubs will die.

An example of a den abandonment in the early stages of denning occurred in January 1985, where a female polar bear appears to have abandoned her den in response to Rolligon traffic within 500 m (1,640 ft) of the den site. In spring 2002, noise associated with a polar bear research camp in close proximity to a bear den is thought to have caused a female bear and her cub(s) to abandon their den and move to the ice prematurely. In spring 2006, a female with two cubs emerged from a den 400 m (1,312 ft) from an active river crossing construction site. The den site was abandoned within hours of cub emergence, and 3 days after the female had emerged. In spring 2009, a female with two cubs emerged from a den within 100 m (328 ft) of an active ice road with heavy traffic and quickly abandoned the site. In January 2015 a freshly dug polar den was discovered in an active gravel pit adjacent to an active landfill and busy road. The bear abandoned the den after 56 days. During the time the bear occupied the den, Industry activity in the area was restricted, and the den was constantly monitored. A subsequent investigation of the den found no evidence that the bear gave birth. It is unknown if or to what extent Industry activity contributed to the bear leaving the den. While such events may have occurred, information indicates they have been infrequent and isolated. It is important to note that the knowledge of these recent examples occurred because of the monitoring and reporting program established by the ITRs.

Conversely, during the denning seasons of 2000–2002, two dens known to be active were located within approximately 0.4 km and 0.8 km (~0.25 mi and ~0.5 mi) of remediation activities on Flaxman Island in the Beaufort Sea with no observed impact to the polar bears. This observation suggests that polar bears exposed to routine industrial noises may habituate to those noises and show less vigilance than bears not exposed to such stimuli. This observation came from a study that occurred in conjunction with industrial activities performed on Flaxman Island in 2002 and a study of undisturbed dens in 2002 and 2003 (N = 8) (Smith *et al.* 2007). Researchers assessed vigilant behavior with two potential measures of disturbance: (1) The proportion of time scanning their surroundings; and (2) the frequency of observable vigilant behaviors. The two bears exposed to the industrial activity spent less time scanning their surroundings than bears in undisturbed areas and engaged in vigilant behavior significantly less often.

The potential for disturbance increases once the female emerges from the den. She is more vigilant against perceived threats and easier to disturb. As noted earlier, in some cases, while the female is in the den, Industry activities have progressed near den site with no observed disturbance. In the 2006 denning example previously discussed, it was believed that Industry activity commenced in the area after the den had been established. Industry activities occurred within 50 m (164 ft) of the den site with no apparent disturbance while the female was in the den. Ongoing activity most likely had been occurring for approximately 3 months in the vicinity of the den.

Likewise, in 2009, two bear dens were located along an active ice road. The bear at one den site appeared to establish her site prior to ice road activity and was exposed to approximately 3 months of activity 100 m (328 ft) away and emerged at the appropriate time. The other den site was discovered after ice road construction commenced. This site was exposed to ice road activity, 100 m (328 ft) away, for approximately 1 month. Known instances of polar bears establishing dens prior to the onset of Industry activity within 500 m (1,640 ft) or less of the den site, but remaining in the den through the normal denning cycle and later leaving with her cubs, apparently undisturbed despite the proximity of sometimes ongoing Industry activity, occurred in 2006, 2009, 2010, and 2011.

Industry observation data suggests that, with proper mitigation measures in place, some activities can continue in the vicinity of dens until the emergence by the female bear. Mitigation measures such as activity shutdowns near the den and 24-hour monitoring of the den site can minimize impacts to the animals and allow the female bear to naturally abandon the den when she chooses. For example, in the spring of 2010, an active den site was observed approximately 60 m (197 ft) from a heavily used ice road. A 1.6-km (1-mi) exclusion zone was established around the den, closing a 3.2 km (2-mi) section of the road. Monitors were assigned to observe bear activity and monitor human activity to minimize any other impacts to the bear group. These mitigation measures minimized disturbance to the bears and allowed them to abandon the den site naturally.

Mobile sources of sound, *e.g.,* vessel-based exploration activities, seismic surveys, or geophysical surveys, may disturb polar bears. In the open-water season, Industry activities are generally limited to relatively ice-free, open water. During this time in the Beaufort Sea, polar bears are typically found either on land or on the pack ice, which limits the chances of the interaction of polar bears with offshore Industry activities. Though polar bears have been observed in open water, miles from the ice edge or ice floes, the encounters are relatively rare. However, if bears come in contact with Industry operations in open water, the effects of such encounters may include short-term behavioral disturbance. Bears in the water could be affected by sound in the water, but received sound in the water would be attenuated near the surface due to the pressure release effect of airgun sounds near the water's surface (Greene and Richardson 1988, Richardson *et al.* 1995). Because polar bears generally do not dive far or for long below the surface and they normally swim with their heads above the surface, it is likely that they would be exposed to very little sound in the water. Exposure to sound in the water would also be short term and temporary for only the time a bear's head was below the surface. It is likely that offshore seismic exploration activities or other geophysical surveys during the open-water season would result in no more than short-term and temporary behavioral disturbance to polar bears, similar to that discussed earlier.

In 2012, during the open-water season, Shell vessels encountered a few polar bears swimming in ice-free water more than 70 mi (112.6 km) offshore in the Chukchi Sea. In those instances the bears were observed to either swim away from or approach the Shell vessels. Sometimes a polar bear would

swim around a stationary vessel before leaving. In at least one instance a polar bear approached, touched, and investigated a stationary vessel from the water before swimming away.

Polar bears are more likely to be affected by on-ice or in-ice Industry activities versus open-water activities. From 2009 through 2014 there were a few Industry observation reports of polar bears during on-ice activities. Those observations were primarily of bears moving through an area during winter seismic surveys on near-shore ice. The disturbance to bears, if any, was minimal, short-term, and temporary due to the mobility of such projects and limited to small-scale alterations to bear movements.

Vessel Traffic

During the open-water season, most polar bears remain offshore associated with the multiyear pack ice and are not typically present in the ice-free areas where vessel traffic occurs. Barges and vessels associated with Industry activities travel in open water and avoid large ice floes. As demonstrated in the 2012 Shell example previously, encounters between vessels and polar bears would most likely result in short-term and temporary behavioral disturbance only.

Aircraft Traffic

Routine Industry aircraft traffic should have little to no effect on polar bears, though frequent and chronic aircraft activity may cause more significant disturbance. Observations of polar bears during fall coastal surveys, which flew at much lower altitudes than is required of Industry aircraft (see mitigation measures), indicate that the reactions of non-denning polar bears should be limited to short-term changes in behavior ranging from no reaction to running away. Such disturbance should have no more than short-term, temporary, and minor impacts on individuals and no discernible impacts on the polar bear population, unless it was chronic and long-term. In contrast, denning bears could prematurely abandon their dens in response to repeated aircraft overflight noise. Mitigation measures, such as minimum flight elevations over polar bears, habitat areas of concern, and flight restrictions around known polar bear dens, will be required, as appropriate, to reduce the likelihood that polar bears are disturbed by aircraft.

Physical Obstructions

Industry facilities may act as physical barriers to movements of polar bears. Most facilities are located onshore and inland where polar bears are less frequently found. The offshore and coastal facilities are more likely to be approached by polar bears. The majority of Industry bear observations occur within 1.6-km (1-mi) of the coastline as bears use this area as travel corridors. As bears encounter these facilities, the chances for human-bear interactions increase. The Endicott and West Dock causeways, as well as the facilities supporting them, have the potential to act as barriers to movements of polar bears because they extend continuously from the coastline to the offshore facility. However, polar bears have frequently been observed crossing existing roads and causeways and appear to traverse the human-developed areas as easily as the undeveloped areas. Offshore production facilities, such as Northstar, Spy Island, and Oooguruk, have frequently been approached by polar bears, but appear to present only a small-scale, local obstruction to the bears' movement. Of greater concern is the increased potential for polar bear-human interaction at these facilities.

Human Encounters

Historically, polar bear observations are seasonally common, but close encounters with Industry personnel are uncommon. These encounters can be dangerous for both polar bears and humans.

Encounters are more likely to occur during the fall at facilities on or near the coast. Polar bear interaction plans, training, and monitoring required by the ITRs have proven effective at reducing polar bear–human encounters and the risks to bears and humans when encounters occur. Polar bear interaction plans detail the policies and procedures that Industry facilities and personnel will implement to avoid attracting and interacting with polar bears as well as minimizing impacts to the bears. Interaction plans also detail how to respond to the presence of polar bears, the chain of command and communication, and required training for personnel.

Industry has also developed and uses technology to aid in detecting polar bears, including bear monitors, closed-circuit television (CCTV), video cameras, thermal cameras, radar devices, and motion-detection systems. In addition, some companies take steps to actively prevent bears from accessing facilities using safety gates and fences.

Known polar bear dens around the oilfield, discovered opportunistically, or as a result of planned surveys, such as tracking marked bears or den detection surveys, are monitored by the Service. However, these sites are only a small percentage of the total active polar bear dens for the SBS stock in any given year. Each year Industry coordinates with the Service to conduct surveys to determine the location of Industry's activities relative to known dens and denning habitat. Industry activities are required to avoid known polar bear dens by 1 mi. There is the possibility that an unknown den may be encountered during Industry activities. When a previously unknown den is discovered in proximity to Industry activity, the Service implements mitigation measures such as the 1.6-km (1-mi) activity exclusion zone around the den and 24-hour monitoring of the site.

Effect on Prey Species

The effects of Industry activity upon polar bear prey, primarily ringed seals, will be similar to that of effects upon walruses, and primarily through noise disturbance or exposure to an oil spill. Seals may be displaced by disturbance from habitat areas such as pupping lairs or haulouts and abandon breathing holes near Industry activity. However, these disturbances appear to have minor, short-term, and temporary effects (NMFS 2013). Effects of contamination from oil discharges for seals are described in the following section.

Evaluation of Effects of Oil and Gas Industry Activity on Pacific Walruses and Polar Bears

Pacific Walrus

Industry activities may result in some incremental cumulative effects to the relatively few walruses exposed to these activities through the potential exclusion or avoidance of walruses from resting areas and disruption of associated biological behaviors. However, based on the habitat use patterns of walruses and their close association with seasonal pack-ice, relatively few animals are likely to be encountered during the open-water season when marine activities are expected to occur. Required monitoring and mitigation measures designed to minimize interactions between Industry activities and walruses are also expected to limit these impacts. Hunting pressure, climate change, and the increase of other human activities in walrus habitat all have potential to impact walruses. But those activities and their impacts are mostly a concern in the Bering and Chukchi seas where large numbers of walruses are found. Therefore, we conclude that in the Beaufort Sea, Industry activities during the 5-year period covered by these regulations, as mitigated through the regulatory process, are not expected to

add significantly to the cumulative impacts on the walrus population.

Polar Bear

The effects of Industry activity are evaluated, in part, through information gained in monitoring reports, which are required for each LOA issued. Information from these reports provides a history of past effects on polar bears from interactions with Industry activities. In addition, information used in our effects evaluation includes published and unpublished polar bear research and monitoring reports, information from the 2008 ESA polar bear listing, stock assessment reports, status reviews, conservation plans, Alaska Native traditional knowledge, anecdotal observations, and professional judgment.

Since 1993, the documented impacts of incidental take by Industry activity in the Beaufort Sea ITR region affected only small numbers of bears, were primarily short-term changes to behavior, and had no long-term impacts on individuals and no impacts on the SBS polar bear population, or the global population. Industry monitoring data has documented various types of interactions between polar bears and Industry. The most significant impacts to polar bears from Industry activity have been the result of close bear–human encounters, some of which have led to deterrence events.

For the analysis of Industry take of polar bears, we included both incidental and intentional takes that occurred from 2010 through 2014. We included intentional takes to provide a transparent and complete analysis of Industry-related polar bear takes on the North Slope of Alaska. Intentional take of polar bears is a separate authorization under sections 101(a)(4)(A), 109(h), and 112(c) of the MMPA and is distinct from the ITRs. Intentional take authorizations allow citizens conducting activities in polar bear habitat to take polar bears by nonlethal, non-injurious harassment for the protection of both human life and polar bears. The purpose of the intentional take authorization is to deter polar bears prior to a bear–human encounter escalating to the use of deadly force against a polar bear. The Service provides guidance and training as to the appropriate harassment response necessary for polar bears. The MMPA-specific authorizations have proven to be successful in preventing injury and death to humans and polar bears.

From 2010 through 2014, a total of 107 LOAs were issued to Industry, and polar bear observations were recorded for 36.4 percent (39) of those LOAs. Industry reported 1,234 observations of 1,911 polar bears. The highest number of bears was observed during the months of August and September. Industry polar bear observations have increased from previous regulatory time periods. The higher number of bear sightings was most likely the result of an increased number of bears using terrestrial habitat as a result of changes in sea-ice, multiple vessel-based projects occurring near barrier islands, and the increased compliance and improved monitoring of Industry projects. This trend in observations is consistent with the anticipation that polar bears will increase their use of coastal habitats during the months when sea-ice is far from shore and over deep water. Because some of the reports were repeat observations of the same bears on different dates, the actual number of individual bears encountered is lower than reported. However, due to the nature of the information in the Industry observation reports, we must accept the information ''as is'' while acknowledging that it collectively over-reports bear numbers.

When we compared the reported bear numbers to the SBS population (*i.e.,* 900 bears), we found that 42 percent of the SBS polar bear population may have been observed by Industry personnel from 2010 to 2014. When we evaluated the effects upon the 1,911 bears observed, we found that 81 percent (1,549) resulted in instances of non-taking. Of the remaining 362 encounters, 78 resulted in Level B takes by incidental disturbance, 260 Level B takes by deterrence, 23 instances of unknown effect, and 1 Level A take associated with Industry activity. Over those 5 years, 338 Level B takes of polar bears occurred, which is approximately 18 percent of the observed bears, or 7.5 percent of the SBS population.

For the 2011–2016 ITR, the Service estimated that takes of polar bears by all Level B harassment events would not exceed 150 per year. Our analysis of Industry polar bear observation reports shows that from 2010 through 2014 an average of 68 Level B harassment events occurred per year, well below our estimated value. Industry activities that occur on or near the Beaufort Sea coast continue to have the greatest potential for encountering polar bears rather than Industry activities occurring inland or far offshore.

From 2010 through 2014, intentional harassment by deterrence of 260 polar bears (14 percent of the observed 1,911) resulted in Level B take. The percentage of polar bear deterrence events that result in Level B take has decreased over time from a high of 39 percent of observed bears in 2005. The Service attributes this long-term decrease in deterrence events to increased polar bear safety and awareness training of Industry personnel as well as our ongoing deterrence education, training, and monitoring programs. We have no indication that nonlethal, non-injurious harassment by deterrence, which temporarily alters the behavior and movement of some bears, has an effect on survival and recruitment in the SBS polar bear population.

Lethal take of polar bears by Industry activity is very rare. Since 1968, three documented cases of lethal take of polar bears associated with oil and gas activities have occurred. In winter 1968–1969, an Industry employee shot and killed a polar bear in defense of human life. In 1990, a female polar bear was killed at a drill site on the west side of Camden Bay, also in defense of human life. Since the beginning of the incidental take program in 1993, which includes measures that minimize impacts to the species, one polar bear has been killed due to encounters associated with current Industry activities on the North Slope. In August 2011, a female polar bear was accidentally killed on the Endicott causeway when an attempt to non-lethally deter the bear was not conducted properly. After the 2011 lethal take incident, the Service reviewed the circumstances that contributed to the death of the bear and implemented a series of corrective actions with Industry. The Service believes that the corrective actions significantly reduce the potential for a similar situation to arise in the future. Therefore, we do not anticipate any lethal take of polar bears during the 5-year period of these ITRs.

Industry activities are likely to result in incremental cumulative effects to polar bears during the 5-year regulatory period. Based on Industry monitoring information, for example, deflection from travel routes along the coast appears to be a common occurrence, where bears move around coastal facilities rather than traveling through them. Incremental cumulative effects could also occur through the potential exclusion or temporary avoidance of polar bears from feeding, resting, or denning areas and disruption of associated biological behaviors. However, based on monitoring results acquired from past ITRs, the level of cumulative effects, including those of climate change, during the 5-year regulatory period would result in negligible effects on the bear population.

Mitigation measures required for all projects will include a polar bear interaction plan, training of personnel, a record of communication with potentially affected communities, and a POC when appropriate. Mitigation measures that may be used on a case-by-case basis include the use of trained marine mammal monitors associated with marine activities, the use of den habitat maps developed by the USGS, surveys to locate polar bear dens, timing of the activity to limit disturbance around dens, the 1.6-km (1-mi) buffer surrounding known dens, and suggested work actions around known dens. The Service implements certain mitigation measures based on need and effectiveness for specific activities based largely on timing and location. For example, the Service will implement different mitigation measures for a 2-month-long exploration project 20 mi inland from the coast, than for an annual nearshore development project in shallow waters.

An example of the application of this process would be in the case of Industry activities occurring around a known polar bear den. Each LOA requires a polar bear interaction plan and a minimum 1.6-km (1-mi) buffer between Industry activities and known denning sites. If a den is discovered after Industry activities have begun, we may require Industry to cease activities within the buffer zone until the bears have left the den and departed the area undisturbed. To further reduce the potential for disturbance to denning females we conduct surveys, in cooperation with Industry, to detect active polar bear dens using remote sensing techniques, such as thermal imagery (Forward Looking Infra-Red, FLIR, cameras), and maps of potential denning habitat along the Beaufort Sea coast.

Thermal imagery, as a mitigation tool, is used in conjunction with polar bear denning habitat maps. Industry activity areas, such as coastal ice roads, are compared to polar bear denning habitat, and transects are then created to survey the specific habitat within the Industry area. FLIR heat signatures within a standardized den location protocol are noted, and further mitigation measures are placed around these locations. FLIR surveys are more effective at detecting polar bear dens than visual observations. The effectiveness increases when FLIR surveys are combined with site-specific, scent-trained dog surveys. These techniques will continue to be required as conditions of LOAs when appropriate.

Industry has sponsored cooperative research evaluating how polar bears perceive and respond to various types of disturbance. This information has been useful to refine site-specific mitigation measures. Using current mitigation measures, Industry activities have had no known polar bear population-level effects during the period of previous regulations. We anticipate that, with continued mitigation measures, the impacts to denning and non-denning polar bears will be at the same low level as under previous regulations.

The Service believes that the required mitigation measures will be effective in minimizing the impacts of Industry activity upon polar bears during the 5-year timeframe of these ITRs as they have in the past.

For further information on the cumulative effects of oil and gas development on polar bears in Alaska, refer to the Service's 2008 ''Range-Wide Status Review of the Polar Bear (*Ursus maritimus*)'' at: *http://www.fws.gov/alaska/fisheries/mmm/polarbear/pdf/Polar_Bear_%20Status_Assessment.pdf.*

Potential Effects of Oil Spills on Pacific Walruses and Polar Bears

Walrus and polar bear ranges overlap with many active and planned Industry activities. There is a risk of oil spills from facilities, ships, and pipelines in both offshore and onshore habitat. To date, no major offshore oil spills have occurred in the Alaska Beaufort Sea. Though numerous small onshore spills have occurred on the North Slope, there have been no documented effects to polar bears.

Oil spills are unintentional releases of oil or petroleum products. In accordance with the National Pollutant Discharge Elimination System Permit Program, all North Slope oil companies must submit an oil spill contingency plan. It is illegal to discharge oil into the environment, and a reporting system requires operators to report spills. Between 1977 and 1999, an average of 70 oil and 234 waste product spills occurred annually on the North Slope oilfields. Although most spills have been small by Industry standards (less than 50 bbl), larger spills (more than 500 bbl) accounted for much of the annual volume. Seven large spills occurred between 1985 and 2009 on the North Slope. The largest spill occurred in the spring of 2006 when approximately 6,190 bbl leaked from flow lines near an oil gathering center. More recently, several large spills have occurred. In 2012, 1,000 bbl of drilling mud and 100 bbl of crude were spilled in separate incidents, in 2013, approximately 166 bbl of crude oil was spilled, and in 2014, 177 bbl of drilling mud was spilled. Those spills occurred primarily in the terrestrial environment in heavily industrialized areas not utilized by walruses or polar bears and posed little risk to the animals.

Walruses and polar bears could encounter spilled oil from exploratory operations, existing offshore facilities, pipelines, or from marine vessels. The shipping of crude oil, oil products, or other toxic substances, as well as the fuel for the shipping vessels, increases the risk of a spill. Future reductions in Arctic sea-ice extent are expected to improve access to Arctic shipping lanes and extend the Arctic shipping season, also increasing the risk of a spill.

Oil spills in the sea-ice environment, at the ice edge, in leads, polynyas, and similar areas of importance to walruses and polar bears, are of particular concern. Oil spilled in those areas presents an even greater challenge because of both the difficulties associated with cleaning oil in sea-ice, and the presence of wildlife in those areas. As additional offshore Industry projects are planned, the potential for large spills in the marine environment increases.

Oiling of food sources, such as ringed seals, may result in indirect effects on polar bears, such as a local reduction in ringed seal numbers, or a change to the local distribution of seals and bears. More direct effects on polar bears could occur from: (1) Ingestion of oiled prey, potentially resulting in reduced survival of individual bears; (2) oiling of fur and subsequent ingestion of oil from grooming; (3) oiling and fouling of fur with subsequent loss of insulation, leading to hypothermia; and (4) disturbance, injury, or death from interactions with humans during oil spill response activities. Polar bears may be particularly vulnerable to disturbance when nutritionally stressed and during denning. Cleanup operations that disturb a den could result in death of cubs through abandonment, and perhaps death of the sow as well. In spring, females with cubs of the year that denned near or on land and migrate to contaminated offshore areas may encounter oil following a spill (Stirling in Geraci and St. Aubin 1990).

In the event of an oil spill, the Service follows oil spill response plans to respond to the spill, coordinate with partners, and reduce the impact of a spill on wildlife. Several factors will be considered when responding to an oil spill. They include the location of the spill, the magnitude of the spill, oil viscosity and thickness, accessibility to spill site, spill trajectory, time of year, weather conditions (*i.e.,* wind, temperature, precipitation), environmental conditions (*i.e.,* presence

and thickness of ice), number, age, and sex of walruses and polar bears that are (or are likely to be) affected, degree of contact, importance of affected habitat, cleanup proposal, and likelihood of human-bear interactions. Response efforts will be conducted under a three-tier approach characterized as: (1) Primary response, involving containment, dispersion, burning, or cleanup of oil; (2) secondary response, involving hazing, herding, preventative capture/relocation, or additional methods to remove or deter wildlife from affected or potentially affected areas; and (3) tertiary response, involving capture, cleaning, treatment, and release of wildlife. If the decision is made to conduct response activities, primary and secondary response options will be vigorously applied. Tertiary response capability has been developed by the Service and partners, though such response efforts would most likely only be able to handle a few animals at a time. More information is available in the Service's oil spill response plans for walruses and polar bears in Alaska is located at: *http://www.fws.gov/alaska/fisheries/contaminants/pdf/Polar%20Bear%20WRP%20final%20v8_Public%20website.pdf* and *https://dec.alaska.gov/spar/ppr/plans/uc/Annex%20G%20(Oct%202012).pdf.*

BOEM has acknowledged that there are difficulties in effective oil-spill response in broken-ice conditions, and the National Academy of Sciences has determined that ''no current cleanup methods remove more than a small fraction of oil spilled in marine waters, especially in the presence of broken ice.'' BOEM advocates the use of nonmechanical methods of spill response, such as in-situ burning, during periods when broken-ice would hamper an effective mechanical response (MMS 2008b). An in-situ burn has the potential to rapidly remove large quantities of oil and can be employed when broken-ice conditions may preclude mechanical response. However, the resulting smoke plume may contain toxic chemicals and high levels of particulates that can pose health risks to marine mammals, birds and other wildlife, as well as to humans. Smoke trajectories must be considered before making the decision to burn spilled oil. Another potential nonmechanical response strategy is the use of chemical dispersants to speed dissipation of oil from the water surface and disperse it within the water column in small droplets. Dispersant use presents environmental trade-offs. While walruses and polar bears would likely benefit from reduced surface or shoreline oiling, dispersant use could have negative impacts on the aquatic food chain. Oil spill cleanup in the broken-ice and open-water conditions that characterize Arctic waters is problematic.

Evaluation of Effects of Oil Spills on Pacific Walruses and Polar Bears

The MMPA does not authorize the incidental take of marine mammals as the result of illegal actions, such as oil spills. Any event that results in an injurious or lethal outcome to a marine mammal is not authorized under these ITRs. However, for the purpose of determining whether Industry activity would have a negligible effect on walruses and polar bears, the Service evaluated the potential impacts of oil spills within the Beaufort Sea ITR region.

Pacific Walrus

As stated earlier, the Beaufort Sea is not within the primary range for walruses. Therefore, the probability of walruses encountering oil or waste products as a result of a spill from Industry activities is low. Onshore oil spills would not impact walruses unless oil moved into the offshore environment. In the event of a spill that occurs during the open-water season, oil in the water column could drift offshore and possibly encounter a small number of walruses. Oil spills from offshore platforms could also contact walruses under certain conditions. Spilled oil during the ice-covered season not cleaned up could become part of the ice substrate and be eventually released back into the environment during the following open-water season. During spring melt, oil would be collected by spill response activities, but it could eventually contact a limited number of walruses.

Little is known about the effects of oil specifically on walruses as no studies have been conducted. Hypothetically, walruses may react to oil much like other pinnipeds. Walruses are not likely to ingest oil while grooming since walruses have very little hair and exhibit no grooming behavior. Adult walruses may not be severely affected by the oil spill through direct contact, but they will be extremely sensitive to any habitat disturbance by human noise and response activities. In addition, due to the gregarious nature of walruses, an oil spill would most likely affect multiple individuals in the area. Walruses may also expose themselves more often to the oil that has accumulated at the edge of a contaminated shore or ice lead if they repeatedly enter and exit the water.

Walrus calves are most likely to suffer the effects of oil contamination. Female walruses with calves are very attentive, and the calf will stay close to its mother at all times, including when the female is foraging for food. Walrus calves can swim almost immediately after birth and will often join their mother in the water. It is possible that an oiled calf will be unrecognizable to its mother either by sight or by smell, and be abandoned. However, the greater threat may come from an oiled calf that is unable to swim away from the contamination and a devoted mother that would not leave without the calf, resulting in the potential mortality of both animals. Further, a nursing calf might ingest oil if the cow was oiled, also increasing the risk of injury or mortality.

Walruses have thick skin and blubber layers for insulation. Heat loss is regulated by control of peripheral blood flow through the animal's skin and blubber. The peripheral blood flow is decreased in cold water and increased at warmer temperatures. Direct exposure of walruses to oil is not believed to have any effect on the insulating capacity of their skin and blubber, although it is unknown if oil could affect their peripheral blood flow.

Damage to the skin of pinnipeds can occur from contact with oil because some of the oil penetrates into the skin, causing inflammation and death of some tissue. The dead tissue is discarded, leaving behind an ulcer. While these skin lesions have only rarely been found on oiled seals, the effects on walruses may be greater because of a lack of hair to protect the skin. Direct exposure to oil can also result in conjunctivitis. Like other pinnipeds, walruses are susceptible to oil contamination in their eyes. Continuous exposure to oil will quickly cause permanent eye damage.

Inhalation of hydrocarbon fumes presents another threat to marine mammals. In studies conducted on pinnipeds, pulmonary hemorrhage, inflammation, congestion, and nerve damage resulted after exposure to concentrated hydrocarbon fumes for a period of 24 hours. If the walruses were also under stress from molting, pregnancy, etc., the increased heart rate associated with the stress would circulate the hydrocarbons more quickly, lowering the tolerance threshold for ingestion or inhalation.

Walruses are benthic feeders, and much of the benthic prey contaminated by an oil spill would be killed immediately. Others that survived would become contaminated from oil in bottom sediments, possibly resulting in slower growth and a decrease in

reproduction. Bivalve mollusks, a favorite prey species of the walrus, are not effective at processing hydrocarbon compounds, resulting in highly concentrated accumulations and long-term retention of the contamination within the organism. Specifically, bivalve mollusks bioconcentrate polycyclic aromatic hydrocarbons (PAHs), a particularly toxic fraction of oil. PAHs may cause a variety of chronic toxic effects in exposed organisms, including enzyme induction, immune impairment, or cancer, among others. In addition, because walruses feed primarily on mollusks, they may be more vulnerable to a loss of this prey species than other pinnipeds that feed on a larger variety of prey. Furthermore, complete recovery of a bivalve mollusk population may take 10 years or more, forcing walruses to find other food resources or move to nontraditional areas.

The relatively few walruses in the Beaufort Sea and the low potential for a large oil spill (1,000 bbl or more), which is discussed in the following Risk Assessment Analysis, limit potential impacts to walruses to only certain events (*i.e.,* a large oil spill) and then only to a limited number of individuals. Fueling crews have personnel that are trained to handle operational spills and contain them. If a small offshore spill occurs, spill response vessels are stationed in close proximity and respond immediately. A detailed discussion of oil spill prevention and response for walruses can be found at: *https://dec.alaska.gov/spar/ppr/plans/uc/Annex%20G%20(Oct%202012).pdf.*

Polar Bear

To date, large oil spills from Industry activities in the Beaufort Sea and coastal regions that would impact polar bears have not occurred, although the interest in, and the development of, offshore hydrocarbon reservoirs has increased the potential for large offshore oil spills. With limited background information available regarding oil spills in the Arctic environment, the outcome of such a spill is uncertain. For example, in the event of a large spill equal to a rupture in the Northstar pipeline and a complete drain of the subsea portion of the pipeline (approximately 5,900 bbl), oil would be influenced by seasonal weather and sea conditions including temperature, winds, wave action, and currents. Weather and sea conditions also affect the type of equipment needed for spill response and the effectiveness of spill cleanup. Based on the experiences of cleanup efforts following the Exxon Valdez oil spill, where logistical support was readily available, spill response may be largely unsuccessful in open-water conditions. Indeed, spill response drills have been unsuccessful in the cleanup of oil in broken-ice conditions.

Small spills of oil or waste products throughout the year could potentially impact some bears. The effects of fouling fur or ingesting oil or wastes, depending on the amount of oil or wastes involved, could be short-term or result in death. For example, in April 1988, a dead polar bear was found on Leavitt Island, northeast of Oliktok Point. The cause of death was determined to be due to a mixture that included ethylene glycol and Rhodamine B dye (Amstrup *et al.* 1989). Again, in 2012, two dead polar bears that had been exposed to Rhodamine B were found on Narwhal Island, northwest of Endicott. While those bears' deaths were clearly human-caused, investigations were unable to identify a source for the chemicals. Rhodamine B is commonly used on the North Slope of Alaska by many people for many uses, including Industry. Without identified sources of contamination, those bear deaths cannot be attributed to Industry activity.

During the ice-covered season, mobile, non-denning bears would have a higher probability of encountering oil or other production wastes than non-mobile, denning females. Current management practices by Industry, such as requiring the proper use, storage, and disposal of hazardous materials, minimize the potential occurrence of such incidents. In the event of an oil spill, it is also likely that polar bears would be intentionally hazed to keep them away from the area, further reducing the likelihood of impacting the population.

In 1980, Oritsland *et al.* (1981) performed experiments in Canada that studied the effects to polar bears of exposure to oil. Effects on experimentally oiled polar bears (where bears were forced to remain in oil for prolonged periods of time) included acute inflammation of the nasal passages, marked epidermal responses, anemia, anorexia, and biochemical changes indicative of stress, renal impairment, and death. Many effects did not become evident until several weeks after the experiment.

Oiling of the pelt causes significant thermoregulatory problems by reducing the insulation value. Irritation or damage to the skin by oil may further contribute to impaired thermoregulation. Experiments on live polar bears and pelts showed that the thermal value of the fur decreased significantly after oiling, and oiled bears showed increased metabolic rates and elevated skin temperature. Oiled bears are also likely to ingest oil as they groom to restore the insulation value of the oiled fur.

Oil ingestion by polar bears through consumption of contaminated prey, and by grooming or nursing, could have pathological effects, depending on the amount of oil ingested and the individual's physiological state. Death could occur if a large amount of oil were ingested or if volatile components of oil were aspirated into the lungs. Indeed, two of three bears died in the Canadian experiment, and it was suspected that the ingestion of oil was a contributing factor to the deaths. Experimentally oiled bears ingested much oil through grooming. Much of it was eliminated by vomiting and in the feces; some was absorbed and later found in body fluids and tissues.

Ingestion of sublethal amounts of oil can have various physiological effects on polar bears, depending on whether the animal is able to excrete or detoxify the hydrocarbons. Petroleum hydrocarbons irritate or destroy epithelial cells lining the stomach and intestine, thereby affecting motility, digestion, and absorption.

Polar bears swimming in, or walking adjacent to, an oil spill could inhale toxic, volatile organic compounds from petroleum vapors. Vapor inhalation by polar bears could result in damage to the respiratory and central nervous systems, depending on the amount of exposure.

Oil may also affect food sources of polar bears. Seals that die as a result of an oil spill could be scavenged by polar bears. This food source would increase exposure of the bears to hydrocarbons and could result in lethal impacts or reduced survival to individual bears. A local reduction in ringed seal numbers as a result of direct or indirect effects of oil could temporarily affect the local distribution of polar bears. A reduction in density of seals as a direct result of mortality from contact with spilled oil could result in polar bears not using a particular area for hunting. Possible impacts from the loss of a food source could reduce recruitment and/or survival.

Spilled oil can concentrate and accumulate in leads and openings that occur during spring breakup and autumn freeze-up periods. Such a concentration of spilled oil would increase the chance that polar bears and their principal prey would be oiled. To access ringed and bearded seals, polar bears in the SBS concentrate in shallow waters less than 300 m (984 ft) deep over the continental shelf and in areas

with greater than 50 percent ice cover (Durner *et al.* 2004).

Due to their seasonal use of nearshore habitat, the times of greatest impact from an oil spill to polar bears are likely the open-water and broken-ice periods (summer and fall). This scenario is important because distributions of polar bears are not uniform through time. Nearshore and offshore polar bear densities are greatest in fall, and polar bear use of coastal areas during the fall open-water period has increased in recent years in the Beaufort Sea. An analysis of data collected from 2001–2005 during the fall open-water period concluded: (1) On average approximately 4 percent of the estimated polar bears in the Southern Beaufort population were observed onshore in the fall; (2) 80 percent of bears onshore occurred within 15 km (9 mi) of subsistence-harvested bowhead whale carcasses, where large congregations of polar bears have been observed feeding; and (3) sea-ice conditions affected the number of bears on land and the duration of time they spent there (Schliebe *et al.* 2006). Hence, bears concentrated in areas where beach-cast marine mammal carcasses occur during the fall would likely be more susceptible to oiling.

The persistence of toxic subsurface oil and chronic exposures, even at sublethal levels, can have long-term effects on wildlife (Peterson *et al.* 2003). Exposure to PAHs can have chronic effects because some effects are sublethal (*e.g.,* enzyme induction or immune impairment) or delayed (*e.g.,* cancer). Although it is true that some bears may be directly affected by spilled oil initially, the long-term impact could be much greater. Long-term effects could be substantial through complex environmental interactions and compromised health of exposed animals. For example, PAHs can impact the food web by concentrating in filter-feeding organisms, thus affecting fish that feed on those organisms, and the predators of those fish, such as the ringed seals that polar bears prey upon. How these complex interactions would affect polar bears is not well understood, but sublethal, chronic effects of an oil spill may affect the polar bear population due to reduced fitness of surviving animals.

Polar bears are biological sinks for some pollutants, such as polychlorinated biphenyls or organochlorine pesticides, because they are an apex predator of the Arctic ecosystem and are also opportunistic scavengers of other marine mammals. Additionally, their diet is composed mostly of high-fat sealskin and blubber (Norstrom *et al.* 1988). The highest concentrations of persistent organic pollutants in Arctic marine mammals have been found in seal-eating walruses and polar bears near Svalbard (Norstrom *et al.* 1988, Andersen *et al.* 2001, Muir *et al.* 1999). As such, polar bears would be susceptible to the effects of bioaccumulation of contaminants, which could affect their reproduction, survival, and immune systems.

In addition, subadult polar bears are more vulnerable than adults to environmental effects (Taylor *et al.* 1987). Subadult polar bears would be most prone to the lethal and sublethal effects of an oil spill due to their proclivity for scavenging (thus increasing their exposure to oiled marine mammals) and their inexperience in hunting. Because of the greater maternal investment a weaned subadult represents, reduced survival rates of subadult polar bears have a greater impact on population growth rate and sustainable harvest than reduced litter production rates (Taylor *et al.* 1987).

Evaluation of the potential impacts of spilled Industry waste products and oil suggest that individual bears could be adversely impacted by exposure to these substances (Oritsland *et al.* 1981). The major concern regarding a large oil spill is the impact such a spill would have on the rates of recruitment and survival of the SBS polar bear population. If an oil spill killed a small number of bears, the SBS population may be able to survive and continue to sustain the current level of subsistence harvest. However, if a large oil spill killed large numbers of polar bears, the SBS population may experience reduced rates of recruitment and survival and subsistence harvest could become unsustainable. Polar bear deaths from an oil spill could be caused by direct exposure to the oil. However, indirect effects, such as a reduction of prey or scavenging contaminated carcasses, could also cause health effects, death, or otherwise affect rates of recruitment and survival. Depending on the type and amount of oil or wastes involved and the timing and location of a spill, impacts could be acute, chronic, temporary, or lethal. In order for the rates of polar bear reproduction, recruitment, or survival to be impacted, a large-volume oil spill would have to take place. The following section analyzes the likelihood and potential effects of such a large-volume oil spill.

Risk Assessment of Potential Effects Upon Polar Bears From a Large Oil Spill in the Beaufort Sea

In this section, we qualitatively assess the likelihood that polar bears may be oiled by a large oil spill. We considered: (1) The probability of a large oil spill occurring in the Beaufort Sea; (2) the probability of that oil spill impacting coastal polar bear habitat; (3) the probability of polar bears being in the area and coming into contact with that large oil spill; and (4) the number of polar bears that could potentially be impacted by the spill. Although the majority of the information in this evaluation is qualitative, the probability of all of these factors occurring sequentially in a manner that impacts polar bears in the Beaufort Sea is low. Since walruses are not often found in the Beaufort Sea, and there is little information available regarding the potential effects of an oil spill upon walruses, this analysis emphasizes polar bears.

The analysis was based on polar bear distribution and habitat use using four sources of information that, when combined, allowed the Service to make conclusions on the risk of oil spills to polar bears. This information included: (1) The description of existing offshore oil and gas production facilities previously discussed in the Description of Activities section; (2) polar bear distribution information previously discussed in the Biological Information section; (3) BOEM Oil-Spill Risk Analysis (OSRA) for the OCS, including polar bear environmental resource areas (ERAs) and land segments (LSs), which allowed us to qualitatively analyze the risk to polar bears and their habitat from a marine oil spill; and (4) the most recent polar bear risk assessment from the previous ITRs.

Development of offshore production facilities with supporting pipelines increases the potential for large offshore spills. The probability of a large oil spill from offshore oil and gas facilities and the risk to polar bears is a scenario that has been considered in previous regulations (71 FR 43926, August 2, 2006 and 76 FR 47010, August 3, 2011). With the limited background information available regarding the effects of large oil spills on polar bears in the marine Arctic environment, the impact of a large oil spill is uncertain. As far as is known, polar bears have not been affected by oil spilled as a result of North Slope Industry activities.

In order to effectively evaluate how a large oil spill may affect polar bears, we considered the following factors in developing our oil spill assessment for polar bears: The origin (location) of a large spill; the volume of a spill; oil viscosity; accessibility to spill site; spill trajectory; time of year; weather conditions (*i.e.,* wind, temperature, precipitation); environmental

conditions (*i.e.,* presence and thickness of ice); number, age, and sex of polar bears that are (or likely to be) affected; degree of contact; importance of affected habitat; and mitigation measures to prevent bears from encountering spilled oil.

The oil-spill scenario for this analysis considers the potential impacts of a large oil spill (*i.e.,* 1,000 bbl or more) from one of the offshore Industry facilities: Northstar, Spy Island, Oooguruk, Endicott, or the future Liberty. Estimating a large oil-spill occurrence is accomplished by examining a wide variety of probabilities. Uncertainty exists regarding the location, number, and size of a large oil spill and the wind, ice, and current conditions at the time of a spill, but we have made every effort to identify the most likely spill scenarios and sources of risk to polar bears. Conditional probabilities analysis assumes that a large spill has occurred and that no cleanup takes place. The probability of a spill occurring would be different for each site depending upon oil type, depth, oil flow rates, etc.

BOEM Oil Spill Risk Analysis

Because the BOEM OSRA provides the most current and rigorous treatment of potential oil spills in the Beaufort Sea Planning Area, our analysis of potential oil spill impacts applied BOEM's OSRA (MMS 2008a) to help analyze potential impacts of a large oil spill originating in the Beaufort Sea ITR region to polar bears. The OSRA is a computer model that analyzes how and where large offshore spills will likely move (Smith *et al.* 1982). To estimate the likely trajectory of large oil spills, the OSRA model used information about the physical environment, including data on wind, sea-ice, and currents. As a conditional model, the OSRA is a hypothetical analysis of an oil spill.

The BOEM OSRA model was developed for the Federal offshore waters and does not include analysis of oil spills in the State of Alaska-controlled nearshore waters. Northstar, Oooguruk, Spy Island, and the Endicott/Liberty complex are located in nearshore State waters. Northstar has one Federal well, and Liberty is a Federal reservoir to be developed from State waters. Although the OSRA cannot calculate trajectories of oil spills originating from specific locations in the nearshore area, it can be used to help examine how habitat may be affected by a spill should one originate in the OCS. We can then compare the location of the affected habitat to habitat use by bears.

The OSRA model predicted where the oil trajectory would go if the oil persisted as a slick at a particular time of year. Oil spills of less than 1,000 bbl are not expected to persist on the water long enough to warrant a trajectory analysis. For this reason, we only analyzed the effects of a large oil spill. Although no large spills from oil and gas activities have occurred on the Alaska OCS to date, the large spill volume assumptions used by BOEM were based on the reported spills from oil exploration and production in the Gulf of Mexico and Pacific OCS regions. BOEM used the median spill size in the Gulf of Mexico and Pacific OCS in the period 1985–1999 as the likely large spill size for analysis purposes. The median size of a large crude oil spill from a pipeline in the period 1985–1999 on the U.S. OCS was 4,600 bbl, and the average was 6,700 bbl (Anderson and LaBelle 2000). The median large spill size for a platform on the OCS over the entire record in the period 1964–1999 is 1,500 bbl, and the average is 3,300 bbl (Anderson and LaBelle 2000).

The OSRA estimated that the statistical mean number of large spills is less than one over the 20-year life of past, present, and reasonably foreseeable developments in the Beaufort Sea Planning Area. In addition large spills are more likely to occur during development and production than during exploration in the Arctic (MMS 2008). Our oil spill assessment during a 5-year regulatory period was predicated on the same assumptions.

Between 1971 and 2007, OCS operators have produced almost 15 billion bbl of oil in the United States. During this period, 2,645 spills totaled approximately 164,100 bbl spilled (~0.001 percent of bbl produced), or about 1 bbl spilled for every 91,400 bbl produced. Between 1993 and 2007, almost 7.5 billion bbl of oil were produced. During this period, 651 spills totaled approximately 47,800 bbl spilled (~0.0006 percent of bbl produced), or approximately 1 bbl spilled for every 156,900 bbl produced.

Between July 1, 2009, and June 30, 2014, the North Slope industrial area reported an average of 59,043 gallons of spilled substances annually, with a total of 138 crude oil spills. Statewide during this period, approximately 5.6 percent of the total volume of spilled material consisted of crude oil. The volume of spilled crude on the North Slope was, therefore, estimated to be approximately 79 bbl (~1,406 × 0.056 = ~79). Recent large spills of crude oil have included a subsurface release of 166 bbl from a well at Milne Point, and a 100 bbl spill from a tank. Secondary containment retained the smaller of these spills.

Two large onshore terrestrial oil spills have occurred as a result of pipeline failures. In the spring of 2006, approximately 6,200 bbl of crude oil spilled from a corroded pipeline operated by BP Exploration (Alaska). The spill impacted approximately 0.8 ha (~2 ac). In November 2009, a spill of approximately 1,150 bbl from a ''common line'' carrying oil, water, and natural gas operated by BP occurred as well, impacting approximately 780 m^2 (~8,400 ft^2). None of these spills were known to impact polar bears, in part due to the locations and timing. Both sites were within or near Industry facilities not frequented by polar bears, and they are not typically observed in the affected areas during the time of the spills and subsequent cleanup.

The BLM and BOEM modelled the likelihood of spills occurring during exploration and development in the NPR–A and in the Beaufort and Chukchi Sea planning area (BLM 2012 and BOEM 2011, respectively). Large (≥1,000 bbl) or very large spills (≥120,000 bbl) were considered extremely unlikely to occur during oil and gas exploration. The two sources of potential large crude oil spills are from pipelines and long-duration blowout resulting from a well-control incident. The loss of the entire volume in an onshore pipeline between two valves would also result in a large spill of crude oil. The BLM estimated a 28 percent chance that one or more large crude oil spills would occur during 50 years. Based on information on past spills, spill volumes close to the lower end of the ''large spill'' range (1,000 bbl) are much more likely than spill volumes in the upper end of the range (119,999 bbl). BOEM (2014) considered spill sizes of 1,700 and 5,100 bbl to be the largest spill size likely to occur from a pipeline or facility, respectively. BOEM estimated that the occurrence and frequency of large and very large spills from OCS exploratory and delineation wells at 0.003 (mean spill frequency per 1,000 years) and 2.39×10^{-5} (mean spill frequency per well), respectively (BOEM 2011). The approximate occurrence rates worldwide for very large oil spills are about one for every 270 billion bbl produced (BLM 2012). More locally (at Northstar), the statistical frequency of a blowout well leading to a very large oil spill was estimated at 9.4×10^{-7} per well drilled (for volumes > 130,000 bbl (BLM 2012)). Thus, while small spills (<50 bbl) are reasonably likely to occur, very large oil spills are extremely unlikely to occur, and none have occurred on Alaska's North Slope or in the Beaufort Sea to date.

Across the United States, in the period 1971–2010, one well control

incident resulted in a spill volume estimated at 4.9 million bbl (210 million gal) and that was the Deepwater Horizon event. The large oil spill estimates for the draft Environmental Impact Statement (DEIS) of the Beaufort Sea and Chukchi Sea Planning Areas are still considered valid despite the Deepwater Horizon oil spill. Geologic and other conditions in the Arctic OCS are substantially different from those in the Gulf of Mexico, including much shallower well depth and the resulting lower pressures, such that BOEM currently does not believe that the Deepwater horizon incident serves as a predictor for the likelihood or magnitude of a very large oil spill event in the Beaufort Sea. Considering the low number of exploratory wells (84) that have occurred in the Beaufort Sea Alaska OCS (BOEM 2011), the low rate of exploratory drilling blowouts per well drilled, and the low rate of well control incidents that spill fluids, it is reasonable to conclude that the chance of a large spill occurring during OCS exploration drilling in the Beaufort is small. In addition, it is important to note that Industry does not plan to conduct drilling operations at more than three exploration sites in the Beaufort Sea OCS for the duration of the 5-year regulatory period.

Trajectory Estimates of Large Offshore Oil Spills

Although it is reasonable to conclude that the chance of one or more large spills occurring during the period of these regulations on the Alaskan OCS from production activities is low, for analysis purposes, we assume that a large spill does occur in order to evaluate potential impacts to polar bears. The BOEM OSRA model analyzes the likely paths of more than two million simulated oil spills in relation to the shoreline and biological, physical, and sociocultural resource areas specific to the Beaufort Sea. The chance that a large oil spill will contact a specific ERA of concern within a given time of travel from a certain location (launch area or pipeline segment) is termed a ''conditional probability.'' Conditional probabilities assume that no cleanup activities take place, and that there are no efforts to contain the spill. We used the BOEM OSRA analysis from the Arctic Multi-sale DEIS to estimate the conditional probabilities of a large spill contacting sensitive ERAs pertinent to polar bears.

Oil-Spill Persistence

How long an oil spill persists on water or on the shoreline can vary, depending upon the size of the oil spill, the environmental conditions at the time of the spill, and the substrate of the shoreline. In its large oil spill analysis, BOEM assumed 1,500-bbl and 4,600-bbl spills could last up to 30 days on the water as a coherent slick based on oil weathering properties and dispersal data specific to North Slope crude oils. Therefore, we assumed that winter spills (October–June) could last up to 180 days as a coherent slick (*i.e.,* if a coherent slick were to freeze into ice over winter, it would melt out as a slick in spring).

We used three BOEM launch areas (LAs), LA 8, LA 10, LA 12, and three pipeline segments (PLs), PL 10, PL 11, and PL 12, from Appendix A of the Arctic Multi-sale DEIS (Map A.1–4) to represent the oil spills moving from hypothetical offshore areas. These LAs and PLs were selected because of their close proximity to current offshore facilities.

Oil-Spill-Trajectory Model Assumptions

For purposes of its oil spill trajectory simulation, BOEM made the following assumptions: All spills occur instantaneously; large oil spills occur in the hypothetical origin areas or along the hypothetical pipeline segments noted above; large spills do not weather for purposes of trajectory analysis; weathering is calculated separately; the model does not simulate cleanup scenarios; the oil spill trajectories move as though no oil spill response action is taken; and large oil spills stop when they contact the mainland coastline.

Analysis of the Conditional Probability Results

As noted above, the chance that a large oil spill will contact a specific ERA of concern within a given time of travel from a certain location (LA or PL), assuming a large spill occurs and that no cleanup takes place, is termed a ''conditional probability.'' From the DEIS, Appendix A, we chose ERAs and LSs to represent areas of concern pertinent to polar bears (MMS 2008a). Those ERAs and LSs and the conditional probabilities that a large oil spill originating from the selected LAs or PLs could affect those ERAs and LSs are presented in Table 1. From Table 1, we noted the highest chance of contact and the range of chances of contact that could occur should a large spill occur from LAs or PLs.

Table 1. Conditional oil spill probabilities (percent) in regards to Environmental Resource Areas and Land Segments for LAs and PLs offshore of four oil and gas industry sites. Values in parentheses are for pipeline segments. * = Less than one-half percent.

Launch Area (Pipeline Segment)	Season of Spill (Duration of Spill)	ERA 55	ERA 92	ERA 93	ERA 94	ERA 95	ERA 96	ERA 100	LS 85	LS 97	LS 102	LS 107	LS 138	LS 144	LS 145
LA 08 (PL 10)	Summer (60 days)	5 (3)	5(8)	*(2)	*(*)	*(*)	1(3)	*(1)	2(1)	1(2)	*(*)	*(*)	*(1)	54(34)	*(*)
	Winter (180 days)	1(1)	2(3)	*(*)	*(*)	*(*)	*(1)	*(*)	2(4)	*(1)	*(*)	*(*)	1(2)	39(29)	*(1)
LA10 (PL 10)	Summer (60 days)	3(3)	11(8)	2(2)	*(*)	*(*)	4(3)	1(1)	1(1)	5(2)	*(*)	*(*)	2(1)	33(34)	*(*)
	Winter (180 days)	1(1)	2(3)	*(*)	*(*)	*(*)	1(1)	*(*)	3(4)	2(1)	*(*)	*(*)	2(2)	29(29)	1(1)
LA 12 (PL 11)	Summer (60 days)	*(2)	12(12)	7(3)	2(1)	1(*)	13(6)	3(2)	*(*)	7(6)	1(1)	1 (1)	9(3)	33(29)	1(*)
	Winter (180 days)	1(1)	11(8)	1(*)	1(*)	*(*)	12(2)	1(*)	3(3)	4(4)	*(*)	*(*)	3(2)	31(28)	2(1)
LA 12 (PL 12)	Summer (60 days)	*(*)	12(9)	7(7)	2(3)	1(1)	13(12)	3(5)	*(*)	7(5)	1(2)	1(3)	9(11)	33(32)	1(1)

Definitions of ERAs and LSs, from Tables A.1-13, A.1-20, and A.1-22 (MMS, 2008)
ERA 55: Point Barrow, Plover Islands (Aug–Nov)
ERA 92: Thetis, Jones, Cottle and Return Islands, West Dock (Jan–Dec)
ERA 93: Cross and No Name Island (Aug–Nov)
ERA 94: Maguire Islands, Flaxman Island, Barrier Islands (Jan–Dec)
ERA 95: Arey and Barter Islands and Bernard Spit (Aug–Nov)
ERA 96: Midway, Cross and Bartlett Islands (May–October)
ERA 100: Jago and Tapkaurak Spits (May–October)
Seasonal LS 85: Barrow, Browerville, Elson Lagoon (August–November)
LS 97: Beechey Point, Bertoncini, Bodfish, Cottle and, Jones Islands, Milne Point, Simpson Lagoon
LS 102: Flaxman Island, Maguire Islands, North Star Island, Point Hopson, Point Sweeney, Point Thomson, Staines River
LS 107: Bernard Harbor, Jago Lagoon, Kaktovik, Kaktovik Lagoon
Grouped LS 138: Arctic National Wildlife Refuge (Jan–Dec)
Grouped LS 144: United States Beaufort Coast (Jan–Dec)
Grouped LS 145: Canada Beaufort Coast (Jan–Dec)

Polar bears are most vulnerable to a large oil spill during the open-water period when bears form aggregations onshore. In the Beaufort Sea these aggregations often form in the fall near subsistence-harvested bowhead whale carcasses. Specific aggregation areas include Point Barrow, Cross Island, and Kaktovik. In recent years, more than 60 polar bears have been observed feeding on whale carcasses just outside of Kaktovik, and in the autumn of 2002, NSB and Service biologists documented more than 100 polar bears in and around Barrow. In order for significant

impacts to polar bears to occur, (1) a large oil spill would have to occur, (2) oil would have to contact an area where polar bears aggregate, and (3) the aggregation of polar bears would have to occur at the same time as the spill. The risk of all three of these events occurring simultaneously is low.

We identified polar bear aggregations in environmental resource areas and non-grouped land segments (ERA 55, 93, 95, 96, 100; LS 85, 107). Assuming a spill occurs during summer or winter, the OSRA estimates the chance of contacting these aggregations is less than 13 percent (Table 1). The OSRA estimates for LA12 has the highest chance of a large spill contacting ERA 96 (Midway, Cross, and Bartlett islands). Some polar bears will aggregate at these islands during August–October (3 months). If a large oil spill occurred and contacted those aggregation sites outside of the timeframe of use by polar bears, potential impacts to polar bears would be reduced.

Coastal areas provide important denning habitat for polar bears, such as the ANWR and nearshore barrier islands (containing tundra habitat) (Amstrup 1993, Amstrup and Gardner 1994, Durner *et al.* 2006, USFWS unpubl. data). Considering that 65 percent of confirmed terrestrial dens found in Alaska in the period 1981–2005 were on coastal or island bluffs (Durner *et al.* 2006), oiling of such habitats could have negative effects on polar bears, although the specific nature and ramifications of such effects are unknown.

Assuming a large oil spill occurs, and extrapolating the OSRA estimates to tundra relief barrier islands (ERA 92, 93, and 94, LS 97 and 102), these areas have up to a 12 percent chance of a large spill contacting them (a range of less than 0.5 percent to 12 percent) from LA 12 (Table 1). The OSRA estimates suggest that there is an 11 percent chance that oil would contact the coastline of the ANWR (LS 138). The Kaktovik area (ERA 95 and 100, LS 107) has up to a 5 percent chance of a spill contacting the coastline, assuming spills occur during the summer season and contact the coastline within 60 days. The chance of a spill contacting the coast near Barrow (ERA 55, LS 85) would be as high as 5 percent (Table 1).

All barrier islands are important resting and travel corridors for polar bears, and larger barrier islands that contain tundra relief are also important denning habitat. Tundra-bearing barrier islands within the geographic region and near oilfield development are the Jones Island group of Pingok, Bertoncini, Bodfish, Cottle, Howe, Foggy, Tigvariak, and Flaxman islands. In addition, Cross Island has gravel relief where polar bears have denned. The Jones Island group is located in ERA 92 and LS 97. If a spill were to originate from an LA 8 pipeline segment during the summer months, the probability that this spill would contact these land segments could be as great as 8 percent. The probability that a spill from LA 10 would contact the Jones Island group would range from 1 percent to as high as 11 percent. Likewise, for LA 12, PL 11 the range would be from 4 percent to as high as 12 percent, and for LA 12, PL 12 the range would be from 3 percent to as high as 12 percent.

Risk Assessment From Prior ITRs

In previous ITRs, we used a risk assessment method that considered oil spill probability estimates for two sites (Northstar and Liberty), oil spill trajectory models, and a polar bear distribution model based on location of satellite-collared females during September and October (68 FR 66744, November 28, 2003; 71 FR 43926, August 2, 2006; and 76 FR 47010, August 3, 2011). To support the analysis for this action, we reviewed the previous analysis and used the data to compare the potential effects of a large oil spill in a nearshore production facility (less than 5 mi), such as Liberty, and a facility located further offshore, such as Northstar. Even though the risk assessment of 2006 did not specifically model spills from the Oooguruk or Nikaitchuq sites, we believe it was reasonable to assume that the analysis for Liberty, and indirectly Northstar, adequately reflected the potential impacts likely to occur from an oil spill at either of these additional locations due to the similarity in the nearshore locations.

Methodology of Prior Risk Assessment

The first step of the risk assessment analysis was to examine oil spill probabilities at offshore production sites for the summer (July–October) and winter (November–June) seasons based on information developed for the original Northstar and Liberty EISs. We assumed that one large spill occurred during the 5-year period covered by the regulations. A detailed description of the methodology can be found at 71 FR 43926 (August 2, 2006). The second step in the risk assessment was to estimate the number of polar bears that could be impacted by a large spill. All modeled polar bear grid cell locations that were intersected by one or more cells of a rasterized spill path (a modeled group of hundreds of oil particles forming a trajectory and pushed by winds and currents and impeded by ice) were considered ''oiled'' by a spill. For purposes of the analysis, if a bear contacted oil, the contact was assumed to be lethal. This analysis involved estimating the distribution of bears that could be in the area and overlapping polar bear distributions and seasonal aggregations with oil spill trajectories. The trajectories previously calculated for Northstar and Liberty sites were used. The trajectories for Northstar and Liberty were provided by the BOEM and reported in Amstrup *et al.* (2006). BOEM estimated probable sizes of oil spills from a pinhole leak to a rupture in the transportation pipeline. These spill sizes ranged from a minimum of 125 to a catastrophic release event of 5,912 bbl. Researchers set the size of the modeled spill at the scenario of 5,912 bbl, caused by a pinhole or small leak for 60 days under ice without detection.

The second step of the risk assessment analysis incorporated polar bear densities overlapped with the oil spill trajectories. To accomplish this, in 2004, USGS completed an analysis investigating the potential effects of hypothetical oil spills on polar bears. Movement and distribution information was derived from radio and satellite locations of collared adult females. Density estimates were used to determine the distribution of polar bears in the Beaufort Sea. Researchers then created a grid system centered over the Northstar production island and the Liberty site to estimate the number of bears expected to occur within each 1-km^2 grid cell. Each of the simulated oil spills were overlaid with the polar bear distribution grid. Finally, the likelihood of occurrence of bears oiled during the duration of the 5-year incidental take regulations was estimated. This likelihood was calculated by multiplying the number of polar bears oiled by the spill by the percentage of time bears were at risk for each period of the year.

In summary, the maximum numbers of bears potentially oiled by a 5,912 bbl spill during the September open-water season from Northstar was 27, and the maximum from Liberty was 23, assuming a large oil spill occurred and no cleanup or mitigation measures take place. Potentially oiled polar bears ranged up to 74 bears with up to 55 bears during October in mixed-ice conditions for Northstar and Liberty, respectively. Median number of bears oiled by the 5,912 bbl spill from the Northstar simulation site in September and October were 3 and 11 bears, respectively. Median numbers of bears oiled from the Liberty simulation site for September and October were 1 and

3 bears, respectively. Variation occurred among oil spill scenarios and was the result of differences in oil spill trajectories among those scenarios and not the result of variation in the estimated bear densities. For example, in October, 75 percent of trajectories from the 5,912 bbl spill affected 20 or fewer polar bears from spills originating at the Northstar simulation site and 9 or fewer bears from spills originating at the Liberty simulation site.

When calculating the probability that a 5,912 bbl spill would oil 5 or more bears during the annual fall period, we found that oil spills and trajectories were more likely to affect fewer than 5 bears versus more than 5 bears. Thus, for Northstar, the chance that a 5,912 bbl oil spill affected (resulting in mortality) 5 or more bears was 1.0–3.4 percent; 10 or more bears was 0.7–2.3 percent; and 20 or more bears was 0.2–0.8 percent. For Liberty, the probability of a spill that would affect 5 or more bears was 0.3–7.4 percent; 10 or more bears, 0.1–0.4 percent; and 20 or more bears, 0.1–0.2 percent.

Discussion of Prior Risk Assessment

After reviewing the prior risk assessment, we have concluded that it remains a valid methodology and analysis for use in this rule. The key conditions and considerations used in the analysis remain valid today. For this reason, we find that it is appropriate to continue to rely on the results of the analysis as it was set forth in 71 FR 43926, August 2, 2006.

The location of Industry sites within the marine environment is important when analyzing the potential for polar bears to contact a large oil spill. Simulations from the prior risk assessment suggested that bears have a higher probability of being oiled from facilities located further offshore, such as Northstar. Northstar Island is nearer the active ice zone and in deeper water than Endicott/Liberty, Oooguruk, and Nikaitchuq, areas where higher bear densities were calculated. Furthermore, Northstar is not sheltered by barrier islands. By comparison through modeling, the land-fast ice inside the shelter of the barrier islands appeared to dramatically restrict the extent of most oil spills in comparison to Northstar, which lies outside the barrier islands and in deeper water. However, it should be noted that while oil spreads more in deep water and breaks up faster in deeper waters where wind and wave action are higher, oil persists longer in shallow waters and along the shore.

Based on the simulations, a nearshore island production site (less than 5 mi from shore) would potentially involve less risk of polar bears being oiled than a facility located further offshore (greater than 5 mi). For any spill event, seasonality of habitat use by bears will be an important variable in assessing risk to polar bears. During the fall season when a portion of the SBS bear population aggregate on terrestrial sites and use barrier islands for travel corridors, spill events from nearshore industrial facilities may pose more chance of exposing bears to oil due to its persistence in the nearshore environment. Conversely, during the ice-covered and summer seasons, Industry facilities located further offshore (greater than 5 mi) may increase the chance of bears being exposed to oil as bears will be associated with the ice habitat.

Conclusion of Risk Assessment

In summary, to date documented oil spill-related impacts in the marine environment to polar bears in the Beaufort Sea by the oil and gas Industry are minimal. No large spills by Industry in the marine environment have occurred in Arctic Alaska. Nevertheless, the possibility of oil spills from Industry activities and the subsequent impacts on polar bears that contact oil remain a major concern.

There has been much discussion about effective techniques for containing, recovering, and cleaning up oil spills in Arctic marine environments, particularly the concern that effective oil spill cleanup during poor weather and broken-ice conditions has not been proven. Given this uncertainty, limiting the likelihood of a large oil spill becomes an even more important consideration. Industry oil spill contingency plans describe methodologies in place to prevent a spill from occurring. For example, all current offshore production facilities have spill containment systems in place at the well heads. In the event an oil discharge should occur, containment systems are designed to collect the oil before it contacts the environment.

With the limited background information available regarding oil spills in the Arctic environment, it is unknown what the outcome of such a spill event would be if one were to occur. Polar bears could encounter oil spills during the open-water and ice-covered seasons in offshore or onshore habitat. Although most polar bears in the SBS population spend a large amount of their time offshore on the pack-ice, it is likely that some bears would encounter oil from a large spill that persisted for 30 days or more.

Although the extent of impacts from a large oil spill would depend on the size, location, and timing of spills relative to polar bear distributions and on the effectiveness of spill response and cleanup efforts, under some scenarios, population-level impacts could be expected. A large spill originating from a marine oil platform could have significant impacts on polar bears if an oil spill contacted an aggregation of polar bears. Likewise, a spill occurring during the broken-ice period could significantly impact the SBS polar bear population in part because polar bears may be more active during this season.

In the event that an offshore oil spill contaminated numerous bears, a potentially significant impact to the SBS population could result. This effect would be magnified in and around areas of polar bear aggregations. Bears could also be affected indirectly either by food contamination or by chronic lasting effects caused by exposure to oil. During the 5-year period of these regulations, however, the chance of a large spill occurring is low.

While there is uncertainty in the analysis, certain factors must align for polar bears to be impacted by a large oil spill occurring in the marine environment. First, a large spill must occur. Second, the large spill must contaminate areas where bears may be located. Third, polar bears must be seasonally distributed within the affected region when the oil is present. Assuming a large spill occurs, BOEM's OSRA estimated that there is up to a 13 percent chance that a large spill from the analyzed sites (LAs 8, 10, and 12 and PLs 10, 11, and 12) would contact Cross Island (ERA 96) within 60 days, as much as an 11 percent chance that it would contact Barter Island and/or the coast of the ANWR (ERA 95 and 100, LS 107 and 138), and up to a 5 percent chance that an oil spill would contact the coast near Barrow (ERA 55, LS 85) during the summer time period. Data from polar bear coastal surveys indicate that polar bears are unevenly and seasonally distributed along the coastal areas of the Beaufort Sea ITR region. Seasonally only a portion of the SBS population utilizes the coastline between the Alaska/Canada border and Barrow and only a portion of those bears could be in the oil-spill-affected region.

As a result of the information considered here, the Service concludes that the likelihood of an offshore spill from an offshore production facility in the next 5 years is low. Moreover, in the unlikely event of a large spill, the likelihood that spills would contaminate areas occupied by large numbers of bears is low. While individual bears could be negatively

affected by a spill, the potential for a population-level effect is low unless the spill contacted an area where large numbers of polar bears were gathered. Known polar bear aggregations tend to be seasonal during the fall, further minimizing the potential of a spill to impact the population. Therefore, we conclude that the likelihood of a large spill occurring is low, but if a large spill does occur, the likelihood that it would contaminate areas occupied by large numbers of polar bears is also low. If a large spill does occur, we conclude that only small numbers of polar bears are likely to be affected, though some bears may be killed, and there would be only a negligible impact to the SBS population.

Take Estimates for Pacific Walruses and Polar Bears

Small Numbers Determination

The following analysis concludes that only small numbers of walruses and polar bears are likely to be subjected to Level B take by harassment incidental to the described Industry activities relative to their respective populations.

1. The number of walruses and polar bears that will be harassed by Industry activity is expected to be small relative to the number of animals in their populations.

As stated previously, walruses are extralimital in the Beaufort Sea with nearly the entire walrus population found in the Chukchi and Bering seas. Industry monitoring reports have observed no more than 35 walruses between 1995 and 2016, with only a few observed instances of disturbance to those walruses (AES Alaska 2015, USFWS unpublished data). Between those years, Industry walrus observations in the Beaufort Sea ITR region averaged approximately two walruses per year, although the actual observations were of a single or a few animals, often separated by several years. We do not anticipate that seasonal movements of a few walruses into the Beaufort Sea will increase. We conclude that over the 5-year period of these ITRs, Industry activities will potentially result in a small number of Level B takes of walruses.

As we stated previously, from 2010 through 2014, Industry made 1,234 reports of polar bears comprising 1,911 bears. We found that as much as 42 percent of the SBS polar bear population may have been observed by Industry personnel over that time period, though this is likely an overestimate due to the nature of the Industry observation data. When we evaluated the effects upon the 1,911 bears observed, we found that 81 percent (1,549) resulted in instances of non-taking. Over those 5 years, Level B takes of polar bears totaled 338, approximately 18 percent of the observed bears, or 7.5 percent of the SBS population. We conclude that over the 5-year period of these ITRs, Industry activities will result in a similarly small number of Level B takes of polar bears.

2. Within the specified geographical region, the area of Industry activity is expected to be small relative to the range of walruses and polar bears.

Walruses and polar bears range well beyond the boundaries of the Beaufort Sea ITR region. The facts that walruses are extralimital in the Beaufort Sea and polar bears move through the areas of Industry activity seasonally suggest that Industry activities in the geographic area of this rule will have relatively few interactions with walruses and polar bears. As reported by AOGA, the total area of infrastructure on the North Slope as of 2012 was approximately 7,462 ha (~18,439 ac), or approximately 0.1 percent of the Arctic Coastal Plain between the Colville and Canning rivers. The 2012 estimated area of Industry activity was approximately 0.025 percent of the geographic region of this rule. This area is smaller when compared to the proportion of the range of walruses or the SBS polar bear population. Allowing for past Industry activity area growth, and anticipating the level of activity for the 5-year period of this rule, the Service concludes that the area of Industry activity will be relatively small compared to the range of walruses and polar bears.

3. Monitoring requirements and adaptive mitigation measures are expected to significantly limit the number of incidental takes of animals.

Holders of an LOA will be required to adopt monitoring requirements and mitigation measures designed to reduce potential impacts of their operations on walruses and polar bears. For Industry activities in terrestrial environments, where denning polar bears may be a factor, mitigation measures will require that den detection surveys be conducted at least a 1.6-km (1-mi) distance from any known polar bear den. A full description of the mitigation, monitoring, and reporting requirements associated with an LOA can be found in 50 CFR 18.128.

Conclusion

We expect that only a small proportion of the Pacific walrus population or the SBS polar bear population are likely to be affected by Industry activities because: (1) Only a small proportion of the walrus or polar bear population will occur in the areas where Industry activities will occur; (2) only small numbers will be impacted because walruses are extralimital in the Beaufort Sea and SBS polar bears are widely distributed throughout their expansive range, which encompasses areas beyond the Beaufort Sea ITR region; and (3) the monitoring requirements and mitigation measures described below will further reduce potential impacts.

Negligible Impacts Determination

Based upon our review of the nature, scope, and timing of Industry activities and required mitigation measures, and in consideration of the best available scientific information, we have determined that the activities will have a negligible impact on walruses and polar bears. Factors considered in our negligible effects determination include:

1. The behavior and distribution of walruses and polar bears in areas that overlap with Industry activities are expected to limit interactions of walruses and polar bears with those activities.

The distribution and habitat use patterns of walruses and polar bears indicates that relatively few animals will occur in the areas of Industry activity at any particular time, and, therefore, few animals are likely to be affected. As discussed previously, only small numbers of walruses are likely to be found in the Beaufort Sea where and when offshore Industry activities are proposed. Likewise, SBS polar bears are widely distributed, are most often closely associated with pack-ice, and are unlikely to interact with open-water industrial activities, and their range is greater than the geographic region of the ITRs.

2. The predicted effects of Industry activities on walruses and polar bears will be nonlethal, temporary takes of animals.

The documented impacts of previous Industry activities on walruses and polar bears, taking into consideration cumulative effects, suggests that the types of activities analyzed for these ITRs will have minimal effects and will be short-term, temporary behavioral changes. The vast majority of reported polar bear observations have been of polar bears moving through the oilfields, undisturbed by the Industry activity.

3. The footprint of the Industry activities is expected to be small relative to the range of the walrus and polar bear populations.

The relatively small area of Industry activity compared to the range of walruses and polar bears will reduce the

potential of their exposure to and disturbance from Industry activities.

4. Mitigation measures will limit potential effects of Industry activities.

Holders of an LOA will be required to adopt monitoring requirements and mitigation measures designed to reduce the potential impacts of their operations on walruses and polar bears. Seasonal restrictions, early detection monitoring programs, den detection surveys for polar bears, and adaptive mitigation and management responses based on real-time monitoring information (described in these regulations) will be used to avoid or minimize interactions with walruses and polar bears and, therefore, limit potential Industry disturbance of these animals.

Conclusion

We, therefore, conclude that any incidental take reasonably likely to or reasonably expected to occur in association with the Industry activities addressed under these regulations will have no more than a negligible impact on walruses and polar bears within the Beaufort Sea region. We do not expect any resulting disturbance to negatively impact the rates of recruitment or survival for the walrus and polar bear populations. These regulations do not authorize lethal take, and we do not anticipate that any lethal take will occur.

Least Practicable Adverse Impacts Determination

We evaluated the practicality and effectiveness of mitigation measures based on the nature, scope, and timing of Industry activities; the best available scientific information; and over 20 years of monitoring data during Industry activities in the Beaufort and Chukchi seas. We have determined that the mitigation measures in these ITRs will ensure the least practicable adverse impacts on Pacific walruses and polar bears from Industry activities. The mitigation measures discussed in these ITRs and specified in section ''18.128 Mitigation, monitoring, and reporting requirements'' are generally intended to ensure the least practicable adverse impacts on Pacific walruses and polar bears from Industry activities.

Polar bear den surveys before activities begin during the denning season, and the resulting 1.6-km (1-mi) operational exclusion zone around all known polar bear dens and restrictions on the timing and types of activities in the vicinity of dens, ensures that impacts to denning female polar bears and their cubs are minimized during this critical time. The operational exclusion zone for vessels of 805-m (0.5-mi) around walruses and polar bears on land or ice and feeding walrus groups, the restrictions on vessels separating members of a group of walruses from other members of the group, and vessel speed reduction in low visibility ensures disturbance from vessels is minimized. The restriction that vessels bound for the Beaufort Sea ITR Region may not transit through the Chukchi Sea prior to July 1 is intended to allow walruses the opportunity to move through the Bering Strait and disperse from the confines of the spring lead system into the Chukchi Sea with minimal disturbance as well as minimize vessel impacts on the availability of walruses for Alaska Native subsistence hunters. We considered a variety of mitigation measures for vessels and aircraft, such as greater distances, increased altitudes, alternate timing, speed reductions, and others. Based on the information we currently have regarding vessels and aircraft disturbances and how walruses and polar bears may be impacted by them, we concluded that we practically and effectively minimize disturbance from these activities with the mitigation measures in these ITRs. We will continue to evaluate the effectiveness of these mitigation measures as more information becomes available.

Mitigation measures are required for sound-producing offshore activities that include monitoring and mitigation zones for activities expected to produce pulsed underwater sounds with received sound levels ≥160 dB re 1 μPa. The acoustically verified zones surrounding a sound source include a walrus monitoring zone where the received pulsed sound level would be ≥ 160 dB re 1 μPa (walruses in this zone are assumed to experience Level B take), a walrus mitigation zone where the received pulsed sound level would be ≥ 180 dB re 1 μPa, and a walrus and polar bear mitigation zone where the received pulsed sound level would be ≥ 190 dB re 1 μPa. We also require adaptive mitigation measures for these zones including sound source ramp-up procedures (*e.g.,* after a power down or in low visibility conditions), power down procedures when walruses are observed in the ≥ 180 dB re 1 μPa zone, and shut down procedures when walruses or polar bears are observed in the ≥ 190 dB re 1 μPa zone.

We considered other acoustic thresholds for underwater sound. For example, NMFS adopts an interim 120 dB re 1 μPa generic acoustic threshold criterion for MMPA Level B take for non-impulsive underwater sounds. Since the development of these thresholds in the late 1990s, the understanding of the effects of noise on marine mammal hearing has advanced. While NMFS has recognized the need for updated acoustic criteria, no final guidance is yet available. In this ITR, we examined the current information to determine the appropriate acoustic threshold levels for walruses exposed to underwater sounds from Industry activities.

Only one study on one individual is available to evaluate walrus underwater hearing (Kastelein et al. 2002), no studies are available to evaluate walrus responses to underwater sounds, and no information is available on which to base walrus hearing thresholds relative to injury and disturbance. The NMFS 120 dB re 1 μPa threshold was developed primarily from behavioral studies of gray whales and bowhead whales rather than pinnipeds (*e.g.,* Malme et al. 1983, 1984, 1988; Richardson et al. 1985, 1986, 1990; Ljungblad et al. 1988; Richardson and Malme 1993). As a proxy for walruses, we considered information on other marine mammals that may have similar hearing characteristics, such as otariid pinnipeds (Kastelein et al. 1996; Hemilä et al. 2006). Among marine mammals, otariid pinnipeds appear to be less sensitive to underwater sound than phocid pinnipeds and many cetaceans (Southall et al. 2007; Finneran 2015). None of the available research indicates that a temporary shift in hearing threshold (TTS; a common approximation of Level B take) is likely to occur in otariid pinnipeds due to short term exposure to 120 dB re 1 μPa non-impulsive underwater sounds sound (Kastak et al. 1999, 2005; Southall et al. 2007). Given the capacity of walruses for travel, extended exposures to high level of sound are unlikely. Pacific walruses may travel up to 30 km per day at rates that can typically range from 0.3–0.5 km/hr and may reach up to 1.3 km/hr or more (Jay et al. 2010, 2014). We determined that there is sufficient evidence to conclude that Pacific walruses are unlikely to experience Level B take from non-impulsive underwater sounds at 120 dB re 1 μPa.

There is even less information available to evaluate underwater polar bear hearing than for walruses. Polar bears could be affected by underwater sound, but underwater sound attenuates near the surface due to the pressure release effect near the surface (Greene and Richardson 1988; Richardson et al. 1995). Because polar bears generally do not spend much time with their heads underwater it is likely that they would be exposed to very little underwater sound. It is likely that polar bears

exposed to underwater sounds would experience no more than short-term and temporary changes in behavior.

We considered acoustic thresholds for underwater sound that would effectively minimize impacts to polar bears. Based on our understanding of polar bear biology and behavior we determined that a polar bear would have to be exposed to relatively loud underwater sound in order to experience disturbance, and even louder sound to risk potential injury. We determined that there is sufficient evidence to conclude that polar bears are unlikely to experience disturbance from underwater sounds at ≥ 160 dB re 1 μPa. We further determined that there is sufficient evidence to conclude that polar bears may experience Level B take from underwater sounds at ≥ 180 dB re 1 μPa and may risk TTS ≥ 190 dB re 1 μPa. We developed the mitigation measures in this ITR accordingly.

Conclusion

We, therefore, conclude that the mitigation measures required by these ITRs will effect the least practicable adverse impacts from any incidental take likely to occur in association with Industry activities.

Findings

We make the following findings regarding this action:

Small Numbers

Pacific Walrus

Walruses are extralimital in the Beaufort Sea, thus, the number of walruses exposed to the impacts of Industry activities will be inherently small. Between 1995 and 2016, Industry observed no more than 35 walruses in the Beaufort Sea ITR region, with only a few instances of disturbance to some of those walruses. We do not anticipate the potential for any lethal take from Industry activities. We estimate that there will be no more than 10 Level B harassment takes of Pacific walruses by Industry activities during the 5-year period of these ITRs.

Polar Bear

Industry observation reports from the period 2010–2014 indicate that on average 383 polar bears were observed annually during Industry activities. Some of these observations are sightings of the same bears on different occasions. While the majority of observations were sightings with no interaction between polar bears and Industry activity (~81 percent of observed bears), takes by harassment do occur. According to Industry monitoring data, the number of Level B takes has averaged 68 per year from 2010 through 2014.

Based on this information, we estimate that there will be no more than 340 Level B harassment takes of polar bears during the 5-year period of these ITRs. All takes are anticipated to be nonlethal Level B harassment involving short-term and temporary changes in bear behavior. The required mitigation and monitoring measures described in the regulations are expected to prevent injurious Level A takes, and, therefore, the number of lethal takes is estimated to be zero.

Negligible Impact

Based on the best scientific information available, the results of Industry monitoring data from the previous ITRs, the review of the information generated by the listing of the polar bear as a threatened species and the designation of polar bear critical habitat, current information on Pacific walruses, the results of our modeling assessments, and the status of the populations, we find that any incidental take reasonably likely to result from Industry, or substantially similar, activities during the period of the ITRs, in the Beaufort Sea and adjacent northern coast of Alaska, will have no more than a negligible impact on walruses and polar bears. We do not expect that the total of these disturbances will affect rates of recruitment or survival for walruses or polar bears. In making this finding, we considered the following: The distribution of the species; the biological characteristics of the species; the nature of Industry activities; the potential effects of Industry activities and potential oil spills on the species; the probability of oil spills occurring; the documented impacts of Industry activities on the species, taking into consideration cumulative effects; the potential impacts of climate change, where both walruses and polar bears can potentially be displaced from preferred habitat; mitigation measures designed to minimize Industry impacts through adaptive management; and other data provided by Industry monitoring programs in the Beaufort and Chukchi seas.

We also considered the specific Congressional direction in balancing the potential for a significant impact with the likelihood of that event occurring. The specific Congressional direction that justifies balancing probabilities with impacts follows:

> If potential effects of a specified activity are conjectural or speculative, a finding of negligible impact may be appropriate. A finding of negligible impact may also be appropriate if the probability of occurrence is low but the potential effects may be significant. In this case, the probability of occurrence of impacts must be balanced with the potential severity of harm to the species or stock when determining negligible impact. In applying this balancing test, the Service will thoroughly evaluate the risks involved and the potential impacts on marine mammal populations. Such determination will be made based on the best available scientific information (53 FR 8474, March 15, 1988; 132 Cong. Rec. S 16305 (October. 15, 1986)).

We reviewed the effects of the oil and gas Industry activities on walruses and polar bears, including impacts from noise, physical obstructions, human encounters, and oil spills. Based on our review of these potential impacts, past LOA monitoring reports, and the biology and natural history of walrus and polar bear, we conclude that any incidental take reasonably likely to or reasonably expected to occur as a result of projected activities will have a negligible impact on the walrus and polar bear populations. Furthermore, we do not expect these disturbances to affect the rates of recruitment or survival for the walrus and polar bear populations. These regulations do not authorize lethal take, and we do not anticipate any lethal take will occur.

The probability of an oil spill that will cause significant impacts to walruses and polar bears appears extremely low. We have included information from both offshore and onshore projects in our oil spill analysis. We have analyzed the likelihood of a marine oil spill of the magnitude necessary to lethally take a significant number of polar bears for offshore projects and, through a risk assessment analysis, found that it is unlikely that there will be any lethal take associated with a release of oil. In the unlikely event of a catastrophic spill, we will take immediate action to minimize the impacts to these species and reconsider the appropriateness of authorizations for incidental taking through section 101(a)(5)(A) of the MMPA.

After considering the cumulative effects of existing and future development, production, and exploration activities, and the likelihood of any impacts, both onshore and offshore, we find that the total expected takings resulting from oil and gas Industry activities will affect no more than small numbers and will have no more than a negligible impact on the walrus and polar bear populations inhabiting the Beaufort Sea area on the North Slope coast of Alaska.

Our finding of negligible impact applies to incidental take associated with Industry, or substantially similar, activities as mitigated through the

regulatory process. The regulations establish monitoring and reporting requirements to evaluate the potential impacts of authorized activities, as well as mitigation measures designed to minimize interactions with and impacts to walruses and polar bears. We will evaluate each request for an LOA based on the specific activity and the specific geographic location where the activities are projected to occur to ensure that the level of activity and potential take is consistent with our finding of negligible impact. Depending on the results of the evaluation, we may grant the authorization, add further operating restrictions, or deny the authorization.

Within the described geographic region of this rule, Industry effects on walruses and polar bears are expected to occur at a level similar to what has taken place under previous regulations. We anticipate that there will be an increased use of terrestrial habitat in the fall period by polar bears. We also anticipate a continued increased use of terrestrial habitat by denning bears. Nevertheless, we expect no significant impact to these species as a result of these anticipated changes. The mitigation measures will be effective in minimizing any additional effects attributed to seasonal shifts in distribution or denning polar bears during the 5-year timeframe of the regulations. It is likely that, due to potential seasonal changes in abundance and distribution of polar bears during the fall, more frequent encounters may occur and Industry may have to implement mitigation measures more often, possibly increasing polar bear deterrence events. In addition, if additional polar bear den locations are detected within industrial activity areas, spatial and temporal mitigation measures, including cessation of activities, may be instituted more frequently during the 5-year period of the rule.

We have evaluated climate change in regard to walruses and polar bears. Climate change is a global phenomenon and was considered as the overall driver of effects that could alter walrus and polar bear habitat and behavior. Though climate change is a pressing conservation issue for walruses and polar bears, we have concluded that the authorized taking of walruses and polar nears during Industry activities during this 5-year rule will not adversely impact the survival of these species and will have no more than negligible effects. The Service is currently involved in research to help us understand how climate change may affect walruses and polar bears. As we gain a better understanding of climate change effects, we will incorporate the information in future actions.

Least Practicable Adverse Impacts

We find that the mitigation measures required by these ITRs will effect the least practicable adverse impacts from any incidental take likely to occur in association with Industry activities. In making this finding, we considered the biological characteristics of Pacific walruses and polar bears, the nature of Industry activities, the potential effects of Industry activities on walruses and polar bears, the documented impacts of Industry activities on walruses and polar bears, data provided by Industry monitoring programs in the Beaufort and Chukchi seas, and alternative mitigation measures.

Impacts on Subsistence Uses

Based on community consultations, locations of hunting areas, the potential overlap of hunting areas and Industry projects, the best scientific information available, and the results of monitoring data, we find that take caused by oil and gas exploration, development, and production activities in the Beaufort Sea and adjacent northern coast of Alaska will not have an unmitigable adverse impact on the availability of walruses and polar bears for taking for subsistence uses during the period of the rule. In making this finding, we considered the following: Records on subsistence harvest from the Service's Marking, Tagging, and Reporting Program; community consultations; effectiveness of the POC process between Industry and affected Native communities; and anticipated 5-year effects of Industry activities on subsistence hunting.

Walruses and polar bears represent a small portion, in terms of the number of animals, of the total subsistence harvest for the communities of Barrow, Nuiqsut, and Kaktovik. However, the low numbers do not mean that the harvest of these species is not important to Alaska Natives. Prior to receipt of an LOA, Industry must provide evidence to us that community consultations have occurred or that an adequate POC has been presented to the subsistence communities. Industry will be required to contact subsistence communities that may be affected by its activities to discuss potential conflicts caused by location, timing, and methods of operations. Industry must make reasonable efforts to ensure that activities do not interfere with subsistence hunting and that adverse effects on the availability of walruses and polar bear are minimized. Although multiple meetings for multiple projects from numerous operators have already taken place, no official concerns have been voiced by the Native communities with regard to Industry activities limiting availability of walruses or polar bears for subsistence uses. However, should such a concern be voiced as Industry continues to reach out to the Native communities, development of POCs, which must identify measures to minimize any adverse effects, will be required. The POC will ensure that oil and gas activities will not have an unmitigable adverse impact on the availability of the species or stock for subsistence uses. This POC must provide the procedures addressing how Industry will work with the affected Native communities and what actions will be taken to avoid interference with subsistence hunting of walruses and polar bears, as warranted.

The Service has not received any reports and is aware of no information that indicates that walruses or polar bears are being or will be deflected from hunting areas or impacted in any way that diminishes their availability for subsistence use by the expected level of oil and gas activity. If there is evidence during the 5-year period of the regulations that oil and gas activities are affecting the availability of walruses or polar bears for take for subsistence uses, we will reevaluate our findings regarding permissible limits of take and the measures required to ensure continued subsistence hunting opportunities.

Monitoring and Reporting

The purpose of monitoring requirements is to document and provide data for the assessment the effects of industrial activities on walruses and polar bears and to ensure that take is consistent with that anticipated in the negligible impact and subsistence use analyses, and to detect any unanticipated effects on the species. Monitoring plans include steps to document when and how bears and walruses are encountered, the number of bears and walruses, and their behavior during the encounter. This information allows the Service to measure encounter rates and trends of walrus and polar bear activity in the industrial areas (such as numbers and gender, activity, seasonal use) and to estimate numbers of animals potentially affected by Industry. Monitoring plans are site-specific, dependent on the proximity of the activity to important habitat areas, such as den sites, travel corridors, and food sources; however, all activities are required to report all sightings of walruses and polar bears. To the extent possible, monitors will

record group size, age, sex, reaction, duration of interaction, and closest approach to Industry onshore. Activities within the geographic region may incorporate daily watch logs as well, which record 24-hour animal observations throughout the duration of the project. Polar bear monitors will be incorporated into the monitoring plan if bears are known to frequent the area or known polar bear dens are present in the area. At offshore Industry sites, systematic monitoring protocols will be implemented to statistically monitor observation trends of walruses or polar bears in the nearshore areas where they usually occur.

Monitoring activities will be summarized and reported in a formal report each year. The applicant must submit an annual monitoring and reporting plan at least 90 days prior to the initiation of the activity, and the applicant must submit a final monitoring report to us no later than 90 days after the expiration of the LOA. We base each year's monitoring objective on the previous year's monitoring results.

We require an approved plan for monitoring and reporting the effects of oil and gas Industry exploration, development, and production activities on polar bear and walruses prior to issuance of an LOA. Since production activities are continuous and long-term, upon approval, LOAs and their required monitoring and reporting plans will be issued for the life of the activity or until the expiration of the regulations, whichever occurs first. Each year, prior to January 15, we require that the operator submit development and production activity monitoring results of the previous year's activity. We require approval of the monitoring results for continued operation under the LOA.

Required Determinations

Treaty Obligations

The ITRs are consistent with the 1973 Agreement on the Conservation of Polar Bears, a multilateral treaty executed in Oslo, Norway among the Governments of Canada, Denmark, Norway, Russia, and the United States. Article II of this Polar Bear Agreement lists three obligations of the Parties in protecting polar bear habitat. Parties are obliged to: (1) Take appropriate action to protect the ecosystem of which polar bears are a part; (2) give special attention to habitat components such as denning and feeding sites and migration patterns; and (3) manage polar bear populations in accordance with sound conservation practices based on the best available scientific data.

This rule is also consistent with the Service's treaty obligations because it incorporates mitigation measures that ensure the protection of polar bear habitat. LOAs for industrial activities are conditioned to include area or seasonal timing limitations or prohibitions, such as placing 1.6-km (1-mi) avoidance buffers around known or observed dens (which halts or limits activity until the bear naturally leaves the den), building roads perpendicular to the coast to allow for polar bear movements along the coast, and monitoring the effects of the activities on polar bears. Available denning habitat maps are provided by the USGS.

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:

(a) Be logically organized:

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

(c) Use clear language rather than jargon;

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

(e) Use lists and tables wherever possible.

Summary of and Responses to Comments and Recommendations

We requested written comments from the public in order to ensure that any final action be as accurate and as effective as possible. The comment period on the proposed ITRs opened on June 7, 2016 (81 FR 36664), and closed on July 7, 2016. During that time, we received nine comment submissions; these included comments on the proposed rule as well as the draft EA.

The Service received comments from the Marine Mammal Commission, private companies, Industry organizations, environmental organizations, and the general public. We reviewed all comments received for substantive issues, new information, and recommendations regarding the ITRs and the EA. The comments on the proposed ITRs, aggregated by subject matter, summarized and addressed below, are incorporated into the final rule as appropriate. The Service has summarized and responded to comments pertaining to the draft EA in our final EA. A summary of the changes to these final ITRs from the proposed ITRs is found in the preamble section ''Summary of Changes from the Proposed Rule.''

Response to Comments

General Comments

Comment 1: Several commenters opposed the promulgation of the ITRs based on a general opposition to Industry activity while several commenters supported the promulgation of the ITRs based on a general support for Industry activity.

Response: Language within section 101(a)(5)(A) of the MMPA requires the Service to allow the incidental taking of small numbers of marine mammals provided the Service has made certain determinations regarding the specified activity. Once we make the required determinations we must promulgate the ITRs. It is not our role in this process to pass judgment on the proposed activities. Our mandate is to identify and assess the potential impact of those activities on marine mammals, and if our analysis concludes that such impacts are consistent with the required determinations, we must promulgate ITRs.

Comment 2: The petitioner provided comments to clarify terminology in the ITRs regarding Industry activity, the purpose of the ITRs under the MMPA, the purpose of the EA under NEPA, and provided clarification for three Industry projects.

Response: The Service revised text throughout the document referring to Industry activity as ''proposed'' or ''lawful'' to simply state Industry activity. We revised text clarifying Caelus Energy Alaska, LLC's Oooguruk production activities, Nuna development activities, and Tulimaniq exploration activities in the ''Description of Activities'' section. Within the EA we also revised text clarifying its purpose.

MMPA Requirements

Comment 3: The description of activities considered for the ITRs and who would be eligible to request LOAs under the ITRs is ambiguous. The Service should address these ambiguities and ensure that the LOA process is not open-ended; and should identify, in section 18.121 of the ITR, the specific activities that we evaluated and what companies/entities would be authorized under the final rule.

Response: The Service believes we have described and evaluated the anticipated activities appropriately. Consistent with numerous previous ITRs, these ITRs provide an overall ''umbrella'' set of requirements which, when followed, allow the incidental take of small numbers of polar bears and Pacific walruses during certain Industry activities. The requirements ensure that

there is no more than a negligible impact on these species, effect the least practicable adverse impacts, and that there will not be unmitigable impacts on the availability of these species for subsistence use. To that end, the Service has described the types of activities to be authorized, the projected scale of each activity, the anticipated impacts that could occur during the 5-year period of the ITR, and included other activities the Service anticipates may occur. We acknowledge that in the planning phases, most projects contain some element of uncertainty. Consequently, in addition to requiring mitigation measures common to all projects, a separate LOA will be required for each project. This allows us to evaluate each LOA request for mitigation methods in addition to those required by the ITRs. The ITRs specify those mitigation measures required for all Industry activities, mitigation measures required for specific activities, and under what circumstances the various mitigation measures will be required. Section 101(a)(5)(A)(i)(II) of the MMPA requires that the ITRs set forth permissible methods of taking, means of effecting the least practicable adverse impact (on the species or stock and its habitat), the availability of such species or stock for subsistence uses, and the monitoring and reporting of such taking. Section 101(a)(5)(A)(i) of the MMPA states that citizens of the United States may request the incidental, but not intentional, taking of marine mammals. To request an LOA under these ITRs an applicant must be a U.S. citizen as defined in 50 CFR 18.27(c). The Service believes we have complied with both the letter and spirit of the MMPA with these ITRs.

Comment 4: The Service should specify, in section 18.121 of the rule, the number of the various exploration, development, and production activities that would be authorized; revise its take estimates based on a more quantitative assessment of proposed activities (including geophysical and geological surveys, exploratory drilling, expanded leasing, and new construction activities, in addition to the development and production activities) and ensure its determinations regarding small numbers, negligible impact, and adverse impact on the availability of the species for subsistence use are valid; and specify, in section 18.121 of the final rule, the numbers of takes to be authorized for both polar bears and walruses (total and/or annual).

Response: The level of quantitative specificity recommended by the commenters regarding the various Industry activities is not available and the petitioners were not able to provide such information. The Service has described the types of activities provided by the petitioner, as well as other activities the Service anticipates may occur, the projected scale of each activity, and the anticipated impacts from those activities. We reiterate that we do not permit or authorize Industry activities; we only authorize the incidental take associated with the activities. Therefore, we have estimated the number of takes likely to occur during the 5-year period of these ITRs. We acknowledge that in the planning phases most projects contain some element of uncertainty. If activities for an individual LOA are proposed that were not included or anticipated in this ITR, the Service will evaluate the potential impacts, and any associated takes of walruses and polar bears, to determine whether they are within the scope of these ITRs. We believe our take estimate and determinations are valid. Further, we do not believe there is a requirement, or even a need, to repeat the description of activities and take estimates again in section 18.121 of the ITRs.

Comment 5: The Service conflates small numbers and negligible impacts and has disregarded the MMPA's prohibition on allowing the take of more than small numbers of marine mammals. The Service's definition of small numbers is flawed and the proposed determination does not meet the small numbers requirement. By defining small numbers to be relative to the overall population, the Service makes that finding the same as a negligible impact determination. The Service's estimate that 340 polar bears will be taken by harassment during the 5-year period of the ITRs is not a small number of polar bears. If each take was a unique bear, it would account for 38 percent of the population. The Service cannot rationally argue that this is a small number. Moreover, 340 polar bears is likely an underestimate because it assumes the same level of oil and gas activities as 2010 to 2014. The proposed rule anticipates but does not evaluate increased oil and gas development during the 5 years of the rule including GMT–1, GMT–2, new drill sites in the Colville-Kuparuk Fairway Units, 200 new wells in Prudhoe Bay, Hilcorp's Liberty project, development of a processing unit, pipeline and airstrip at Point Thompson and the Alaska LNG or Alaska Stand Alone Gas Pipeline. The assumption that the level of take will remain constant is also inconsistent with the increased terrestrial presence of polar bears, which the Service acknowledges will increase interactions.

Response: The Service believes we have complied with the separate small numbers and negligible impacts determination requirements of the MMPA. As we explain in the preamble of this ITR, we do not rely upon the definition of ''small numbers'' found in 50 CFR 18.27 as it conflates ''small numbers'' with ''negligible impacts.'' We recognize ''small numbers'' and ''negligible impacts'' as two separate and distinct requirements under the MMPA. For our small numbers determination, we estimate the likely number of takes of marine mammals, and evaluate if that take is small relative to the size of the population or stock. For the sake of clarity we have revised language in section 18.121 explaining how the term ''small numbers'' is defined for these ITRs.

The Service disagrees with the logic that ''If each take was a unique bear, it would account for 38 percent of the population.'' The comment is a fundamental mischaracterization of our analysis. The Service explained how we conducted our analysis of takes and arrived at our determination of small numbers in the preamble section ''Take Estimates for Pacific Walruses and Polar Bears.'' Our analysis uses data gathered from Industry observation reports. Those data show that individual polar bears may experience multiple takes over time. The number 340 in our determination refers to polar bear takes, not the number of individual polar bears potentially taken. Further, the best available information shows that only a portion of the SBS polar bear stock encounters Industry activity, and only a portion of those bears experience harassment that is considered ''take'' as defined by the MMPA. The Service believes that based on the nature of the data used to conduct our analysis the results are likely an overestimate rather than an underestimate.

The Service does not assume that the level of Industry activity during the 5-year period of these ITRs would be the same as the previous 5-year period as the commenters assert. During the 5 years that the ITRs will be in place, Industry activities are expected to be generally similar in type, timing, and effect to activities that have been evaluated under the prior ITRs. We assume the overall annual level of Industry activity will be similar to, but not the same as, that which occurred under the previous regulations, although exploration and development may shift to new locations and new facilities will add to the overall Industry footprint. The Service evaluated the

level of Industry activities for the 5-year period of these ITRs allowing for a rate of growth similar to previous ITR periods. Further, the Service did evaluate all of the projects and activities the commenters specified. A description of those projects, along with the others we evaluated, is found in the preamble section ''Description of Activities.''

The Service does not assume that ''the level of take will remain constant'' as the commenters assert. The timing and nature of polar bear/Industry interactions in the Beaufort Sea ITR Region are seasonal and variable over time. Though overall polar bear observation reports from Industry are increasing, that does not automatically equate to an increase of takes. The Service believes this is largely due to the mitigation measures found in this and previous ITRs, as well the polar bear/human conflict management programs run by the Service.

Comment 6: The rationale that the agency gives for its negligible impact conclusion is inadequate because it fails to analyze what impact the take of 340 bears by harassment will be on the whole population. The Service uses the size and location of activities as a proportion of the range of the marine mammals to make its negligible impact determination, and then it concludes that it will not affect recruitment or survival without any explanation. The range of a species is not determinative of the impact of take on a population. During the fall, polar bears congregate in the coastal areas near Industry operations and essential reproductive functions of denning occur in these areas. Despite the range of the bears, Industry activities harass polar bears during times they tend to congregate onshore and den with potentially significant impacts on the population. The Service fails to acknowledge that vessel interactions with polar bears may be significant and fails to adequately include an increase of polar bear deterrence events in its analysis.

Response: The Service believes our negligible impacts analysis and determinations are thorough and based on the best available information. We used the results of Industry monitoring data from the previous ITRs, information from the listing of the polar bear as a threatened species under the ESA, information from the designation of polar bear critical habitat, current information about Pacific walruses and their habitat, the results of modeling assessments, and the status of the populations. For the risk of oil spills, we also considered Congressional direction in balancing the potential for a significant impact with the likelihood of that event occurring:

> If potential effects of a specified activity are conjectural or speculative, a finding of negligible impact may be appropriate. A finding of negligible impact may also be appropriate if the probability of occurrence is low but the potential effects may be significant. In this case, the probability of occurrence of impacts must be balanced with the potential severity of harm to the species or stock when determining negligible impact. In applying this balancing test, the Service will thoroughly evaluate the risks involved and the potential impacts on marine mammal populations. Such determination will be made based on the best available scientific information [53 FR 8474, March 15, 1988; 132 Cong. Rec. S 16305 (October. 15, 1986)].

We evaluated the effects of Industry activities on walruses and polar bears, including impacts from noise, physical obstructions, human encounters, and oil spills, including the cumulative effects of existing and future development, production, and exploration activities, and the likelihood of impacts, both onshore and offshore. The evaluation of the scale of Industry activities in comparison with the range of SBS polar bears was only one part of the complete analysis. The Service does not state that the range of a species alone is determinative of the impact of take on a population. Rather, we conclude that the relatively small area of Industry activity compared to the range of walruses and polar bears will reduce the potential of their exposure to and disturbance from Industry activities.

The Service is not aware of any information that indicates harassment from Industry activities has significant impacts on the polar bear population. These ITRs, and previous ITRs, include specific mitigation measures to protect denning polar bears. These mitigation measures have proven very effective for protecting denning polar bears.

The best available information indicates that encounters between vessels and polar bears will likely result in no more than short-term and temporary behavioral disturbance and likely have no significant effects. The Service considered deterrence events of polar bears in addition to incidental takes for a more thorough analysis, as well as for the sake of transparency. The Service believes we have thoroughly evaluated the anticipated number of takes of polar bears and Pacific walruses likely to occur during the 5-year period of these ITRs. Again as stated in the response to comment 5, 340 refers to the number of polar bear takes, not the number of individual polar bears. Likewise, the estimate of up to 10 Pacific walruses refers to the number of takes and not the number of individual Pacific walruses.

Comment 7: Industry activities and incidental take authorization could have an adverse impact on Alaska Native subsistence use of marine mammals.

Response: The Service thoroughly evaluated the potential effects of Industry activity upon the availability of polar bears and Pacific walruses for the subsistence use of Alaska Natives. Though we are aware that some Alaska Native communities have expressed general concerns regarding impacts of Industry activities on subsistence resources, such as caribou and fish, the issue addressed here is whether these ITRs might impact the availability of polar bears and walruses for subsistence uses. We are not aware of any concerns voiced by Alaska Native communities, hunter organizations, co-management organizations, or other representative groups that ITRs and the take associated with Industry activities would do so, or have in the past. One goal of Service management and conservation efforts is to ensure that polar bears and walruses remain available for subsistence harvest into the future. We work with Alaska Native partners and co-management organizations to achieve that goal.

The LOA process described in these ITRs ensures the opportunity for communities to review Industry plans and make recommendations for additional mitigation measures. The process requires Industry to work with Alaska Native communities to address concerns and mitigate impacts to resource availability. Industry must provide the Service documentation of communication and coordination with Alaska Native communities during our consideration of each individual LOA. The Service offers guidance during the POC process, and must review and approve Industry POCs to ensure that the process and content are sufficient.

The Service's finding is based on the best available information, such as the polar bear and walrus harvest data provided by Alaska Native subsistence hunters through the Service's Marking, Tagging, and Reporting Program. That information indicates that activities will not have an unmitigable, adverse impact on the availability of species for subsistence take. We also based our finding on: (1) The results of coastal aerial surveys; (2) direct observations of polar bears occurring near bowhead whale carcasses on Barter Island and on Cross Island during the annual fall bowhead whaling efforts; (3) community consultations; (4) locations of hunting areas; (5) the potential overlap of hunting areas and Industry projects; (6) results of monitoring data; and (7)

anecdotal reports of North Slope residents. The Service has not received any reports and is unaware of any information that indicates that polar bears or walruses are being affected by Industry activity in a way that diminishes their availability for Alaska Native subsistence use.

Comment 8: The Service should analyze the corresponding impacts of climate change and sea ice decline on the polar bear population when assessing whether Industry activities will have a ''negligible'' impact on the population. The Service should consider the most recent science such as the recent study by Atwood, T.C., E. Peacock, M.A. McKinney, K. Lillie, R. Wilson, D.C. Douglas, S. Miller, P. Terletzky, Rapid Environmental Changes Drives Increased Land Use by an Arctic Marine Predator, available at *http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0155932.*

Response: The study the commenters refer to was not publicly available during the development of the proposed ITRs. The Service reviewed the study and found the conclusions consistent with our understanding of SBS polar bear seasonal terrestrial habitat use, as well as confirming widely held views regarding how polar bears in the SBS respond to seasonally diminished sea ice. We find the conclusions of the study useful and consistent with our analysis and determinations for these ITRs. We revised text in the ''Climate Change'' section of the preamble citing this study.

The Service recognizes the primary threat to the continued existence of polar bears is loss of sea ice habitat due to climate change and that sea ice habitat is also of concern for Pacific walruses. The Service addressed its position on greenhouse gas (GHG) in the Final Polar Bear Special Rule (78 FR 11766, February 20, 2013) and previous ITRs for the Beaufort Sea and Chukchi Sea. The Service considered the effects of climate change upon polar bears, walruses, and their habitats (particularly the effects upon sea ice) while developing these ITRs. Broader questions about climate change and how it may cause additive stress on polar bear and walrus populations over the long term are beyond the scope of these ITRs analysis but are explored generally in the EA.

Comment 9: The Service must consider the baseline conditions that face polar bears and Pacific walruses in determining to authorize incidental take of these species by Industry activities.

Response: The Service used the best available information to conduct our analyses and make our determinations for these ITRs. We thoroughly evaluated the population status of each species, their range, distribution, habitat requirements, and the condition of habitat for each species, among other things. Collectively, that information constitutes what the commenter refers to as ''baseline conditions.'' We evaluated current and potential Industry activities, the known and potential impacts of those activities, and the risk and potential impacts of oil spills. As new information becomes available we will continue to evaluate how Industry activities affect polar bears and walruses.

Mitigation Measures

Comment 10: The Service should clarify when it is appropriate for LOA applicants to submit a POC (*e.g.,* geographic locations, timing of activities, etc.).

Response: The Service agrees that we should clarify when we consider a POC appropriate. Accordingly, we have revised text in the preamble section ''Description of Plans of Cooperation (POCs).''

Comment 11: In section 18.128(e)(1)(i) of the final rule the Service should: (1) Include monitoring measures for the 160 dB monitoring zone for polar bears as well as walruses; and (2) specify that any individual of either species would be considered taken if observed within the monitoring zone.

Response: The Service believes that the monitoring and mitigation measures in section 18.128(e)(1)(i), and the ITRs as a whole, are appropriate. The underwater hearing characteristics of polar bears are poorly known and we are not aware of any information that indicates that underwater sound ≥ 160 dB re 1 μPa may cause biologically significant changes in behavior to polar bears, much less an injury. Section 18.128(e)(1)(i) states that walruses observed in the ≥ 160 dB re 1 μPa monitoring zone are assumed to experience Level B take. Based on the available information, biology, and behavior of polar bears, the Service does not believe polar bears within the ≥ 160 dB re 1 μPa monitoring zone will experience Level B take.

Comment 12: The acoustic thresholds established in the ITRs for Level A and Level B take, and for monitoring and mitigation measure implementation, are insufficient and do not use the best available science. The Service should reassess whether Level B harassment takes of both polar bears and walruses are expected to occur from drilling and ice-breaking activities based on the 120-dB re 1 μPa threshold and include the requirement to monitor the 120-dB re 1 μPa monitoring zone for continuous sources under section 18.128(e)(1)(i) of the final rule.

Response: The Service believes that the monitoring and mitigation measures in section 18.128(e)(1)(i), and the ITRs as a whole, are appropriate. The underwater hearing characteristics of polar bears and walruses are poorly known and we are not aware of any information that indicates that continuous underwater sound of 120 dB re 1 μPa may cause biologically significant changes in behavior to polar bears or walruses, much less an injury. The acoustic thresholds established in the ITRs are based upon the best available information for polar bears and walruses. There is some information for underwater hearing for certain otarriid pinnipeds that the Service uses as a proxy for walruses, however, there is not sufficient information to conclude that walruses are likely to experience harassment or injury due solely to exposures of 120 dB re 1 μPa from continuous sound sources. Based on the available information, biology, and behavior of polar bears and walruses, the Service does not believe a 120 dB re 1 μPa threshold and monitoring zone for continuous underwater sound from drilling activities, ice-breaking activities, or other sound sources is appropriate. As new information becomes available the Service will continue to evaluate how Industry activities affect polar bears and walruses and what mitigation measures are required to minimize the impacts of such activities. The Service may amend these ITRs if new information indicates changes are appropriate.

Comment 13: The Service should coordinate with the NMFS on any questions it may have regarding the appropriateness of the Level B harassment thresholds.

Response: The Service welcomes collaboration and coordination with NMFS, when appropriate, for the management of marine mammal species under the Service's jurisdiction. The Service and NMFS share some common conservation and management responsibilities. However, the Service and NMFS are distinct agencies with significantly unique missions, mandates, and procedures. While NMFS has responsibility for most marine mammals, the Service has responsibility for polar bears, Pacific walruses, sea and marine otters, three species of manatees, and dugongs. There are significant and fundamental differences in the biology, behavior, conservation, and management needs between these species and those under the jurisdiction

of NMFS, *i.e.,* cetaceans and pinnipeds other than walruses. The Service relies on our own expertise regarding marine mammals under our jurisdiction and will continue to collaborate and coordinate with NMFS, when appropriate.

Comment 14: The Service has failed to implement the least practicable impact by eliminating mitigation measures, by using mitigation measures that are known to be ineffective, and failing to adopt additional mitigation measures.

Response: The Service thoroughly considered how to implement the least practicable adverse impacts as we developed these ITRs. We rely upon the best available information, which includes over 20 years of monitoring data from the Chukchi and Beaufort Seas during Industry activities, to evaluate the impacts of those activities. The Service believes that these ITRs and the mitigation measures set forth herein are effective and proven to implement least practicable adverse impacts from Industry activities upon polar bears and walruses.

The commenter suggests that we eliminated the mitigation measure regarding groups of 12 or more walruses from these ITRs because it was impractical. That was not the case. We eliminated it because it was irrelevant in the Beaufort Sea. Groups of 12 or more walruses have not been observed in the Beaufort Sea ITR Region for more than 20 years. If the Service becomes aware of information that walruses begin to occur in the Beaufort Sea in groups of 12 or more, we will re-evaluate the need for such a mitigation measure.

As we point out in the preamble, we may require additional mitigation measures when we determine they would be needed to implement least practicable adverse impacts during an activity. We may also decline to issue an LOA if the impacts of an activity exceed the scope and determinations of these ITRs. As new evidence or specific information on the effectiveness of the mitigation, monitoring and reporting measures for these ITRs becomes available, we will consider it and make any appropriate changes.

For the sake of clarity on how we addressed the least practicable adverse impacts requirement, we revised text in the ''Take Estimates for Pacific Walruses and Polar Bears'' section by adding a subsection titled ''Least Practicable Adverse Impacts Determination'' and we revised text in the ''Findings'' section by adding a subsection titled ''Least Practicable Adverse Impacts.''

Comment 15: The Service has not justified why the mitigation measure described in section 18.128(c)(4) of the ITRs is appropriate in the Beaufort Sea and should be removed. The mitigation measure contradicts the Service's findings that Pacific walruses are not commonly found in the Beaufort Sea. Section 18.128(c)(4) states that ''The transit of operational and support vessels through the specified geographic region is not authorized prior to July 1. This operating condition is intended to allow walruses the opportunity to disperse from the confines of the spring lead system and minimize interactions with subsistence walrus hunters. Exemption waivers to this operating condition may be issued by the Service on a case-by-case basis, based upon a review of seasonal ice conditions and available information on walrus and polar bear distributions in the area of interest.''

Response: The Service agrees that the mitigation measure described in section 18.128(c)(4) of the ITRs seems confusing and inconsistent with the findings for these ITRs. That mitigation measure is intended to be relevant for vessels transiting through the Chukchi Sea bound for the Beaufort Sea. We have revised the text of section 18.128(c)(4) accordingly.

Comment 16: The Service should consider mitigation measures that would fund or promote the Service's implementation of the polar bear recovery plan.

Response: The Service developed these ITRs to be compatible with the implementation of the Service's Polar Bear Conservation Management Plan (what the commenter referred to as the polar bear recovery plan). We do not believe that section 101(a)(5)(A) of the MMPA provides the authority, nor is intended, to create a funding mechanism for conservation and management efforts. Rather, the mitigation measures set forth in these ITRs are intended to ensure the least practicable adverse impact upon polar bears and walruses from the Industry activities described and evaluated. We will continue to work with partners and collaborators on a variety of research and conservation projects as opportunities develop.

NEPA

Comment 17: The draft environmental assessment is inadequate, and the Service must prepare a full environmental impact assessment.

Response: Section 1501.4(b) of NEPA, found at 40 CFR Chapter V, notes that, in determining whether to prepare an EIS, a Federal agency may prepare an EA and, based on the EA document, make a determination whether to prepare an EIS. The Department of the Interior's policy and procedures for compliance with NEPA (69 FR 10866, March 8, 2004) further affirms that the purpose of an EA is to allow the responsible official to determine whether to prepare an EIS or a ''Finding of No Significant Impact'' (FONSI). The Service analyzed the proposed activity, *i.e.,* issuance of implementing regulations, in accordance with the criteria of NEPA, and made a determination that it does not constitute a major Federal action significantly affecting the quality of the human environment. It should be noted that the Service does not authorize the actual Industry activities, as those activities are authorized by other State and Federal agencies. The Service merely authorizes the incidental take of polar bears and walruses incidental to those activities. We note that these ITRs provide the Service with a means of interacting with Industry through the mitigation, monitoring, and reporting requirements for individual projects to ensure that the impacts to polar bears and Pacific walruses are minimized. The ITRs will affect the nonlethal, incidental take of only small numbers of polar bears and Pacific walruses, will have only a negligible impact on the species or stocks, and will not cause an unmitigable adverse impact on the availability of the species for subsistence use. As a result, we determined the regulations will not significantly affect the quality of the human environment and, therefore, a FONSI is appropriate. Accordingly, an EIS is not required under NEPA.

Comment 18: The stated purpose of the action predetermines that the authorization will issue. ''The primary purpose of our Proposed Action—the issuance of ITRs for the Beaufort Sea—is to authorize the nonlethal incidental take by harassment of small numbers of polar bears and Pacific walruses.'' The purpose should instead be to limit the impacts of oil and gas activities on polar bears and walrus as required by the MMPA.

Response: The Service believes the commenters misunderstand the requirements set forth in NEPA and the MMPA. The Service believes we are in full compliance of both the letter and spirit of both NEPA and the MMPA. We refer to our response to comment 14 for an explanation of NEPA requirements and we refer to the ''Background'' section of the preamble of these ITRs for an explanation of MMPA requirements.

Comment 19: The analysis of the ''no action'' alternative is invalid and has

been rejected by the courts. The Service must consider additional alternatives.

Response: The Service believes the ''no action'' alternative is valid and is in compliance with relevant court rulings (see, for example, *Center for Biological Diversity* v. *Kempthorne,* 588 F.3d 701, 9th Cir. 2009). The action being considered is the issuance of the ITRs. Therefore, the ''no action'' alternative would be not to issue ITRs. However, Section 101(a)(5)(A) of the MMPA specifies that the Secretary of the Interior (Secretary), through the Director of the Service, *shall* [emphasis added] allow the incidental, but not intentional, taking of small numbers of marine mammals in response to requests by U.S. citizens engaged in a specified activity (other than commercial fishing) in a specified geographic region if the Secretary finds that the total of such taking will have a negligible impact on the species or stock and will not have an unmitigable adverse impact on the availability of the species or stock for subsistence uses. Therefore, if a citizen petitions the Service to promulgate regulations, we are required to initiate the process and make the appropriate findings. If there is no request for ITRs because there are no industry activities, as suggested by the commenters, there would be no need for any analysis, including alternatives. Since Industry activities have occurred in the Beaufort Sea ITR Region for over 40 years and are ongoing, we do not consider an alternative that excludes them as being a reasonable alternative.

Comment 20: The EA fails to account for marine mammal take resulting from hydraulic fracturing.

Response: Hydraulic fracturing is one of many standard Industry drilling practices in the oil fields of the north slope of Alaska, and has been for many years. The Service has described the types of activities to be authorized, as requested by the petitioner, as well as other activities the Service anticipates may occur, the projected scale of each activity, and the anticipated impacts that could occur during the 5-year period the ITRs will be in effect. See also our response to comments 2 and 3. We understand that the types of Industry activities described in these ITRs, such as drilling, involve many separate actions and activities that together constitute the types of activities. Since the Service does not authorize or regulate the actual Industry activity, only the incidental take associated with that activity, we do not consider it appropriate to sub-divide Industry activities into each separate component. Potential effects from a component part of an Industry activity are considered in our analysis.

The commenters provided information regarding the potential impacts of hydraulic fracturing, most of which is not relevant for the type and scale of hydraulic fracturing conducted in the Beaufort Sea ITR Region. The Service is not aware of any information (and none was provided by the commenter) that indicates that polar bears or walruses have experienced take, as defined by the MMPA, or other negative effects, from hydraulic fracturing on the North Slope.

The Service agrees that the release of toxic substances, from hydraulic fracturing or any other source, into the habitat of polar bears and Pacific walruses may have detrimental effects upon those animals exposed. The Service's analysis acknowledges there is a potential for spills to occur. The accidental release of toxic substances, such as in the case of an oil spill, is an illegal act. No part of this rule authorizes the release of toxic substances into the environment, or the exposure of wildlife to such toxins. For these ITRs, we evaluated the probability of an oil spill and the dynamics of how polar bears and walruses would interact with a potential spill through their behavior, physiology, and habitat use. Using this information the Service has developed mitigation measures and response plans to minimize impacts on these species in the event of a spill. The Service believes that the occurrence of such an event is minimized by adherence to the regulatory standards that are in place. This is supported by historical evidence, which shows that adherence to oil spill plans and best management practices has resulted in no major spills in the nearshore and offshore areas where Industry activities occur in the Beaufort Sea ITR Region. In the event of a spill, we would reassess the impacts to the polar bear and walrus populations and reconsider the appropriateness of authorizations for taking through Section 101(a)(5)(A) of the MMPA.

Comment 21: The Service's cumulative impacts analysis is deficient. The indirect and cumulative impacts of greenhouse gas pollution from operations and downstream consumption of fossil fuels must be analyzed.

Response: The Service believes the cumulative impacts analysis is valid. We considered the best available information regarding potential impacts of climate change and analyzed all relevant direct, indirect, and cumulative effects on polar bears and Pacific walruses, and their habitat, potentially caused by Industry activities in the Beaufort Sea ITR Region during the 5-year period of these ITRs. The level of analysis the commenters suggest is beyond the scope appropriate for these ITRs. We do consider broader questions about climate change and how it may cause additive stress on polar bear and walrus populations over the long term generally in the EA.

While we recognize that the primary threat to the continued existence of the polar bear is loss of sea ice habitat due to climate change, and that loss of sea ice habitat is also of concern for the Pacific walrus. The Service addressed its position on GHG in the Final Polar Bear Special Rule (78 FR 11766, February 20, 2013) and previous ITRs for the Beaufort Sea and Chukchi Sea. The Service finds that while GHG emissions are clearly contributing to climate change, the comprehensive authority to regulate those emissions is not found in the statutes that govern the management of marine mammals. The challenge posed by climate change and its ultimate solution is much broader than the scope and scale of these ITRs.

Comment 22: The Service should consider an alternative that only authorizes polar bear and walrus harassment by renewable energy development or those industrial projects that are consistent with the nation's climate goals of limiting warming to 1.5 degrees C [Celsius] and conservation of threatened SBS polar bears.

Response: The Service does not believe that an alternative that ''only authorizes polar bear and walrus harassment by renewable energy development'' is reasonable. The commenter does not describe what ''those industrial projects that are consistent with the nation's climate goals of limiting warming to 1.5 degrees C and conservation of threatened SBS polar bears'' might be. Such alternatives are beyond our authority and are outside the scope, purpose, and needs of the action (*i.e.,* the ITRs). Therefore, the Service did not consider the suggested alternatives.

ESA

Comment 23: The Service must comply with the Endangered Species Act.

Response: The Service completed intra-agency consultation under the ESA for polar bears and their critical habitat, and intra-agency conference for Pacific walruses prior to finalizing these ITRs. We believe we are in full compliance with the ESA.

Oil Spill Analysis

Comment 24: The Service based its oil spill risk analysis on outdated science, information, and techniques for modeling oil spill risks. The Service should incorporate updated spill trajectory data for all sites (Oooguruk, Nikaitchuq, Northstar, and Endicott/Liberty) and updated polar bear movement and distribution data to reassess the risk of oil spills to polar bears. The Service should further analyze that oil and gas activities increase the risk of an oil spill that is impossible to clean up. The Service should include more dynamic and updated oil spill trajectory modeling and better account for the long-term risks to polar bear and walrus populations in the event of a large oil spill. The Service should utilize stochastic output models in addition to conditional impact probabilities to obtain a more complete oil spill trajectory analysis to better inform its decision-making process.

Response: The Service analysis of Industry activities for these ITRs used the best available information and encapsulates all of the known and anticipated Industry activities that will occur in the Beaufort Sea ITR Region during the 5-year period of these ITRs. The Service considers spill probabilities alone insufficient to assess the risk to polar bears and walruses. To address this issue, our risk assessment incorporates the likelihood that a spill would occur as well as the potential impacts of such a spill. We understand that variables for risk assessment from various offshore sites will be different; however, our analysis was not intended to assess the risk of an oil spill from each individual site. The Service believes analysis of the Northstar and Liberty sites led to a valid representation of the types of risks polar bears would encounter if a large spill occurred in the nearshore areas of the Beaufort Sea. The rule contains a discussion of these quantified impacts as well as qualitative analysis of other potential sources, such as spills from pipelines, and sizes of oil spills. Although spill probabilities for other offshore facilities, and those in development, would provide the Service better insights into the impacts of oil spills on polar bears and walrus, oil spill trajectories were unavailable for these other sites. The analysis presented represents the best data and science available. The Service is currently working on an updated oil spill trajectory analysis, an updated oil spill impacts analysis, and an updated polar bear distribution analysis. However, those studies are not completed and not available for consideration for these ITRs. The Service will continue to evaluate the potential risk and impacts of oil spills as new information becomes available.

National Environmental Policy Act (NEPA) Considerations

We have prepared an environmental assessment (EA) in conjunction with this rulemaking, and have determined that this rulemaking is not a major Federal action significantly affecting the quality of the human environment within the meaning of Section 102(2)(C) of the NEPA of 1969. For a copy of the EA, go to *http://www.regulations.gov* and search for Docket No. FWS–R7–ES–2016–0060 or contact the individual identified above in **FOR FURTHER INFORMATION CONTACT**.

Endangered Species Act

In 2008, the Service listed the polar bear as a threatened species under the ESA (73 FR 28212, May 15, 2008) and later designated critical habitat for polar bear populations in the United States, effective January 6, 2011 (75 FR 76086, December 7, 2010). Section 7(a)(1) and (2) of the ESA (16 U.S.C. 1536(a)(1) and (2)) directs the Service to review its programs and to utilize such programs in the furtherance of the purposes of the ESA and to ensure that an action is not likely to jeopardize the continued existence of an ESA-listed species or result in the destruction or adverse modification of critical habitat. In addition, the status of Pacific walruses rangewide was reviewed for potential listing under the ESA. The listing of walruses was found to be warranted, but precluded due to higher priority listing actions (*i.e.,* walrus is a candidate species) on February 10, 2011 (76 FR 7634). Consistent with our statutory obligations, the Service's Marine Mammal Management Office initiated an intra-Service section 7 consultation regarding the effects of these regulations on the polar bear and its designated critical habitat with the Service's Fairbanks' Ecological Services Field Office. Consistent with established agency policy, we also conducted a conference regarding the effects of these ITRs on the Pacific walrus. In a biological opinion issued on July 27, 2016, the Service concluded that the action is not likely to jeopardize the continued existence of polar bears or Pacific walruses or adversely affect designated polar bear critical habitat.

Regulatory Planning and Review

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget will review all significant rules. OIRA has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

OIRA bases its determination upon the following four criteria: (a) Whether the rule will have an annual effect of $100 million or more on the economy or adversely affect an economic sector, productivity, jobs, the environment, or other units of the government; (b) Whether the rule will create inconsistencies with other Federal agencies' actions; (c) Whether the rule will materially affect entitlements, grants, user fees, loan programs, or the rights and obligations of their recipients; (d) Whether the rule raises novel legal or policy issues.

Expenses will be related to, but not necessarily limited to: The development of applications for LOAs; monitoring, recordkeeping, and reporting activities conducted during Industry oil and gas operations; development of polar bear interaction plans; and coordination with Alaska Natives to minimize effects of operations on subsistence hunting. Compliance with the rule is not expected to result in additional costs to Industry that it has not already borne under all previous ITRs. Realistically, these costs are minimal in comparison to those related to actual oil and gas exploration, development, and production operations. The actual costs to Industry to develop the petition for promulgation of regulations and LOA requests probably do not exceed $500,000 per year, short of the ''major rule'' threshold that would require preparation of a regulatory impact analysis. As is presently the case, profits will accrue to Industry; royalties and taxes will accrue to the Government; and the rule will have little or no impact

on decisions by Industry to relinquish tracts and write off bonus payments.

Small Business Regulatory Enforcement Fairness Act

We have determined that this rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. The rule is also not likely to result in a major increase in costs or prices for consumers, individual industries, or government agencies or have significant adverse effects on competition, employment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Regulatory Flexibility Act

We have also determined that this rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Oil companies and their contractors conducting exploration, development, and production activities in Alaska have been identified as the only likely applicants under the regulations, and these potential applicants have not been identified as small businesses. Therefore, neither a Regulatory Flexibility Analysis nor a Small Entity Compliance Guide is required. The analysis for this rule is available from the individual identified above in the section **FOR FURTHER INFORMATION CONTACT**.

Takings Implications

This rule does not have takings implications under Executive Order 12630 because it authorizes the nonlethal, incidental, but not intentional, take of walruses and polar bears by oil and gas Industry companies and, thereby, exempts these companies from civil and criminal liability as long as they operate in compliance with the terms of their LOAs. Therefore, a takings implications assessment is not required.

Federalism Effects

This rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132. The MMPA gives the Service the authority and responsibility to protect walruses and polar bears.

Unfunded Mandates Reform Act

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*), this rule will not ''significantly or uniquely'' affect small governments. A Small Government Agency Plan is not required. The Service has determined and certifies pursuant to the Unfunded Mandates Reform Act that this rulemaking will not impose a cost of $100 million or more in any given year on local or State governments or private entities. This rule will not produce a Federal mandate of $100 million or greater in any year, *i.e.,* it is not a ''significant regulatory action'' under the Unfunded Mandates Reform Act.

Government-to-Government Relationship With Native American Tribal Governments

In accordance with the President's memorandum of April 29, 1994, ''Government-to-Government Relations with Native American Tribal Governments'' (59 FR 22951, May 4, 1994), Executive Order 13175, Department of the Interior Secretarial Order 3225 of January 19, 2001 (Endangered Species Act and Subsistence Uses in Alaska (Supplement to Secretarial Order 3206)), Department of the Interior Secretarial Order 3317 of December 1, 2011 (Tribal Consultation and Policy), Department of the Interior Memorandum of January 18, 2001 (Alaska Government-to-Government Policy), the Department of the Interior's manual at 512 DM 2, and the Native American Policy of the U.S. Fish and Wildlife Service, January 20, 2016, we readily acknowledge our responsibility to communicate and work directly on a Government-to-Government basis with federally recognized Tribes in developing programs for healthy ecosystems, to seek their full and meaningful participation in evaluating and addressing wildlife conservation concerns, to remain sensitive to Alaska Native culture, and to make information available to Alaska Natives. Furthermore, and in accordance with Department of the Interior Policy on Consultation with Alaska Native Claims Settlement Act of 1971 (ANCSA) Corporations, August 10, 2012, we likewise acknowledge our responsibility to communicate and work directly with ANCSA Corporations.

Prior to publication of the proposed ITR, we sent letters to the Alaska Native communities and co-management organizations within the Beaufort Sea ITR Region to notify them of the AOGA petition for ITRs and invited them to contact us directly if they had comments, questions, or concerns. We received no replies to those letters.

Furthermore, to facilitate co-management activities we continue to maintain cooperative agreements with subsistence hunting and co-management organizations, such as the NSB, EWC, and the Qayassiq Walrus Commission (QWC). We previously maintained a cooperative agreement with the ANC and look forward to working with its successor organization. The cooperative agreements fund a wide variety of management issues, including: Commission co-management operations; biological sampling programs; harvest monitoring; collection of Native knowledge in management; international coordination on management issues; cooperative enforcement of the MMPA; and development of local conservation plans. To help realize mutual management goals, the Service, NSB, EWC, and QWC regularly hold meetings to discuss future expectations and outline a shared vision of co-management.

The Service also has ongoing cooperative relationships with the NSB and the Inupiat-Inuvialuit Game Commission where we work cooperatively to ensure that data collected from harvest and research are used to ensure that polar bears are available for harvest in the future; provide information to co-management partners that allows them to evaluate harvest relative to their management agreements and objectives; and provide information that allows evaluation of the status, trends, and health of polar bear populations.

Civil Justice Reform

The Departmental Solicitor's Office has determined that this regulation does not unduly burden the judicial system and meet the applicable standards provided in Sections 3(a) and 3(b)(2) of Executive Order 12988.

Paperwork Reduction Act

This rule contains information collection requirements. We may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. OMB has reviewed and approved the information collection requirements included in this rule and assigned OMB control number 1018–0070, which expires March 31, 2017. This control number covers the information collection, recordkeeping, and reporting requirements in 50 CFR 18, subpart J, which are associated with the development and issuance of specific regulations and LOAs.

Energy Effects

Executive Order 13211 requires agencies to prepare Statements of Energy Effects when undertaking certain

actions. This rule provides exceptions from the taking prohibitions of the MMPA for entities engaged in the exploration of oil and gas in the Beaufort Sea and adjacent coast of Alaska. By providing certainty regarding compliance with the MMPA, this rule will have a positive effect on Industry and its activities. Although the rule requires Industry to take a number of actions, these actions have been undertaken by Industry for many years as part of similar past regulations. Therefore, this rule is not expected to significantly affect energy supplies, distribution, or use and does not constitute a significant energy action. No Statement of Energy Effects is required.

References

For a list of the references cited in this rule, see Docket No. FWS–R7–ES–2016–0060, available at *http://www.regulations.gov*.

List of Subjects in 50 CFR Part 18

Administrative practice and procedure, Alaska, Imports, Indians, Marine mammals, Oil and gas exploration, Reporting and recordkeeping requirements, Transportation.

Final Regulation Promulgation

For the reasons set forth in the preamble, the Service amends part 18, subchapter B of chapter 1, title 50 of the Code of Federal Regulations as set forth below.

PART 18—MARINE MAMMALS

■ 1. The authority citation of part 18 continues to read as follows:

Authority: 16 U.S.C. 1361 *et seq.*

■ 2. Revise subpart J to read as follows:

Subpart J—Nonlethal Taking of Marine Mammals Incidental to Oil and Gas Exploration, Development, Production and Other Substantially Similar Activities in the Beaufort Sea and Adjacent Northern Coast of Alaska

Sec.

Subpart J—Nonlethal Taking of Marine Mammals Incidental to Oil and Gas Exploration, Development, Production and Other Substantially Similar Activities in the Beaufort Sea and Adjacent Northern Coast of Alaska

§ 18.121 Specified activities covered by this subpart.

Regulations in this subpart apply to the nonlethal incidental, but not intentional, take of small numbers of polar bear and Pacific walrus by U.S. citizens while engaged in oil and gas exploration, development, production, and/or other substantially similar activities in the Beaufort Sea and adjacent northern coast of Alaska. ''U.S. citizens'' is defined in 50 CFR 18.27(c). The term ''small numbers'' is also defined in 50 CFR 18.27(c), however, we do not rely on that definition here as it conflates ''small numbers'' with ''negligible impacts.'' Regulations in this subpart rely on a small numbers determination where we estimated the likely number of takes of polar bears and Pacific walruses during the specified activities, and evaluated if that take is small relative to the size of the population or stock.

§ 18.122 Specified geographic region where this subpart applies.

This subpart applies to the specified geographic region that encompasses all Beaufort Sea waters east of a north-south line through Point Barrow, Alaska (71°23′29″ N., −156°28′30″ W., BGN 1944), and approximately 322 kilometers (km) (~200 miles (mi)) north of Point Barrow, including all Alaska State waters and Outer Continental Shelf (OCS) waters, and east of that line to the Canadian border.

(a) The offshore boundary of the Beaufort Sea incidental take regulations (ITR) region will match the boundary of the Bureau of Ocean Energy Management (BOEM) Beaufort Sea Planning area, approximately 322 km (~200 mi) offshore. The onshore region is the same north/south line at Barrow, 40.2 km (25 mi) inland and east to the Canning River.

(b) The Arctic National Wildlife Refuge is not included in the Beaufort Sea ITR region. Figure 1 shows the area where this subpart applies.

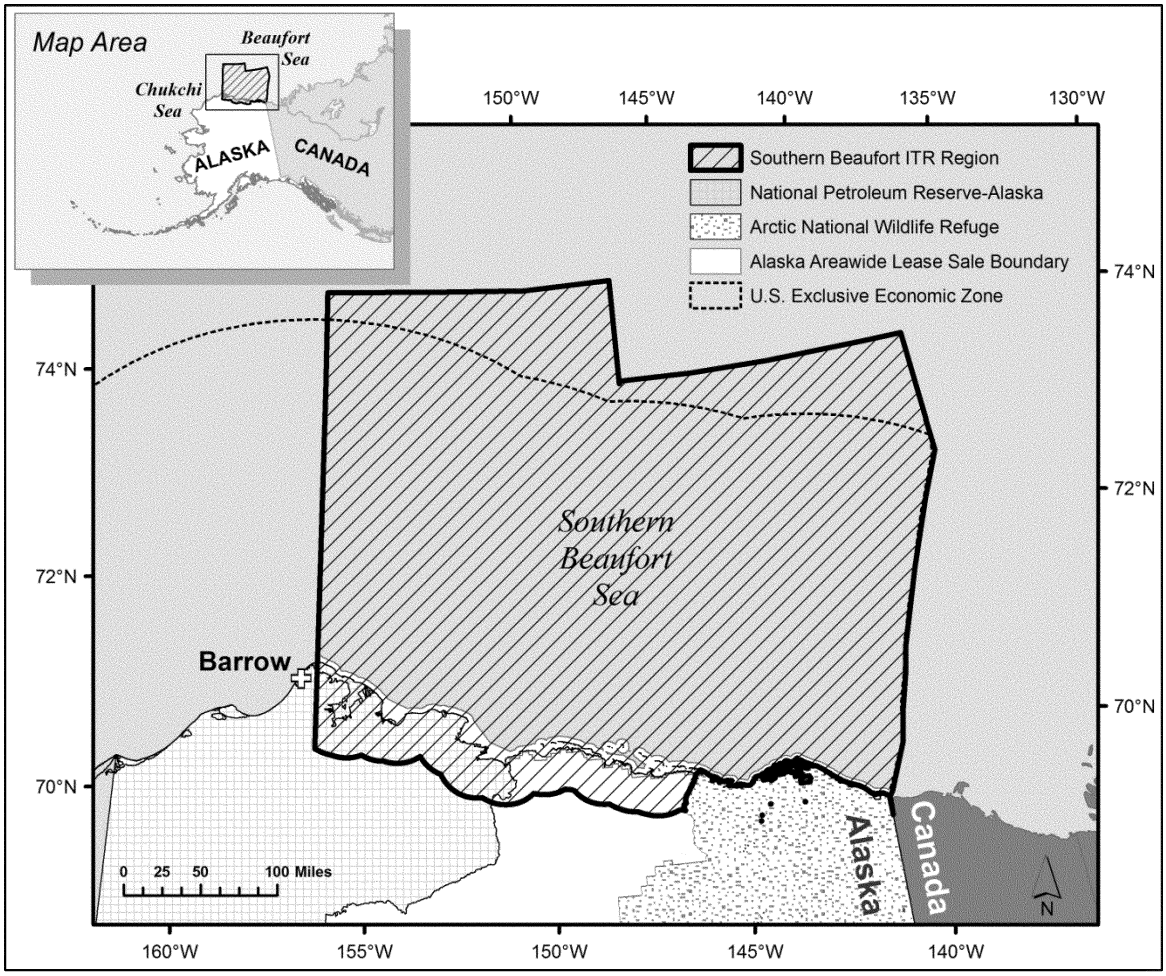

Figure 1. Map of the Beaufort Sea ITR region.

§ 18.123 Dates this subpart is in effect.

Regulations in this subpart are effective from August 5, 2016, through August 5, 2021, for year-round oil and gas exploration, development, production and other substantially similar activities.

§ 18.124 Procedure to obtain a Letter of Authorization (LOA).

(a) An applicant must be a U.S. citizen as defined in § 18.27(c).

(b) If an applicant proposes to conduct oil and gas industry exploration, development, production, and/or other substantially similar activity in the Beaufort Sea ITR region described in § 18.122 that may cause the taking of Pacific walruses and/or polar bears and wants nonlethal incidental take authorization under the regulations in this subpart J, the applicant must apply for an LOA. The applicant must submit the request for authorization to the Service's Alaska Region Marine Mammals Management Office (see § 2.2 for address) at least 90 days prior to the start of the activity.

(c) The request for an LOA must include the following information and must comply with the requirements set forth in § 18.128:

(1) A plan of operations that describes in detail the activity (*e.g.,* type of project, methods, and types and numbers of equipment and personnel, etc.), the dates and duration of the activity, and the specific locations of and areas affected by the activity.

(2) A site-specific marine mammal monitoring and mitigation plan to monitor and mitigate the effects of the activity on Pacific walruses and polar bears.

(3) A site-specific Pacific walrus and polar bear safety, awareness, and interaction plan. The plan for each activity and location will detail the policies and procedures that will provide for the safety and awareness of personnel, avoid interactions with Pacific walruses and polar bears, and minimize impacts to these animals.

(4) A Plan of Cooperation (POC) to mitigate potential conflicts between the activity and subsistence hunting, where relevant. Applicants must provide documentation of communication with potentially affected subsistence communities along the Beaufort Sea coast (*i.e.,* Kaktovik, Nuiqsut, and Barrow) and appropriate subsistence user organizations (*i.e.,* the Eskimo Walrus Commission or North Slope Borough) to discuss the location, timing, and methods of activities and identify and mitigate any potential conflicts with subsistence walrus and polar bear hunting activities. Applicants must specifically inquire of relevant communities and organizations if the activity will interfere with the availability of Pacific walruses and/or polar bears for the subsistence use of those groups. Applications for Letters of Authorization must include documentation of all consultations with potentially affected user groups. Documentation must include a summary of any concerns identified by community members and hunter organizations, and the applicant's responses to identified concerns.

§ 18.125 How the Service will evaluate a request for a Letter of Authorization (LOA).

(a) We will evaluate each request for an LOA based on the specific activity and the specific geographic location. We will determine whether the level of activity identified in the request exceeds that analyzed by us in considering the number of animals likely to be taken and evaluating whether there will be a negligible impact on the species or an adverse impact on the availability of the species for subsistence uses. If the level of activity is greater, we will reevaluate our findings to determine if those findings continue to be appropriate based on the greater level of activity that the applicant has requested. Depending on the results of the evaluation, we may grant the authorization, add further conditions, or deny the authorization.

(b) In accordance with § 18.27(f)(5), we will make decisions concerning withdrawals of an LOA, either on an individual or class basis, only after notice and opportunity for public comment.

(c) The requirement for notice and public comment in paragraph (b) of this section will not apply should we determine that an emergency exists that poses a significant risk to the well-being of the species or stocks of polar bears or Pacific walruses.

§ 18.126 Authorized take allowed under a Letter of Authorization (LOA).

(a) An LOA allows for the nonlethal, non-injurious, incidental, but not intentional take by Level B harassment, as defined in § 18.3 and under section 3 of the Marine Mammal Protection Act (16 U.S.C. 1371 *et seq.*), of Pacific walruses and/or polar bears while conducting oil and gas industry exploration, development, production, and/or other substantially similar activities within the Beaufort Sea ITR region described in § 18.122.

(b) Each LOA will identify terms and conditions for each activity and location.

§ 18.127 Prohibited take under a Letter of Authorization (LOA).

Except as otherwise provided in this subpart, prohibited taking is described in § 18.11 as well as:

(a) Intentional take, Level A harassment, as defined in section 3 of the Marine Mammal Protection Act (16 U.S.C. 1371 *et seq.*), and lethal incidental take of polar bears or Pacific walruses; and

(b) Any take that fails to comply with this subpart or with the terms and conditions of an LOA.

§ 18.128 Mitigation, monitoring, and reporting requirements.

(a) *Mitigation measures for all Letters of Authorization (LOAs).* Holders of an LOA must implement policies and procedures to conduct activities in a manner that minimizes to the greatest extent practicable adverse impacts on Pacific walruses and/or polar bears, their habitat, and the availability of these marine mammals for subsistence uses. Adaptive management practices, such as temporal or spatial activity restrictions in response to the presence of marine mammals in a particular place or time or the occurrence of Pacific walruses and/or polar bears engaged in a biologically significant activity (*e.g.,* resting, feeding, denning, or nursing, among others) must be used to avoid interactions with and minimize impacts to these animals and their availability for subsistence uses.

(1) All holders of an LOA must:

(i) Cooperate with the Service's Marine Mammals Management Office and other designated Federal, State, and local agencies to monitor and mitigate the impacts of oil and gas industry activities on Pacific walruses and polar bears.

(ii) Designate trained and qualified personnel to monitor for the presence of Pacific walruses and polar bears, initiate mitigation measures, and monitor, record, and report the effects of oil and gas industry activities on Pacific walruses and/or polar bears.

(iii) Have an approved Pacific walrus and polar bear safety, awareness, and interaction plan on file with the Service's Marine Mammals Management Office and onsite, and provide polar bear awareness training to certain personnel. Interaction plans must include:

(A) The type of activity and where and when the activity will occur (*i.e.,* a summary of the plan of operation);

(B) A food, waste, and other ''bear attractants'' management plan;

(C) Personnel training policies, procedures, and materials;

(D) Site-specific walrus and polar bear interaction risk evaluation and mitigation measures;

(E) Walrus and polar bear avoidance and encounter procedures; and

(F) Walrus and polar bear observation and reporting procedures.

(2) All applicants for an LOA must contact affected subsistence communities and hunter organizations to discuss potential conflicts caused by the activities and provide the Service documentation of communications as described in § 18.124.

(b) *Mitigation measures for onshore activities.* Holders of an LOA must undertake the following activities to limit disturbance around known polar bear dens:

(1) *Attempt to locate polar bear dens.* Holders of an LOA seeking to carry out onshore activities in known or suspected polar bear denning habitat during the denning season (November–April) must make efforts to locate occupied polar bear dens within and near areas of operation, utilizing appropriate tools, such as forward-looking infrared (FLIR) imagery and/or polar bear scent-trained dogs. All observed or suspected polar bear dens must be reported to the Service prior to the initiation of activities.

(2) *Observe the exclusion zone around known polar bear dens.* Operators must observe a 1.6-km (1-mi) operational exclusion zone around all known polar bear dens during the denning season (November–April, or until the female and cubs leave the areas). Should previously unknown occupied dens be discovered within 1 mi of activities, work must cease and the Service contacted for guidance. The Service will evaluate these instances on a case-by-case basis to determine the appropriate action. Potential actions may range from cessation or modification of work to conducting additional monitoring, and the holder of the authorization must comply with any additional measures specified.

(3) *Use the den habitat map developed by the USGS.* A map of potential coastal polar bear denning habitat can be found at: *http://alaska.usgs.gov/science/biology/polar_bears/denning.html.* This measure ensures that the location of potential polar bear dens is considered when conducting activities in the coastal areas of the Beaufort Sea.

(4) *Polar bear den restrictions.* Restrict the timing of the activity to limit disturbance around dens.

(c) *Mitigation measures for operational and support vessels.* (1) Operational and support vessels must be staffed with dedicated marine mammal observers to alert crew of the presence of walruses and polar bears and initiate adaptive mitigation responses.

(2) At all times, vessels must maintain the maximum distance possible from concentrations of walruses or polar bears. Under no circumstances, other than an emergency, should any vessel approach within an 805-m (0.5-mi) radius of walruses or polar bears observed on land or ice.

(3) Vessel operators must take every precaution to avoid harassment of concentrations of feeding walruses when a vessel is operating near these animals. Vessels should reduce speed

and maintain a minimum 805-m (0.5-mi) operational exclusion zone around feeding walrus groups. Vessels may not be operated in such a way as to separate members of a group of walruses from other members of the group. When weather conditions require, such as when visibility drops, vessels should adjust speed accordingly to avoid the likelihood of injury to walruses.

(4) Vessels bound for the Beaufort Sea ITR Region may not transit through the Chukchi Sea prior to July 1. This operating condition is intended to allow walruses the opportunity to move through the Bering Strait and disperse from the confines of the spring lead system into the Chukchi Sea with minimal disturbance. It is also intended to minimize vessel impacts upon the availability of walruses for Alaska Native subsistence hunters. Exemption waivers to this operating condition may be issued by the Service on a case-by-case basis, based upon a review of seasonal ice conditions and available information on walrus and polar bear distributions in the area of interest.

(5) All vessels must avoid areas of active or anticipated walrus or polar bear subsistence hunting activity as determined through community consultations.

(6) In association with marine activities, we may require trained marine mammal monitors on the site of the activity or on board drill ships, drill rigs, aircraft, icebreakers, or other support vessels or vehicles to monitor the impacts of Industry's activity on polar bear and Pacific walruses.

(d) *Mitigation measures for aircraft.* (1) Operators of support aircraft should, at all times, conduct their activities at the maximum distance possible from concentrations of walruses or polar bears.

(2) Under no circumstances, other than an emergency, should aircraft operate at an altitude lower than 457 m (1,500 ft) within 805 m (0.5 mi) of walruses or polar bears observed on ice or land. Helicopters may not hover or circle above such areas or within 805 m (0.5 mile) of such areas. When weather conditions do not allow a 457-m (1,500-ft) flying altitude, such as during severe storms or when cloud cover is low, aircraft may be operated below this altitude. However, when weather conditions necessitate operation of aircraft at altitudes below 457 m (1,500 ft), the operator must avoid areas of known walrus and polar bear concentrations and should take precautions to avoid flying directly over or within 805 m (0.5 mile) of these areas.

(3) Plan all aircraft routes to minimize any potential conflict with active or anticipated walrus or polar bear hunting activity as determined through community consultations.

(e) *Mitigation measures for sound-producing offshore activities.* Any offshore activity expected to produce pulsed underwater sounds with received sound levels ≥160 dB re 1 μPa will be required to establish and monitor acoustically verified mitigation zones surrounding the sound source and implement adaptive mitigation measures as follows:

(1) *Mitigation zones.* (i) A walrus monitoring zone is required where the received pulsed sound level would be ≥ 160 dB re 1 μPa. Walruses in this zone are assumed to experience Level B take.

(ii) A walrus mitigation zone is required where the received pulsed sound level would be ≥ 180 dB re 1 μPa.

(iii) A walrus or polar bear mitigation zone is required where the received pulsed sound level would be ≥ 190 dB re 1 μPa.

(2) *Adaptive mitigation measures.*

(i) *Ramp-up procedures.* For all sound sources, including sound source testing, the following sound ramp-up procedures must be used to allow walruses and polar bears to depart the mitigation zones:

(A) Visually monitor the ≥180 dB re 1 μPa and ≥190 dB re 1 μPa mitigation zones and adjacent waters for walruses and polar bears for at least 30 minutes before initiating ramp-up procedures. If no walruses or polar bears are detected, ramp-up procedures may begin. Do not initiate ramp-up procedures when mitigation zones are not observable (*e.g.,* at night, in fog, during storms or high sea states, etc.).

(B) Initiate ramp-up procedures by activating a single, or least powerful, sound source, in terms of energy output and/or volume capacity.

(C) Continue ramp-up by gradually increasing sound output over a period of at least 20 minutes, but no longer than 40 minutes, until the desired operating level of the sound source is obtained.

(ii) *Power down.* Immediately power down a sound source when:

(A) One or more walruses is observed or detected within the area delineated by the pulsed sound ≥180 dB re 1 μPa walrus mitigation zone; and

(B) One or more walruses or polar bears are observed or detected within the area delineated by the pulsed sound ≥190 dB re 1 μPa walrus or polar bear mitigation zone.

(iii) *Shut down.* (A) If the power down operation cannot reduce the received pulsed sound level to <180 dB re 1 μPa (walrus) or <190 dB re 1 μPa (walrus or polar bear), the operator must immediately shut down the sound source.

(B) If observations are made or credible reports are received that one or more walruses or polar bears within the area of the sound source activity are believed to be in an injured or mortal state, or are indicating acute distress due to received sound, the sound source must be immediately shut down and the Service contacted. The sound source will not be restarted until review and approval has been given by the Service. The ramp-up procedures must be followed when restarting.

(f) *Mitigation measures for the subsistence use of walruses and polar bears.* Holders of Letters of Authorization must conduct their activities in a manner that, to the greatest extent practicable, minimizes adverse impacts on the availability of Pacific walruses and polar bears for subsistence uses.

(1) *Community consultation.* Prior to receipt of an LOA, applicants must consult with potentially affected communities and appropriate subsistence user organizations to discuss potential conflicts with subsistence walrus and polar bear hunting caused by the location, timing, and methods of operations and support activities (see § 18.124 for details). If community concerns suggest that the activities may have an adverse impact on the subsistence uses of these species, the applicant must address conflict avoidance issues through a POC as described in paragraph (f)(2) of this section.

(2) *Plan of Cooperation (POC).* When appropriate, a holder of an LOA will be required to develop and implement a Service-approved POC. The POC must include:

(i) A description of the procedures by which the holder of the LOA will work and consult with potentially affected subsistence hunters; and

(ii) A description of specific measures that have been or will be taken to avoid or minimize interference with subsistence hunting of walruses and polar bears and to ensure continued availability of the species for subsistence use.

(iii) The Service will review the POC to ensure that any potential adverse effects on the availability of the animals are minimized. The Service will reject POCs if they do not provide adequate safeguards to ensure the least practicable adverse impact on the availability of walruses and polar bears for subsistence use.

(g) *Monitoring requirements.* Holders of an LOA will be required to:

(1) Develop and implement a site-specific, Service-approved marine mammal monitoring and mitigation plan to monitor and evaluate the effectiveness of mitigation measures and the effects of activities on walruses, polar bears, and the subsistence use of these species.

(2) Provide trained, qualified, and Service-approved onsite observers to carry out monitoring and mitigation activities identified in the marine mammal monitoring and mitigation plan.

(3) For offshore activities, provide trained, qualified, and Service-approved observers on board all operational and support vessels to carry out monitoring and mitigation activities identified in the marine mammal monitoring and mitigation plan. Offshore observers may be required to complete a marine mammal observer training course approved by the Service.

(4) Cooperate with the Service and other designated Federal, State, and local agencies to monitor the impacts of oil and gas activities on walruses and polar bears. Where information is insufficient to evaluate the potential effects of activities on walruses, polar bears, and the subsistence use of these species, holders of an LOA may be required to participate in joint monitoring and/or research efforts to address these information needs and ensure the least practicable impact to these resources.

(h) *Reporting requirements.* Holders of an LOA must report the results of monitoring and mitigation activities to the Service's Marine Mammals Management Office via email at: *fw7_mmm_reports@fws.gov.*

(1) *In-season monitoring reports*—(i) *Activity progress reports.* Holders of an LOA must:

(A) Notify the Service at least 48 hours prior to the onset of activities;

(B) Provide the Service weekly progress reports of any significant changes in activities and/or locations; and

(C) Notify the Service within 48 hours after ending of activities.

(ii) *Walrus observation reports.* Holders of an LOA must report, on a weekly basis, all observations of walruses during any Industry activity. Upon request, monitoring report data must be provided in a common electronic format (to be specified by the Service). Information in the observation report must include, but is not limited to:

(A) Date, time, and location of each walrus sighting;

(B) Number of walruses;

(C) Sex and age (if known);

(D) Observer name and contact information;

(E) Weather, visibility, sea state, and sea-ice conditions at the time of observation;

(F) Estimated range at closest approach;

(G) Industry activity at time of sighting;

(H) Behavior of animals sighted;

(I) Description of the encounter;

(J) Duration of the encounter; and

(K) Mitigation actions taken.

(iii) *Polar bear observation reports.* Holders of an LOA must report, within 48 hours, all observations of polar bears and potential polar bear dens, during any Industry activity. Upon request, monitoring report data must be provided in a common electronic format (to be specified by the Service). Information in the observation report must include, but is not limited to:

(A) Date, time, and location of observation;

(B) Number of bears;

(C) Sex and age (if known);

(D) Observer name and contact information;

(E) Weather, visibility, sea state, and sea-ice conditions at the time of observation;

(F) Estimated closest distance of bears from personnel and facilities;

(G) Industry activity at time of sighting;

(H) Possible attractants present;

(I) Bear behavior;

(J) Description of the encounter;

(K) Duration of the encounter; and

(L) Mitigation actions taken.

(2) *Notification of LOA incident report.* Holders of an LOA must report, as soon as possible, but within 48 hours, all LOA incidents during any Industry activity. An LOA incident is any situation when specified activities exceed the authority of an LOA, when a mitigation measure was required but not enacted, or when injury or death of a walrus or polar bear occurs. Reports must include:

(i) All information specified for an observation report;

(ii) A complete detailed description of the incident; and

(iii) Any other actions taken.

(3) *Final report.* The results of monitoring and mitigation efforts identified in the marine mammal monitoring and mitigation plan must be submitted to the Service for review within 90 days of the expiration of an LOA, or for production LOAs, an annual report by January 15th of each calendar year. Upon request, final report data must be provided in a common electronic format (to be specified by the Service). Information in the final (or annual) report must include, but is not limited to:

(i) Copies of all observation reports submitted under the LOA;

(ii) A summary of the observation reports;

(iii) A summary of monitoring and mitigation efforts including areas, total hours, total distances, and distribution;

(iv) Analysis of factors affecting the visibility and detectability of walruses and polar bears during monitoring;

(v) Analysis of the effectiveness of mitigation measures;

(vi) Analysis of the distribution, abundance, and behavior of walruses and/or polar bears observed; and

(vii) Estimates of take in relation to the specified activities.

§ 18.129 Information collection requirements.

(a) We may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. OMB has approved the collection of information contained in this subpart and assigned OMB control number 1018–0070. You must respond to this information collection request to obtain a benefit pursuant to section 101(a)(5) of the Marine Mammal Protection Act. We will use the information to:

(1) Evaluate the application and determine whether or not to issue specific Letters of Authorization; and

(2) Monitor impacts of activities and effectiveness of mitigation measures conducted under the Letters of Authorization.

(b) Comments regarding the burden estimate or any other aspect of this requirement must be submitted to the Information Collection Clearance Officer, U.S. Fish and Wildlife Service, at the address listed in 50 CFR 2.1.

Dated: August 1, 2016.

Michael J. Bean,

Principal Deputy Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2016–18583 Filed 8–4–16; 8:45 am]

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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 August 4, 2016

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